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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission, or entity in accordance with § 4-29-121(b).

Agency/Board/Commission:	Environment and Conservation
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Revision Type (check all that apply):

X Amendment
X New
___ Repeal

___ Content based on previous emergency rule filed on _____
___ Content is identical to the emergency rule

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	**Chapter Title**
0400-20-04	General Provisions
Rule Number	**Rule Title**
0400-20-04-.07	Notifications, Reports and Other Communications
0400-20-04-.11	Posting of Notices to Workers

Chapter Number	**Chapter Title**
0400-20-05	Standards for Protection Against Radiation
Rule Number	**Rule Title**
0400-20-05-.70	General Survey and Monitoring Requirements
0400-20-05-.115	Procedures for Receiving and Opening Packages
0400-20-05-.141	Notification of Incidents
0400-20-05-.145	Notifications, Records, and Reports of Misadministration
0400-20-05-.165	Report, Notification, and Records of a Dose to an Embryo/Fetus or a Nursing Child

Chapter Number	**Chapter Title**

0400-20-06	Use of X-Ray Apparatus
Rule Number	**Rule Title**
0400-20-06-.05	Medical X-Ray Installations
0400-20-06-.09	Appendix A

Chapter Number	**Chapter Title**
0400-20-07	Use of Radionuclides In The Healing Arts
Rule Number	**Rule Title**
0400-20-07-.05	Definitions
0400-20-07-.11	Application for License, Amendment, or Renewal
0400-20-07-.13	License Amendments
0400-20-07-.14	Notifications
0400-20-07-.15	Exemptions Regarding Specific Licenses of Broad Scope
0400-20-07-.17	Authority and Responsibilities for the Radiation Protection Program
0400-20-07-.20	Written Directives
0400-20-07-.21	Procedures for Administrations Requiring a Written Directive
0400-20-07-.23	Training for Radiation Safety Officer
0400-20-07-.24	Training for an Authorized Medical Physicist
0400-20-07-.25	Training for an Authorized Nuclear Pharmacist
0400-20-07-.26	Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist
0400-20-07-.31	Authorization for Calibration, Transmission, and Reference Sources
0400-20-07-.39	Training for Uptake, Dilution, and Excretion
0400-20-07-.41	Radionuclide Contaminants
0400-20-07-.43	Training for Imaging and Localization
0400-20-07-.44	Use of Unsealed Radioactive Material for Which a Written Directive is Required
0400-20-07-.47	Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required
0400-20-07-.48	Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicurries)
0400-20-07-.49	Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicurries)
0400-20-07-.50	Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive
0400-20-07-.51	Use of Sealed Sources for Manual Brachytherapy
0400-20-07-.57	Decay of Strontium-90 Sources for Ophthalmic Treatments
0400-20-07-.59	Training for Use of Manual Brachytherapy Sources
0400-20-07-.60	Training for Ophthalmic Use of Strontium-90
0400-20-07-.61	Use of Sealed Sources for Diagnosis
0400-20-07-.62	Training for Use of Sealed Sources for Diagnosis
0400-20-07-.63	Use of Sealed Source in Remote Afterloader Unit, Teletheraphy Unit, or Gamma Stereotactic Radiosurgery Unit
0400-20-07-.66	Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units
0400-20-07-.77	Five Year Inspection for Teletherapy Units and Gamma Stereotactic Radiosurgery Units
0400-20-07-.80	Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
0400-20-07-.82	Records of Authority and Responsibilities for Radiation Protection Programs
0400-20-07-.96	Records of Safety Instruction and Training
0400-20-07-.110	Records of Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units
0400-20-07-.114	Report and Notification for an Eluate Exceeding Permissible Molybdenium-99, Strontium-82, and Strontium-85 Concentrations

Chapter Number	**Chapter Title**
0400-20-08	Radiation Safety Requirements for Industrial Radiography
Rule Number	**Rule Title**
0400-20-08-.05	Personal Radiation Safety Requirements for Radiographers and Radiographer's Assistants

0400-20-08-.12	Reporting Requirements
0400-20-08-.15	Recordkeeping Requirements

Chapter Number	**Chapter Title**
0400-20-10	Licensing and Registration
Rule Number	**Rule Title**
0400-20-10-.13	Special Requirements for Issuance of Specific Licenses
0400-20-10-.16	Specific Terms and Conditions of Licenses
0400-20-10-.27	Inspections
0400-20-10-.30	Packaging and Transportation of Radioactive Material
0400-20-10-.31	Fees for Licenses
0400-20-10-.34	Supplemental Fees for Calendar Year 2013
0400-20-10-.38	Appendix-Schedules

Chapter Number	**Chapter Title**
0400-20-12	Radiation Safety Requirements for Well Logging
Rule Number	**Rule Title**
0400-20-12-.20	Personnel Monitoring

Chapter Number	**Chapter Title**
0400-20-13	Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material
Rule Number	**Rule Title**
0400-20-13-.02	Background Investigations and Access Authorization Program
0400-20-13-.03	Physical Protection Requirements During Use
0400-20-13-.04	Physical Protection in Transit

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to https://sos.tn.gov/products/division-publications/rulemaking-guidelines.

Chapter 0400-20-04
General Provisions

Amendments

The table of contents for Chapter 0400-20-04 General Provisions is amended by deleting the title for Rule 0400-20-04-.07 Notifications, Reports and Other Communications in its entirety and substituting instead the following:

Notifications, Reports, and Other Communications

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

Paragraph (1) of Rule 0400-20-04-.07 Notifications, Reports, and Other Communications is amended by adding a new subparagraph (e) after subparagraph (d) to read as follows:

(e) Electronic Mail: division.radiological.health@tn.gov.

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

Rule 0400-20-04-.11 Posting of Notices to Workers is amended by deleting it in its entirety and substituting instead the following:

(1) Each licensee or registrant shall post current copies of the following documents, as applicable, in a sufficient number of places to permit workers to observe them on the way to or from any particular licensed or registered activity location to which the document applies. Documents shall be placed in a conspicuous position and replaced if removed or altered:

(a) "State Regulations for Protection Against Radiation";

(b) Radioactive material license, license conditions, and documents incorporated into a license by reference and amendments thereto;

(c) Certified registration and amendments thereto;

(d) Registration of x-ray producing equipment;

(e) Operating and emergency procedures applicable to licensed or registered activities;

(f) Any written notice that these regulations have been violated shall be posted within two working days after receipt of the documents from the Division and the licensee's or registrant's response. These documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later; and

(g) Form RHS 8-3 (Notice to Employees). Copies of this form may be obtained by visiting the Division website under Helpful Documents and Links at https://www.tn.gov/environment/program-areas/rh-radiological-health1/rh-helpful-links.html.

(2) Instead of posting a document specified in subparagraphs (1)(a) through (e) of this rule, the licensee or registrant may post a notice that describes the document and states where it may be examined.

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

Chapter 0400-20-05
Standards for Protection Against Radiation

Amendments

The table of contents for Chapter 0400-20-05 Standards for Protection Against Radiation is amended by deleting the title for Rule 0400-20-05-.145 Notifications, Records and Reports of Misadministration in its entirety and substituting instead the following:

0400-20-05-.145 Notifications, Records, and Reports of Misadministration

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

Paragraph (4) of Rule 0400-20-05-.70 General Survey and Monitoring Requirements is amended by deleting it in its entirety and substituting instead the following:

(4) Except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities, all personnel dosimeters that require processing for determining the dose and are used to comply with these standards or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

(a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(b) Approved for processing and evaluating dosimeters exposed to the type of radiation(s) included in the NVLAP program that most closely approximates the type of radiation(s) being monitored by the dosimeter.

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

The introductory text of paragraph (4) of Rule 0400-20-05-.115 Procedures for Receiving and Opening Packages is amended by deleting it and substituting a new introductory text to read as follows, without impacting any of its subparagraphs:

(4) The licensee shall immediately notify the final delivery carrier and the Division by telephone, facsimile, or electronic mail, as set forth in Rule 0400-20-04-.07, when either removable radioactive surface contamination or external radiation levels exceed the following:

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

Part 3 of subparagraph (b) of paragraph (3) of Rule 0400-20-05-.141 Preparation and Submission of Reports is amended by deleting it in its entirety and substituting instead the following:

3. The isotopes, quantities, activity, manufacturer, model and serial number of source (if applicable), leak test results, and chemical and physical forms of the licensable material involved;

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

Rule 0400-20-05-.145 Notifications, Records, and Reports of Misadministration is amended by deleting it in its entirety and substituting instead the following:

0400-20-05-.145 Notifications, Records, and Reports of Misadministration.

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

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

organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin; and

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

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

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

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

1. An administration of a wrong radioactive drug or the wrong radionuclide for a brachytherapy procedure;

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

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

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

5. A leaking sealed source.

(c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

1. 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

2. 50 percent or more the expected dose to that site from the procedure if the administration has been given in accordance with the written directive prepared or revised before administration.

(d) A therapeutic radiation machine dose:

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

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

3. When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or

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

(2) For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(a) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(b) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(c) An administration that includes any of the following:

1. The wrong radionuclide;

2. The wrong individual or human research subject;

3. Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

4. A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

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

(4) A licensee or registrant shall notify the Division at the number given in Rule 0400-20-04-.07 no later than the next calendar day after discovery of the misadministration.

(5) A licensee or registrant shall submit a written report to the Division at the address listed in Rule 0400-20-04-.07 within 15 days after discovery of the misadministration.

(a) The written report must include:

1. The licensee or registrant's name;

2. The name of the prescribing physician;

3. A brief description of the event;

4. Why the event occurred;

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

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

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

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

(6) A licensee or registrant shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee or registrant either that they will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee or registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee or registrant shall notify the individual as soon as possible thereafter. The licensee or registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this rule, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee or registrant shall inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee or registrant shall provide a written description if requested.

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

(8) A licensee or registrant shall:

(a) Retain a record of a misadministration in accordance with this rule for three years;

(b) Annotate a copy of the report of a misadministration provided to the Division with:

1. The licensee's or registrant's name;

2. The names of the individuals involved;

3. The identification number, or if no other identification number is available, the social security number of the individual who is the subject of the misadministration;

4. A brief description of the event and why it occurred;

5. The effect, if any, on the individual;

6. The actions, if any, taken, or planned, to prevent recurrence; and

7. Whether the licensee or registrant notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(c) Provide a copy of the annotated report to the referring physician if other than the licensee or registrant within 15 days after discovery of the misadministration.

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

Paragraph (6) of Rule 0400-20-05-.165 Report, Notification, and Records of a Dose to an Embryo/Fetus or a Nursing Child is amended by deleting it in its entirety and substituting instead the following:

(6) A licensee or registrant shall:

(a) Retain a record of a dose to an embryo/fetus or a nursing child in accordance with this rule for three years;

(b) Annotate a copy of the report of the event provided to the Division with:

1. The licensee's or registrant's name;

2. The names of the individuals involved;

3. The identification number, or if no other identification number is available, the social security number of the individual who is subject of the event;

4. A brief description of the event and why it occurred;

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

6. The actions, if any, taken or planned, to prevent recurrence; and

7. Whether the licensee or registrant notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(c) Provide a copy of the annotated report to the referring physician if other than the licensee or registrant within 15 days after discovery of the event.

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

Amendments

Part 2 of subparagraph (b) of paragraph (2) of Rule 0400-20-06-.05 Medical X-Ray Installations is amended by deleting it in its entirety and substituting instead the follow:

2. Reserved.

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

Subparagraph (a) of paragraph (1) of Rule 0400-20-06-.09 Appendix A is amended by deleting it in its entirety and substituting instead the following:

(a) All x-ray equipment.

For x-ray equipment to which this chapter and 21 C.F.R. §§ 1020.31 and 1020.32 are applicable, there shall be provided:

1. Adequate instructions concerning any radiological safety procedures and precautions that may be necessary because of unique features of the equipment; and

2. A schedule of the maintenance necessary to keep the equipment in compliance with this chapter and 21 C.F.R. §§ 1020.31 and 1020.32.

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

Chapter 0400-20-07
Use of Radionuclides In The Healing Arts

Amendments

The title of Chapter 0400-20-07 Use of Radionuclides In The Healing Arts is amended by deleting it its entirety and substituting instead the following:

Use of 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.

The table of contents of Chapter 0400-20-07 Use of Radionuclides in the Healing Arts is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.19	Supervision	0400-20-07-.76	Radiation Surveys
0400-20-07-.20	Written Directives	0400-20-07-.77	Full-Inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units
0400-20-07-.21	Procedures for Administrations Requiring a Written Directive	0400-20-07-.78	Therapy-Related Computer Systems
0400-20-07-.22	Suppliers for Sealed Sources or Devices for Medical Use	0400-20-07-.79	Reserved
0400-20-07-.23	Training for Radiation Safety Officer and Associate Radiation Safety Officer	0400-20-07-.80	Training for Use of Remote Afterloader Unit, Teletherapy Units and Gamma Stereotactic Radiosurgery Units
0400-20-07-.24	Training for an Authorized Medical Physicist	0400-20-07-.81	Other Medical Uses of Radioactive Material or Radiation from Radioactive Material
0400-20-07-.25	Training for an Authorized Nuclear Pharmacist	0400-20-07-.82	Records of Authority and Responsibilities for Radiation Protection Programs
0400-20-07-.26	Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist	0400-20-07-.83	Records of Radiation Protection Program Changes
0400-20-07-.27	Recentness of Training	0400-20-07-.84	Records of Written Directives
0400-20-07-.28	Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material	0400-20-07-.85	Reserved
0400-20-07-.29	Calibration of Survey Instruments	0400-20-07-.86	Reserved
0400-20-07-.30	Determination of Dosages of Unsealed Radioactive Material for Medical Use	0400-20-07-.87	Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material
0400-20-07-.31	Authorization for Calibration, Transmission, and Reference Sources	0400-20-07-.88	Records of Radiation Survey Instrument Calibrations
0400-20-07-.32	Requirements for Possession of Sealed Sources and Brachytherapy Sources	0400-20-07-.89	Records of Dosages of Unsealed Radioactive Material for Medical Use
0400-20-07-.33	Labeling of Vials and Syringes	0400-20-07-.90	Reserved
0400-20-07-.34	Surveys of Ambient Radiation Dose Rate and Contamination	0400-20-07-.91	Records of Surveys for Ambient Radiation Exposure Rate
0400-20-07-.35	Release of Individuals Containing Radioactive Drugs or Implants	0400-20-07-.92	Records of the Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material
0400-20-07-.36	Provision of Mobile Medical Service	0400-20-07-.93	Records of Mobile Medical Services
0400-20-07-.37	Decay-in-Storage	0400-20-07-.94	Records of Decay-in-Storage
0400-20-07-.38	Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required	0400-20-07-.95	Records of Radionuclide Contaminants
0400-20-07-.39	Training for Uptake, Dilution, and Excretion Studies	0400-20-07-.96	Records of Safety Instruction and Training
0400-20-07-.40	Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required	0400-20-07-.97	Records of Radiation Surveys of Patients and Human Research Subjects
0400-20-07-.41	Permissible Molybdenum-99,	0400-20-07-.98	Records of Brachytherapy Source

	Strontium-82, and Strontium-85 Concentrations		Accountability
0400-20-07-.42	Reserved	0400-20-07-.99	Records of Calibration Measurements of Brachytherapy Sources
0400-20-07-.43	Training for Imaging and Localization Studies	0400-20-07-.100	Records of Decay of Strontium-90 Sources for Ophthalmic Treatments
0400-20-07-.44	Use of Unsealed Radioactive Material for Which a Written Directive is Required	0400-20-07-.101	Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
0400-20-07-.45	Safety Instruction	0400-20-07-.102	Records of Safety Procedures
0400-20-07-.46	Safety Precautions	0400-20-07-.103	Records of Dosimetry Equipment
0400-20-07-.47	Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required	0400-20-07-.104	Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations
0400-20-07-.48	Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicurries)	0400-20-07-.105	Records of Periodic Spot-Checks for Teletherapy Units
0400-20-07-.49	Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicurries)	0400-20-07-.106	Records of Periodic Spot-Checks for Remote Afterloader Units
0400-20-07-.50	Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive	0400-20-07-.107	Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Unit
0400-20-07-.51	Use of Sealed Sources for Manual Brachytherapy	0400-20-07-.108	Records of Additional Technical Requirements for Mobile Remote Afterloader Units
0400-20-07-.52	Surveys After Source Implant and Removal	0400-20-07-.109	Records of Surveys of Therapeutic Treatment Units
0400-20-07-.53	Brachytherapy Source Accountability	0400-20-07-.110	Records of Full-Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units
0400-20-07-.54	Safety Instruction	0400-20-07-.111	Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy Sources
0400-20-07-.55	Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy	0400-20-07-.112	Report of Procedures for Administrations Requiring a Written Directive
0400-20-07-.56	Calibration Measurements of Brachytherapy Sources	0400-20-07-.113	Report of a Leaking Source
0400-20-07-.57	Strontium-90 Sources for Ophthalmic Treatments	0400-20-07-.114	Report and Notification for an Eluate Exceeding Permissible Molybdenium-99, Strontium-82, and Strontium-85 Concentrations

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

Rule 0400-20-07-.05 Definitions is amended by deleting it in its entirety and substituting instead the following:

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) “Associate radiation safety officer” means an individual who:

(a) Meets the requirements in Rules 0400-20-07-.23 and 0400-20-07-.27; and

(b) Is currently identified as an associate radiation safety officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the radiation safety officer on:

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

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

(4) “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.

(5) “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.

(6) “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.

(7) “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.

(8) “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.

(9) “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.

(10) “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.

(11) “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.

(12) “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.

(13) “Division” means the Division of Radiological Health.

(14) “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.

(15) “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.

(16) “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.

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

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

(19) “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.

(20) “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.

(21) “Misadministration” means an event that meets the criteria in Rule 0400-20-05-.145.

(22) “Mobile medical service” means the transportation of radioactive material to and its medical use at the client’s address.

(23) “Ophthalmic physicist” means an individual who:

(a) Meets the requirements in Rules 0400-20-07-.57 and 0400-20-07-.27; and

(b) Is identified as an ophthalmic physicist on a:

1. Specific medical use license issued by the U.S. Nuclear Regulatory Commission or Agreement State;

2. Permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee;

3. Medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; or

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

(24) “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.

(25) “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.

(26) “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.

(27) “Physician” means a doctor of medicine or doctor of osteopathy licensed by a 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.

(28) “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.

(29) “Positron Emission Tomography (PET) radionuclide production facility” is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(30) “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, a radiation safety officer, or an associate radiation safety officer.

(31) “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.

(32) “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.

(33) “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.

(34) “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.

(35) "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.

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

(37) “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.

(38) “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.

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

(40) “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.

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

(42) “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.

(43) “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.

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

(45) “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.

(46) “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.

(47) “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.

Rule 0400-20-07-.11 Application for License, Amendment, or Renewal is amended by deleting it in its entirety and substituting instead the following:

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 that includes the facility diagram, equipment, and training and experience qualifications of the radiation safety officer, associate radiation safety officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); 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 of either:

1. A completed Form CN 0716, “Application for Radioactive Material License”; or

2. A letter containing all information required by Form CN 0716; 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:

(a) Information regarding any additional radiation safety aspects of the medical use of the material that is not addressed in this chapter;

(b) Identification of, and commitment to follow, the applicable radiation safety program requirements in this chapter that are appropriate for the specific Rule 0400-20-07-.81 medical use; and

(c) Any additional 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.

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

(e) 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.

Rule 0400-20-07-.13 License Amendments is amended by deleting it in its entirety and substituting instead the following:

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, ophthalmic physicist, or an authorized medical physicist under the license, except:

1. For an authorized user, an individual who meets the requirements in Rule 0400-20-07-.27, 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, and 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. An individual who is identified as an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic 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. An individual who is identified as an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic 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 allows anyone to work as an associate radiation safety officer, or before the radiation safety officer assigns duties and tasks to an associate radiation safety officer that differ from those for which this individual is authorized on the license;

(e) 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;

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

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

(h) Before the licensee revises procedures required by Rule 0400-20-07-.66, 0400-20-07-.72, 0400-20-07-.73, and 0400-20-07-.74, as applicable, where such revision reduces radiation safety;

(i) Before the licensee changes statements, representations, and procedures that are incorporated into the license;

(j) Before the licensee releases licensed facilities for unrestricted use; and

(k) Before the licensee receives a sealed source from a different manufacturer or of a different model number than authorized by its license, unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

(2) Reserved.

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

Paragraphs (1) and (2) of Rule 0400-20-07-.14 Notifications is amended by deleting them in their entirety and substituting instead the following:

(1) A licensee shall provide the Division, no later than 30 days after the date that the licensee allows an individual to work under the provisions of subparagraph (1)(b) of Rule 0400-20-07-.13 as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist the following:

(a) A copy of the board certification and, as appropriate, verification of completion of:

1. Training for the authorized medical physicist under Rule 0400-20-07-.24;

2. Any additional case experience required in item (1)(b)1(ii)(VI) of Rule 0400-20-07-.47 for an authorized user under Rule 0400-20-07-.44; or

3. Device-specific training in subparagraph (1)(c) of Rule 0400-20-07-.80 for the authorized user under Rule 0400-20-07-.63; or

(b) A copy of the U.S, Nuclear Regulatory Commission or Agreement State license, the permit issued by a U.S. Nuclear Regulatory Commission master material licensee, the permit issued by a U.S. Nuclear Regulatory Commission or Agreement State licensee of broad scope, the permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission for each individual whom the licensee permits to work under the provisions of this rule.

(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, an associate radiation safety officer, an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

(b) The licensee allows an individual qualified to be a radiation safety officer under Rule 0400-20-07-.23 and 0400-20-07-.27 to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with paragraph (3) of Rule 0400-20-07-.17;

(c) The licensee's mailing address changes;

(d) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in paragraph (2) of Rule 0400-20-10-.16; or

(e) 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 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide or PET radioactive drug production area; or

(f) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in Rule 0400-20-07-.13. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

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

Paragraphs (3) and (4) of Rule 0400-20-07-.15 Exemptions Regarding Specific Licenses of Broad Scope is amended by deleting them in their entirety and substituting instead the following:

(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 identified in the application or on 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 or an ophthalmic physicist;

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

Paragraphs (2) and (3) of Rule 0400-20-07-.17 Authority and Responsibilities for the Radiation Protection Program is amended by deleting them in their entirety and substituting instead the following:

(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. A licensee's management may appoint, in writing, one or more associate radiation safety officers to support the radiation safety officer. The radiation safety officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each associate radiation safety officer. These duties and tasks are restricted to the types of use for which the associate radiation safety officer is listed on a license. The radiation safety officer may delegate duties and tasks to the associate radiation safety officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

(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 and notifies the Division in accordance with paragraph (2) of Rule 0400-20-07-.14.

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

Paragraph (2) of Rule 0400-20-07-.20 Written Directives is amended by deleting it in its entirety and substituting instead the following:

(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 I131: 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;

(f) For permanent implant brachytherapy:

1. Before implantation:

(i) The treatment site;

(ii) The radionuclide; and

(iii) The total source strength; and

2. After implantation but before the patient leaves the post-treatment recovery area:

(i) The treatment site;

(ii) The number of sources implanted,

(iii) The total source strength implanted: and

(iv) The date; or

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

1. Before implantation:

(i) The treatment site;

(ii) The radionuclide; and

(iii) The dose; and

2. After implantation but before completion of the procedure:

(i) The radionuclide;

(ii) The treatment site;

(iii) The number of sources;

(iv) The total source strength and exposure time (or the total dose); and

(v) The date.

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

Paragraph (2) of Rule 0400-20-07-.21 Procedures for Administrations Requiring a Written Directive is amended by deleting it in its entirety and substituting instead the following:

(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;

(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;

(e) Determining if a patient or medical event, as defined in Rule 0400-20-07-.114, has occurred; and

(f) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

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

Rule 0400-20-07-.23 Training for Radiation Safety Officer is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.23 Training for Radiation Safety Officer and Associate 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 or an individual assigned duties and tasks as an associate 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 paragraph (4) of this rule. The names of board certifications that have been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page. To have its certification process 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 five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics; and

3. Pass an examination administered by diplomates of the specialty board that 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 at least two years of full-time practical training and/or supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by

a specialty board recognized by the U.S. Nuclear Regulatory Commission or an Agreement State; or

(ii) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users under 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. One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a Division, U.S. Nuclear Regulatory Commission, or Agreement State license or a permit issued by a Commission master material licensee that authorizes a similar type or types of use or uses of radioactive material. An associate radiation safety officer may provide supervision for those areas for which the associate radiation safety officer is authorized on a Division, U.S. Nuclear Regulatory Commission, or an Agreement State license or permit issued by a U.S. Nuclear Regulatory Commission master material licensee. The full-time radiation safety experience must involve 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; and

(b) This individual must obtain a written attestation, signed by a preceptor radiation safety officer or associate radiation safety officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation must state that the individual has satisfactorily completed the requirements of subparagraph (a) of this paragraph and paragraph (4) of this rule, and is able to independently fulfill the radiation safety-related duties as a radiation safety officer or as an associate radiation safety officer for a medical use license; 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 or as an associate radiation safety officer and who meets the requirements in paragraph (4) of this rule; or

(b) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a U.S. Nuclear Regulatory Commission or an Agreement State license, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by a U.S. Nuclear Regulatory Commission or an Agreement State licensee of broad scope, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the radiation safety officer or associate radiation safety officer, and meets the requirements in paragraph (4) of this rule; or

(c) Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the radiation safety officer and the authorized user on the same new medical use license or new medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee. The individual must also meet the requirements in paragraph (4) of this rule.

(4) 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 a radiation safety officer, an associate radiation safety officer, an authorized medical physicist, authorized nuclear pharmacist, or an authorized user, 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.

Rule 0400-20-07-.24 Training for an Authorized Medical Physicist is amended by deleing it in its entirety and substituting instead the following:

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 paragraph (3) of this rule. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

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

2. In clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to one 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, that assesses knowledge

and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

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

1. Performing sealed source leak tests and inventories;

2. Performing decay corrections;

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

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

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in subparagraphs (1)(a) and (1)(b) and paragraph (3), or subparagraph (2)(a) and paragraph (3) of this rule, and is able to independently fulfill the radiation safety-related duties 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.

Rule 0400-20-07-.25 Training for an Authorized Nuclear Pharmacist is amended by deleting it in its entirety and substituting instead the following:

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. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Have graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) (previously named the American Council on Pharmaceutical Education) 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 that 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 subparagraph (2)(a) of this rule is able to independently fulfill the radiation safety-related duties 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.

Rule 0400-20-07-.26 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.26 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist.

(1) An individual identified on a U.S. Nuclear Regulatory Commission or an Agreement State license or a permit issued by a 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 as a radiation safety officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before the effective date of these rules need not comply with the training requirements of Rule 0400-20-07-.23, Rule 0400-20-07-.24, or Rule 0400-20-07-.25, respectively, except the radiation safety officers and authorized medical physicists identified in this paragraph must meet the training requirements in paragraph (4) of Rule 0400-20-07-.23 or paragraph (3) of Rule 0400-20-07-.24, as appropriate, for any material or uses for which they were not authorized prior to this date.

(2) Any individual certified by the: American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005 need not comply with the training requirements of Rule 0400-20-07-.23 to be identified as a radiation safety officer or as an associate radiation safety officer on a Division, U.S. Nuclear Regulatory Commission, or an Agreement State license or U.S. Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in Rule 0400-20-07-.24, for those materials and uses that these individuals performed on or before October 24, 2005.

(4) 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 on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of Rules 0400-20-07-.38, 0400-20-07-.39, 0400-20-07-.40, 0400-20-07-.43, 0400-20-07-.45, 0400-20-07-.46, 0400-20-07-.47, 0400-20-07-.48, 0400-20-07-.49, 0400-20-07-.52, 0400-20-07-.53, 0400-20-07-.54, 0400-20-07-.55, 0400-20-07-.56, 0400-20-07-.58, 0400-20-07-.59, 0400-20-07-.60, 0400-20-07-.62, and 0400-20-07-.80.

(5) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by a U.S. Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued in accordance with a U.S. Nuclear Regulatory Commission master material license of broad scope on or before October 24, 2005, 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 for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

(a) For uses authorized under Rules 0400-20-07-.38 and 0400-20-07-.40, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in one of the following: nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(b) For uses authorized under Rule 0400-20-07-.44, a physician who was certified on or before October 24, 2005, by one of the following: the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(c) For uses authorized under Rules 0400-20-07-.51 and 0400-20-07-.63, a physician who was certified on or before October 24, 2005, in one of the following: radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(d) For uses authorized under Rule 0400-20-07-.61, a physician who was certified on or before October

24, 2005, in one of the following: radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(6) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a State of Tennessee agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Division, need not comply with the training requirements of Rules 0400-20-07-.38, 0400-20-07-.39, 0400-20-07-.40, 0400-20-07-.43, 0400-20-07-.45, 0400-20-07-.46, 0400-20-07-.47, 0400-20-07-.48, 0400-20-07-.49, 0400-20-07-.52, 0400-20-07-.53, 0400-20-07-.54, 0400-20-07-.55, 0400-20-07-.56, 0400-20-07-.58, 0400-20-07-.59, 0400-20-07-.60, 0400-20-07-.62 and 0400-20-07-.80, when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

(7) 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.

Rule 0400-20-07-.31 Authorization for Calibration, Transmission, and Reference Sources is amended by deleting it in its entirety and substituting instead the following:

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 not exceeding 1.11 gigibecquerels (30 mCi) each, manufactured and distributed by persons specifically licensed under 10 C.F.R. § 32.74, Chapter 0400-20-10, or equivalent Agreement State regulations;

(b) Sealed sources, not exceeding 1.11 gigibecquerels (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 not longer than 120 days in individual amounts not to exceed 0.56 gigibecquerels (15 mCi);

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

1. 7.4 megabecquerels (200 µCi); or

2. 1,000 times the quantities in Schedule RHS 8-30 Chapter 0400-20-10; and

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

(2) Radioactive material in sealed sources authorized by this provision shall not be:

(a) Used for medical use as defined in paragraph (19) of Rule 0400-20-07-.05, except in accordance with the requirements of Rule 0400-20-07-.61; or

(b) Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of

any single sealed source authorized under this rule.

(3) A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraph (1) or (2) of this rule need not list these sources on a specific medical use license.

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

Rule 0400-20-07-.39 Training for Uptake, Dilution, and Excretion Studies is amended by deleting it in its entirety and substituting instead the following:

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. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates 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 eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Rule 0400-20-07-.26, this rule, Rule 0400-20-07-.43, or Rule 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 that the individual has satisfactorily completed the requirements in part 1 of this subparagraph and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Rule 0400-20-07-.38. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements of this rule, Rule 0400-20-07-.26, Rule 0400-20-07-.43, Rule 0400-20-07-.47, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of Rule 0400-20-07-.26, this rule, Rule 0400-20-07-.43, Rule 0400-20-07-.47, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, and that faculty member concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in part 1 of this subparagraph.

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

Rule 0400-20-07-.41 Radionuclide Contaminants is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.41 Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

1) A licensee shall not administer to humans a radiopharmaceutical that contains:

(a) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium99m (0.15 µCi 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 µCi 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 µCi of Sr-85 per mCi of Rb-82).

(2) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with paragraph (1) of this rule.

(3) A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph (1) of this rule.

(4) If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with Rule 0400-20-

07-.95.

(5) A licensee shall report immediately to the Division each occurrence of radionuclide contaminant concentration exceeding the limits specified in paragraph (1) of this rule at the time of generator elution, in accordance with Rule 0400-20-07-.114.

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

Rule 0400-20-07-.43 Training for Imaging and Localization Studies is amended by deleting it in its entirety and substituting instead the following:

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. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page. To have its certification process 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; and

(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. An authorized nuclear pharmacist who meets the requirements in Rule 0400-20-07-.25 or 0400-20-07-.26 may provide the supervised work experience for item (VII) of this subpart. 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 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 that the individual has satisfactorily completed the requirements in part 1 of this subparagraph and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Rules 0400-20-07-.39 and 0400-20-07-.40. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in Rule 0400-20-07-.26, this rule, 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; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rule 0400-20-07-.26, this rule, 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, and concurs with the attestation provided by the residency program director. The residency training program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in part 1 of this subparagraph.

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

Rule 0400-20-07-.44 Use of Unsealed Radioactive Material for Which a Written Directive is Required is amended by deleting it in its entirety and substituting instead the following:

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 identified in item (1)(b)1(ii)(VI) of Rule 0400-20-07-.47 prepared for medical use and for which a written directive is required that is:

(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 or U.S. Nuclear Regulatory Commission requirements;

(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;

(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.

Rule 0400-20-07-.47 Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required is amended by deleting it in its entirety and substituting instead the following:

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) of this rule. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit 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 Council on Postdoctoral Training of the American Osteopathic Association; and

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

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

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements of this rule, 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 from the four categories in this item. Radioactive drugs containing radionuclides in categories not included in this item are regulated under Rule 0400-20-07-.81. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

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

II. Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

III. Parenteral administration of any radioactive drug that contains a radionuclide primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

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

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in 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 for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in this rule, Rule 0400-20-07-.26, or equivalent Agreement State or equivalent U.S. Nuclear Regulatory Commission requirements and who has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents

the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this rule, Rule 0400-20-07-.26, or equivalent Agreement State or equivalent U.S. Nuclear Regulatory Commission requirements, who has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and who concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association, and must include training and experience specified in part 1 of this subparagraph.

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

Rule 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 Millicurries) is amended by deleting it in its entirety and substituting instead the following:

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 Millicurries).

(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 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 of subparagraph (c) of this paragraph and whose certification has been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page; or

(b) Is an authorized user under Rule 0400-20-07-.47 for uses listed in subitems (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 of Rule 0400-20-07-.26, Rule 0400-20-07-.47, Rule 0400-20-07-.48, Rule 0400-20-07-.49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of subparagraph (1)(b) of Rule 0400-20-07-.47 must also have experience administering dosages as specified in subitems (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 three cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(d) Has obtained written attestation that the individual has satisfactorily completed the requirements of parts (c)1 and (c)2 of this paragraph and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodine I-131 for medical uses authorized under Rule 0400-20-07-.44. The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements of Rule 0400-20-07-.26, Rule 0400-20-07-.47, this rule, Rule 0400-20-07-.49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements and who has experience in administering dosages as specified in subitem (1)(b)1(ii)(VI)I or II of Rule 0400-20-07-.47; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of Rule 0400-20-07-.26, Rule 0400-20-07-.47, this rule, Rule 0400-20-07-.49, or equivalent Agreement State requirements, who has experience in administering dosages as specified in subitem (1)(b)1(ii)(VI)I or II of Rule 0400-20-07-.47, and who concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in parts (c)1 and (c)2 of this paragraph.

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

Rule 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 Millicurries) is amended by deleting it in its entirety and substituting instead the following:

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 Millicurries).

(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 of parts (c)1 and (c)2 of this paragraph and whose certification has been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit 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, Rule 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 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 three 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 of 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 of Rule 0400-20-07-.26, Rule 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 of 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.

(d) Has obtained written attestation that the individual has satisfactorily completed the requirements of parts (c)1 and (c)2 of this paragraph and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodine I-131 for medical uses authorized under Rule 0400-20-07-.44. The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements of Rule 0400-20-07-.26, Rule 0400-20-07-.47, Rule 0400-20-07-.48, this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements and who has experience in administering

dosages as specified in subitem (1)(b)1(ii)(VI)I or II of Rule 0400-20-07-.47; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of Rule 0400-20-07-.26, Rule 0400-20-07-.47, Rule 0400-20-07-.48, this rule, or equivalent Agreement State requirements, who has experience in administering dosages as specified in subitem (1)(b)1(ii)(VI)I or II of Rule 0400-20-07-.47, and who concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in parts (c)1 and (c)2 of this paragraph.

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

Rule 0400-20-07-.50 Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive is amended by deleting it in its entirety and substituting instead the following:

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;

(b) Is an authorized user under Rule 0400-20-07-.59 or Rule 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;

(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 Rule 0400-20-07-.80, and who meets the requirements in subparagraph (d) of this paragraph; or

(d) 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in subitem (1)(b)1(ii)(VI)III of Rule 0400-20-07-.47. 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, Rule 0400-20-07-.47 or this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, in the parenteral administration listed in subitem (1)(b)1(ii)(VI)III of Rule 0400-20-07-.47. A supervising authorized user who meets the requirements in Rule 0400-20-07-.47, this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements must have experience in administering dosages in the same category or categories 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 to patients or human research subjects, that include at least 3 cases involving the parenteral administrations as specified in subitem (1)(b)1(ii)(VI)III of Rule 0400-20-07-.47; 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 obtained from either:

(i) A preceptor authorized user who meets the requirements in Rule 0400-20-07-.26, Rule 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, this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rule 0400-20-07-.26, Rule 0400-20-07-.47, Rule 0400-20-07-.50, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in parts 1 and 2 of this subparagraph.

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

Rule 0400-20-07-.51 Use of Sealed Sources for Manual Brachytherapy is amended by deleting it in its entirety and substituting instead the following:

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 for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research to deliver therapeutic doses for medical use 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.

Rule 0400-20-07-.57 Decay of Strontium-90 Sources for Ophthalmic Treatments is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.57 Strontium-90 Sources for Ophthalmic Treatments.

(1) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph (2) of this rule are performed by either:

(a) An authorized medical physicist; or

(b) An individual who:

1. Is identified as an ophthalmic physicist on a specific medical use license issued by the U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; or permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee; and

2. Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

3. Has successfully completed one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

4. Has documented training in:

(i) The creation, modification, and completion of written directives;

(ii) Procedures for administrations requiring a written directive; and

(iii) Performing the calibration measurements of brachytherapy sources as detailed in Rule 0400-20-07-.56.

(2) The individuals identified in paragraph (1) of this rule must:

(a) 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; and

(b) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (1) of this rule will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

(3) Licensees must 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.

Rule 0400-20-07-.59 Training for Use of Manual Brachytherapy Sources is amended by deleting it in its entirety and substituting instead the following:

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. The names of board certifications which have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of three years of residency training in a radiation 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 Council on Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, that 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 facility authorized to use radioactive materials under Rule 0400-20-07-.51, 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; and

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

2. Has completed three 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 Agreement State or U.S. Nuclear Regulatory Commission 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 Council 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 parts 1 and 2 of this subparagraph and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under Rule 0400-20-07-.51. The attestation must be obtained from either:

(i) 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; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is 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 and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in parts 1 and 2 of the subparagraph.

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

Part 3 of subparagraph (b) of paragraph (1) of Rule 0400-20-07-.60 Training for ophthalmic use of strontium-90 is amended by deleting it in its entirety and substituting instead the following:

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Rule 0400-20-07-.26, Rule 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 is able to independently fulfill the radiation safety-related duties 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.

Rule 0400-20-07-.61 Use of Sealed Sources for Diagnosis is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.61 Use of Sealed Sources and Medical Devices for Diagnosis.

(1) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(2) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(3) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration 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.

Rule 0400-20-07-.62 Training for Use of Sealed Sources for Diagnosis is amended by deleting it in its entirety and substituting instead the following:

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

(1) Except as provided in Rule 0400-20-07-.26, a licensee shall require the authorized user of a diagnostic sealed source or 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 of subparagraphs (c) and (d) 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 that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page; or

(b) Is an authorized user for uses listed in Rule 0400-20-07-.40 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

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

1. Radiation physics and instrumentation;

2. Radiation protection;

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

4. Radiation biology; and

(d) 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.

Rule 0400-20-07-.63 Use of Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.63 Use of Sealed Source in Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

(1) A licensee must only use sealed sources:

(a) As approved in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

(b) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active investigational device exemption (IDE) application accepted by the U.S. Food and Drug Administration (FDA) provided the requirements in paragraph (1) of Rule 0400-20-07-.22 are met.

(2) A licensee may only use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(a) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but such devices must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research in accordance with an active IDE application accepted by the 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.

Paragraph (4) of Rule 0400-20-07-.66 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units is amended by deleting it in its entirety and substituting instead the following:

(4) (a) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

(b) A licensee shall provide operational and safety instructions initially and at least annually, to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in:

1. The procedures identified in subparagraph (1)(d) of this rule; and

2. The operating procedures for the unit.

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

Paragraph (7) of Rule 0400-20-07-.66 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units is amended by deleting it in its entirety and substituting instead the following:

(7) A licensee shall retain a copy of the procedures required by subparagraph (1)(d) of this rule and part (4)(b)2 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.

Rule 0400-20-07-.77 Five Year Inspection for Teletherapy Units and Gamma Stereotactic Radiosurgery Units is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.77 Full-Inspection Servicing for Teletherapy 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 to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.

(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.

Rule 0400-20-07-.80 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.is amended by deleting it in its entirety and substituting instead the following:

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 Rule 0400-20-07-.63 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in subparagraph (c) of this paragraph. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted

on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

2. Pass an examination, administered by diplomates of the specialty board, that 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 facility that is authorized to use radioactive materials in Rule 0400-20-07-.63, involving:

(I) Reviewing full calibration measurements and periodic spot-checks;

(II) Preparing treatment plans and calculating treatment doses and times;

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

(IV) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(V) Checking and using survey meters; and

(VI) Selecting the proper dose and how it is to be administered; and

2. Has completed three years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in this rule, 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 Council 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 of part (a)1 of this paragraph, parts 1 and 2 of this subparagraph, and subparagraph (c) of this paragraph and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements of this rule, Rule 0400-20-07-.26, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements for an authorized user for each type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this rule, Rule 0400-20-07-.26, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, for the type(s) of therapeutic medical unit for which the individual is requesting user status, and who concurs with the attestations provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in parts 1 and 2 of this subparagraph; 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.

Rule 0400-20-07-.82 Records of Authority and Responsibilities for Radiation Protection Programs is amended by deleting it in its entirety and substituting instead the following:

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 five 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.

(4) For each associate radiation safety officer appointed under paragraph (2) of Rule 0400-20-07-.17, the licensee shall retain, for five years after the associate radiation safety officer is removed from the license, a copy of the written document appointing the associate radiation safety officer signed by the licensee's management.

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

Rule 0400-20-07-.96 Records of Safety Instruction and Training is amended by deleting it in its entirety and substituting instead the following:

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 0400-20-07-.66 for three years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

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

Rule 0400-20-07-.110 Records of Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.110 Records of Full-Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

(1) A licensee shall maintain a record of the full-inspection servicing 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.

New Rule

Rule 0400-20-07-.114 Report and Notification for an Eluate Exceeding Permissible Molybdenium-99, Strontium-82, and Strontium-85 Concentrations is added to Chapter 0400-20-07 following Rule 0400-20-07-.113 Report of a Leaking Source to read as follows:

0400-20-07-.114 Report and Notification for an Eluate Exceeding Permissible Molybdenium-99, Strontium-82, and Strontium-85 Concentrations

(1) The licensee shall notify by telephone the Division and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in paragraph (1) of Rule 0400-20-07-.41 at the time of generator elution. The telephone report to the Division must include:

(a) The name of the manufacturer;

(b) The model number and serial number (or lot number) of the generator;

(c) The results of the measurement;

(d) The date of the measurement;

(e) Whether dosages were administered to patients or human research subjects, when the distributor was notified; and

(f) The action taken.

(2) By an appropriate method listed in Rule 0400-20-04-.07, the licensee shall submit a written report to the Division within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the:

(a) Action taken by the licensee;

(b) Patient dose assessment;

(c) Methodology used to make this dose assessment if the eluate was administered to patients or human research subjects;

(d) Probable cause and an assessment of failure in the licensee's equipment, procedures, or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and

(e) Information in the telephone report as required by 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.

Amendments

Paragraph (3) of Rule 0400-20-08-.05 Personal Radiation Safety Requirements for Radiographers and Radiographer's Assistants is amended by deleting it in its entirety and substituting instead the following:

(3) Personnel monitoring.

(a) The licensee or registrant shall not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct–reading dosimeter, an operating alarm ratemeter, and personnel dosimeter. At permanent radiography installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

1. Pocket dosimeters shall have a range from zero to two millisieverts (200 millirems) and shall be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

2. Each personnel dosimeter shall be assigned to and worn only by one individual.

3. Film badges must be replaced monthly and all other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

(b) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters shall be read and the exposures recorded at the beginning and end of each shift. In accordance with Rule 0400-20-08-.15, the licensee or registrant shall maintain each record of these exposures for inspection by the Division for three years after the record is made.

(c) Pocket dosimeters, or electronic personal dosimeters, shall be checked at periods not to exceed 12 months for correct response to radiation. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure. In accordance with Rule 0400-20-08-.15, the licensee or registrant shall maintain each record of these exposures for inspection by the Division for three years after the record is made.

(d) If an individual's pocket chamber is found to be off-scale, or if his or her electronic personal dosimeter reads greater than two millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter shall be sent for processing and evaluation within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation dose has been made. This determination shall be made by the RSO or the RSO's designee. The results of this determination shall be included in the records maintained in accordance with Rule 0400-20-08-.15.

(e) If the personnel dosimeter required by subparagraph (a) of this paragraph is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements of subparagraph (a) of this paragraph is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the period for which the personnel dosimeter was lost or damaged shall be included in the records maintained in accordance with Rule 0400-20-08-.15.

(f) Dosimetry results must be retained in accordance with Rule 0400-20-08-.15.

(g) Each alarm ratemeter shall:

1. Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift;

2. Be set to give an alarm signal at a preset dose rate of five mSv/hr (500 mrem/hr); with an accuracy of plus or minus 20 percent of the true radiation dose rate;

3. Require special means to change the preset alarm function; and

4. Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarm ratemeter calibrations in accordance with Rule 0400-20-08-.15.

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

Subparagraph (c) of paragraph (2) of Rule 0400-20-08-.12 Reporting Requirements is amended by deleting it in its entirety and substituting instead the following:

(c) Manufacturer and model number of equipment involved in the incident as well as activity, model, and serial number of source (if applicable).

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

Subparagraph (b) of paragraph (1) of Rule 0400-20-08-.15 Recordkeeping Requirements is amended by deleting it in its entirety and substituting instead the following:

(b) Each licensee and registrant shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite:

1. The license or registration authorizing the use of licensed material or registered equipment;

2. A copy of “State Regulations for Protection Against Radiation”;

3. Utilization records for each radiographic exposure device dispatched from that location as required by paragraph (7) of Rule 0400-20-08-.04;

4. Records of equipment problems identified in daily checks of equipment as required by paragraph (8) of Rule 0400-20-08-.04. The licensee or registrant shall maintain each record for three years after it is made. The record shall include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done;

5. Records of alarm system and entrance control checks required by paragraph (9) of Rule 0400-20-08-.04, if applicable. The licensee or registrant shall maintain each record for three years after it is made;

6. Records of direct reading dosimeters such as pocket dosimeter and/or electronic personal dosimeters readings as required by paragraph (3) of Rule 0400-20-08-.05. The licensee or registrant shall maintain each record for three years after it is made;

7. Records of dosimetry reports as required by paragraph (3) of Rule 0400-20-08-.05. The licensee or registrant shall maintain each record until the Division terminates the license or registration;

8. Operating and emergency procedures required by paragraph (2) of Rule 0400-20-08-.05. The licensee or registrant shall maintain a copy of current operating and emergency procedures until the Division terminates the license or registration. Superseded material shall be retained for three years after the change is made;

9. Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by paragraph (4) of Rule 0400-20-08-.04. The licensee or registrant shall maintain each record for three years after it is made;

10. Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket

dosimeters and/or electronic personal dosimeters as required by paragraph (3) of Rule 0400-20-08-.05. The licensee or registrant shall maintain each record for three years after it is made;

11. Latest survey records required by paragraph (4) of Rule 0400-20-08-.06. The licensee or registrant shall maintain the record of each exposure device survey conducted before the device is placed in storage, if that survey is the last one performed in the workday, for three years after it is made;

12. The shipping papers for the transportation of radioactive materials required by Chapter 0400-20-10;

13. When operating under reciprocity pursuant to Rule 0400-20-10-.29, a copy of the Agreement State license authorizing the use of licensed materials; and

14. Records of estimates of exposures because of off-scale personal direct reading dosimeters or of lost or damaged personnel dosimeters until the Division terminates the license or registration.

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

Amendments

Paragraph (10) of Rule 0400-20-10-.13 Special Requirements for Issuance of Specific Licenses is amended by deleting it in its entirety and substituting instead the following:

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

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceuticals containing radioactive material for use by persons authorized pursuant to Chapter 0400-20-07 will be approved if:

1. The applicant satisfies the general requirements of Rule 0400-20-10-.12;

2. The applicant submits evidence that the applicant is at least one of the following:

(i) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 C.F.R. § 207.20(a);

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

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

(iv) Operating as a nuclear pharmacy within a Federal medical institution; or

(v) A Positron Emission Tomography (PET) drug production facility registered with a state agency.

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

4. The applicant commits to the following labeling requirements:

(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL”; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half–life greater than 100 days, the time may be omitted.

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

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

1. May prepare radiopharmaceuticals for medical use, as defined in Rule 0400-20-07-.05, provided that the radiopharmaceuticals are prepared by either an authorized nuclear pharmacist, as specified in parts 2 and 4 of this subparagraph, or an individual under the supervision of an authorized nuclear pharmacist as specified in Rule 0400-20-07-.19.

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

(i) This individual qualifies as an authorized nuclear pharmacist as defined in Rule 0400-20-07-.05,

(ii) This individual meets the requirements specified in paragraph (2) of Rule 0400-20-07-.25 and Rule 0400-20-07-.27, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

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

3. May take the actions authorized in parts 1 and 2 of this subparagraph notwithstanding more restrictive language in license conditions.

4. May designate a pharmacist (as defined in Rule 0400-20-07-.05) as an authorized nuclear pharmacist if the individual was a nuclear pharmacist at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission.

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

(i) Certification by a specialty board whose certification process has been recognized by the Division, U.S. Nuclear Regulatory Commission, or an Agreement State as specified in paragraph (1) of Rule 0400-20-07-.25; or

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

(iii) U.S. Nuclear Regulatory Commission master materials licensee permit; or

(iv) The permit issued by a licensee or U.S. Nuclear Regulatory Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorization nuclear pharmacist; or

(v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission; and

(vi) A copy of the state pharmacy licensure or registration no later than 30 days after the date that the licensee allows the individual to work as an authorized nuclear pharmacist under subparts 2(i) and (ii) of this subparagraph.

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

1. Perform tests before initial use, periodically and following repair on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments when necessary; and

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

(d) A licensee shall satisfy the labeling requirements of part (a)4 of this paragraph.

(e) Nothing in this rule relieves the licensee from complying with applicable FDA, other federal, and other state requirements governing radioactive drugs.

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

Paragraph (6) of Rule 0400-20-10-.16 Specific Terms and Conditions of Licenses is amended by deleting it in its entirety and substituting instead the following:

(6) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Rule 0400-20-07-.41. The licensee shall record the results of each test and retain each record for three years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in paragraph (1) of Rule 0400-20-07-.41 at the time of generator elution, in accordance with Rule 0400-20-07-.114.

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

Subparagraph (b) of paragraph (5) of Rule 0400-20-10-.27 Inspections is amended by deleting it in its entirety and substituting instead the following:

(b) The qualified individual performing the inspection shall record the results of the inspection on evaluation forms provided by the Division, one form for each facility plus an appropriate form, or forms, for each piece of equipment. The evaluation forms shall describe the compliance status of the facility and equipment as it exists at the time of the inspection.

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

Rule 0400-20-10-.27 Inspections is amended by adding a new paragraph (6) to read as follows:

(6) If a registrant who has previously employed inspection services of registered individuals, other than employees of the Division, as authorized by paragraph (4) of Rule 0400-20-10-.27, chooses to discontinue those services, then the registrant shall notify the Division 90 days prior to the end of the respective inspection cycle. Should the registrant fail to notify the Division within this time frame, a penalty consistent with T.C.A. § 68-202-212(b) may be assessed.

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

Subpart (iii) of part 2 of subparagraph (b) of paragraph (7) of Rule 0400-20-10-.30 Packaging and Transportation of Radioactive Material is amended by deleting it in its entirety and substituting instead the following:

(iii) Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 C.F.R. § 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.

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

Subparagraph (c) of paragraph (21) of Rule 0400-20-10-.30 Packaging and Transportation of Radioactive Material is amended by deleting it in its entirety and substituting instead the following:

(c) Procedures for submitting advance notification.

1. The notification shall be made in writing to the office of each appropriate governor or governor's designee, the office of each appropriate Tribal official or Tribal official's designee, the Director, Division of Radiological Health, and to the Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

2. A notification delivered by mail shall be postmarked at least seven days before the

beginning of the seven-day period during which departure of the shipment is estimated to occur.

3. A notification delivered by any other means than mail shall reach the office of the governor, or of the governor's designee, the Tribal official or Tribal official's designee, and the Director, Division of Radiological Health, at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur.

(i) Reserved.

(ii) Contact information for each state, including telephone and mailing addresses of governors and governors' designees, and participating Tribes, including telephone and mailing addresses of Tribal officials and Tribal officials' designees, is available on the U.S. Nuclear Regulatory Commission Web site at: https://scp.nrc.gov/special/designee.pdf.

(iii) A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(iv) The licensee shall retain a copy of the notification as a record for three years.

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

Subparagraph (c) of paragraph (5) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting it in its entirety and substituting instead the following:

(c) Upon receipt of an application, the Division must examine it to ensure that it is complete and advise the applicant in writing of its findings via electronic mail. Sixty days will be allowed for the initial and each subsequent review per part 3 of this subparagraph.

1. If an application is determined to be incomplete, the Division must notify the applicant in writing via electronic mail of the finding with a brief explanation of the deficiencies. The application filing fee shall be retained by the Division.

2. After receiving notice from the Division that the application was incomplete, the applicant shall have 180 calendar days to correct the deficiencies. If properly corrected, the application will be processed and no additional application fee is required, except for the possibility of those above Category 8. If the deficiencies are not corrected within the 180-day correction period, the fee will be forfeited in its entirety to the Division with no further action taken on the application by the Division. If the applicant re-applies, a new application fee must be paid in full.

3. Upon receipt of a corrected application revised pursuant to part 1 or 2 of this subparagraph, the Division shall re-evaluate the application and notify the applicant of its finding as to whether the deficiencies in the application have been corrected. The same procedure to notify an applicant as to whether the application is complete will follow the requirements specified by this subparagraph, with the exception being that the 180-day correction period begins from the receipt of the initial application - not receipt of the revised application.

4. Any person possessing licensable quantities of unlicensed radioactive material during the review of an application for a license for the radioactive material shall be in violation of Rule 0400-20-10-.02.

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

Rule 0400-20-10-.34 Supplemental Fees for Calendar Year 2013 is amended by deleting it in its entirety and substituting instead the following:

0400-20-10-.34 Reserved.

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

The specific activity for the symbol of radionuclide “Sm-147” under the units (TBq/g) in Table A-1—A_1 and A_2 VALUES FOR RADIONUCLIDES that follows subparagraph (b) of paragraph (5) of Rule 0400-20-10-.38 Appendix-- Schedules is amended by deleting the value “$8.5X10^{-1}$” and substituting in its place the value “$8.5X10^{-10}$” so that as amended the entry for “Sm-147” shall read as follows:

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5x10^{-10}$	$2.3X10^{-8}$

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

Amendments

Paragraph (1) of Rule 0400-20-12-.20 Personnel Monitoring is amended by deleting it in its entirety and substituting instead the following:

(1) The licensee or registrant shall not permit an individual to act as a logging supervisor or logging assistant unless that person wears a personnel dosimeter at all times during the handling of licensed radioactive materials. Each personnel dosimeter shall be assigned to and worn by only one individual. Film badges shall be replaced at least monthly and other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly, or promptly after replacement, whichever is more frequent.

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

Amendments

Part 2 of subparagraph (b) of paragraph (2) of Rule 0400-20-13-.02 Background Investigations and Access Authorization Program is amended by deleting it in its entirety and substituting instead the following:

2. Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee to the ATTN: Director, Tennessee Division of Radiological Health at the address prescribed in Rule 0400-20-04-.07. The fingerprints of the named reviewing official must be taken by a law enforcement agency, federal or state agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a state to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every ten years in accordance with subparagraph (3)(c) of this rule.

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

Subparagraph (c) of paragraph (4) of Rule 0400-20-13-.02 Background Investigations and Access Authorization Program is amended by deleting it in its entirety and substituting instead the following:

(c) Procedures for processing of fingerprint checks.

1. For the purpose of complying with this chapter, licensees shall use an appropriate method listed in 10 C.F.R. § 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-07D04M, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at https://www.nrc.gov/security/chp.html.

2. Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Division of Physical and Cyber Security Policy by e-mailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the U.S. Nuclear Regulatory Commission's public Web site. (To find the current fee amount, go to the Licensee Criminal History Records Checks & Firearms Background Check information page at https//www.nrc.gov/security/chp.html and see the link for How do I determine how much to pay for the request?).

3. The Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

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

Subparagraph (d) of paragraph (2) of Rule 0400-20-13-.03 Physical Protection Requirements During Use is amended by deleting it in its entirety and substituting instead the following:

(d) Protection of information.

1. Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

2. Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan, implementing procedures, and the list of individuals who have been approved for unescorted access.

3. Before granting an individual access to the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access, licensees shall:

   (i) Evaluate an individual's need to know the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access; and

   (ii) If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in parts (3)(a)2 through 7 of Rule 0400-20-13-.02.

4. Licensees need not subject the following individuals to the background investigation elements for protection of information:

   (i) The categories of individuals listed in parts (5)(a)1 through 13 of Rule 0400-20-13-.02; or

   (ii) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in parts (3)(a)2 through 7 of Rule 0400-20-13-.02, has been provided by the security service provider.

5. The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access.

6. Licensees shall maintain a list of persons currently approved for access to the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to obtain the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access.

7. When not in use, the licensee shall store its security plan, implementing procedures, and the list of individuals who have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

8. The licensee shall retain as a record for three years after the document is no longer needed:

   (i) A copy of the information protection procedures; and

   (ii) The list of individuals approved for access to the security plan, implementing procedures, or the list of individuals who have been approved for unescorted access.

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

Part 1 of subparagraph (a) of paragraph (4) of Rule 0400-20-13-.04 Physical Protection in Transit is amended by deleting it in its entirety and substituting instead the following:

1. The notification must be made to the Division and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the U.S. Nuclear Regulatory Commission's Web site at https://scp.nrc.gov/special/designee.pdf. Notifications to the Division should be in accordance with the methods set out in 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.

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Commissioner on 10/10/2023, and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 07/12/2023

Rulemaking Hearing(s) Conducted on: (add more dates). 09/07/2023

Date: October 10, 2023

Signature: 

Name of Officer: David W. Salyers, P.E.

Title of Officer: Commissioner

Agency/Board/Commission: Commissioner of the Department of Environment and Conservation

Rule Chapter Number(s): 0400-20-04, 0400-20-05, 0400-20-06, 0400-20-07, 0400-20-08, 0400-20-10, 0400-20-12, and 0400-20-13

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Jonathan Skrmetti
Attorney General and Reporter

Nov. 29, 2023
Date

Department of State Use Only

Filed with the Department of State on: 12/4/2023

Effective on: 3/3/2024

Tre Hargett
Secretary of State

Public Hearing Comments

One copy of a document that satisfies T.C.A. § 4-5-222 must accompany the filing.

During the comment period, the Department received four written comments from one commenter and there were no comments received at the rulemaking hearing.

1. Comment: A commenter pointed out that the first sentence in subparagraph (3)(c) of Rule 0400-20-07-.23 does not agree with its federal analog at 10 C.F.R. § 35.50 and contains a typographical error. The word “license” should be “licensee.”

   Response: The Commissioner agrees, and the typographical error has been corrected.

2. Comment: A commenter made the Department aware that the American Council on Pharmaceutical Education as cited in subparagraph (1)(a) of Rule 0400-20-07-.25 has changed its name to Accreditation Council for Pharmacy Education and recommended the name be updated.

   Response: The Commissioner agrees, and the name has been changed as suggested.

3. Comment: A commenter pointed out that paragraph (5) of Rule 0400-20-07-.26 does not agree with its federal analog at 10 C.F.R. § 35.57(b)(2) that correctly identifies that permits were not issued “by” but “in accordance with” a Commission master material license of broad scope on or before October 25, 2005. The commenter recommends that the Department make this correction to paragraph (5) of Rule 0400-20-07-.26.

   Response: The Commissioner agrees, and the paragraph was revised as suggested.

4. Comment: A commenter pointed out that the purpose of amending Rule 0400-20-07-.41 is to align the rule with 10 C.F.R. § 35.204. However, the current language in paragraph (2) was replaced in its entirety with the federal analog in 10 C.F.R. § 35.204(b), and the federal analog to 10 C.F.R. § 35.204(c) was intended to be retained and amended as paragraph (3) with the remaining paragraphs renumbered. The commenter suggested that the Rule 0400-20-07-.41 be revised as originally intended.

   Response: The Commissioner agrees, and the rule was revised as suggested.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

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

The bulk of this rulemaking focuses on the medical use of radioactive materials. The affected medical organizations could include dentists, physicians, and medical facilities licensed to use radioactive materials in their practice. Many of these organizations are small businesses. Using the Nuclear Regulatory Commission's (NRC) Regulatory Analysis, the average initial implementation cost per licensee is $1,100 and the estimated average annual cost per licensee is $100.

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

This rule requires no additional reporting, no additional recordkeeping, and no other administrative costs to remain in compliance with the proposed rule. No additional professional skills are necessary for preparation of reports or records as a result of this rule.

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

This rule provides a positive effect on impacted businesses by ensuring that all licensed businesses are adequately trained to use nuclear materials in the performance of practices in a manner that minimizes undue exposure to themselves and to their clients. These rules should increase consumer's confidence in the health and safety practices of their caregivers.

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

The Department is not aware of a less burdensome, less intrusive, or less costly alternative method of achieving the objectives of this rule, because this rule substantially codifies existing federal law. Tennessee is an Agreement State with the NRC and desires to remain an Agreement State.

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

The amended rules, when effective, will make the Department's rules comparable to the Conference of Radiation Control Program Directors Suggested State Regulations (SSRs): Part G - Use of Radionuclides in the Healing Arts. In addition, the rulemaking references 10 C.F.R. part 35 – Medical Use of Byproduct Material. These rules are necessary for Agreement States to align with federal regulations to remain an Agreement State the same as other states.

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

Exemption of small businesses from any part of the requirements proposed in these rules would pose a potential health risk to persons being exposed to radioactive materials during processing or transportation. In addition, small businesses are required to adhere to licensing standards in the same manner as larger businesses. The consequences of not adopting these rules could affect the State of Tennessee status as an NRC Agreement State.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228, “On any rule and regulation proposed to be promulgated, the proposing agency shall state in a simple declarative sentence, without additional comments on the merits or the policy of the rule or regulation, whether the rule or regulation may have a projected financial impact on local governments. The statement shall describe the financial impact in terms of increase in expenditures or decrease in revenues.”

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

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The new rule and amendments bring the regulations of the Division of Radiological Health into compliance with changes that the U.S. Nuclear Regulatory Commission (NRC) has made to Title 10 of the Code of Federal Regulations. This compatibility is required for Tennessee to maintain its status as an Agreement State. The rulemaking amends Chapters 0400-20-04, 0400-20-05, 0400-20-06, 0400-20-07, 0400-20-08, 0400-20-10, 0400-20-12, and Chapter 0400-20-13 to update regulatory requirements to:

- Establish separate requirements for identifying and reporting medical events involving permanent implant brachytherapy.
- Amend training and experience requirements in multiple sections to remove the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State.
- Change the requirements for measuring the molybdenum-99 (Mo-99) concentration for elutions of Mo-99/Technetium-99m (Tc-99m) generators and add requirements for reporting and notification of a generator eluate exceeding permissible Mo-99, strontium-82 (Sr-82), or strontium-85 (Sr-85) concentrations.
- Allow licensees to appoint a qualified individual with expertise in certain uses of byproduct material to be named on a license to serve as an associate radiation safety officer (ARSO).
- Remove text requiring processing and evaluation by National Voluntary Laboratory Accreditation Program processor.
- Change in Sm-147 value in Table A-1.
- Add Social Security Number fraud prevention measures.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

The rulemaking is pursuant to Tennessee Code Annotated section 68-202-206 authorizing the Commissioner to promulgate rules and regulations for implementation of the Radiological Health Service Act. In addition, 10 C.F.R. part 150 defines activity in Agreement States as well as the regulatory authority of the Nuclear Regulatory Commission within Agreement States.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

No representatives of any potentially affected company or organization have urged adoption or rejection of these amendments.

(D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

The Department is not aware of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

This rulemaking is not likely to increase or decrease state or local government revenue or expenditures.

(F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Andrew Holcomb
Division of Radiological Health
Department of Environment and Conservation
(615) 532-3038
Andrew.Holcomb@tn.gov

(G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Alli Williamson
Legislative Liaison
Office of General Counsel

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

William R. Snodgrass Tennessee Tower
312 Rosa L. Parks Avenue, 2nd Floor
Nashville, Tennessee 37243
(629) 401-9485
Alli.F.Williamson@tn.gov

(I) Any additional information relevant to the rule proposed for continuation that the committee requests.

(1) A description of the action proposed, the purpose of the action, the legal authority for the action and the plan for implementing the action.

The action proposed is the adoption of the rules contained herein amending Chapters 0400-20-04, 0400-20-05, 0400-20-06, 0400-20-07, 0400-20-08, 0400-20-10, 0400-20-12, and 0400-20-13 to maintain compatibility with federal regulations that is required for Tennessee to maintain its status as an Agreement State. These rules are implemented pursuant to Tennessee Code Annotated section 68-202-206 authorizing the Commissioner to promulgate rules and regulations for implementation of the Radiological Health Service Act.

(2) A determination that the action is the least-cost method for achieving the stated purpose.

This rulemaking is the least-cost method to achieve the stated purpose. As an Agreement State, the Department is required to maintain a degree of compatibility with the Nuclear Regulatory Commission (NRC) regulations. Therefore, our rulemaking is not allowed a high degree of latitude to make significant changes.

(3) A comparison of the cost-benefit relation of the action to nonaction.

These rule amendments are being promulgated to meet legislative and regulatory requirements as an Agreement State with the NRC. The cost of these rules is anticipated to be the work hours dedicated to making the rulemaking effective. If the rules are not promulgated, the absence of legislative compatibility could affect our status as an Agreement State via heightened oversight which would necessitate many avoidable work hours dedicated to the oversight requirements. Based on this comparison, the benefits of moving forward with this rulemaking outweigh the costs.

(4) A determination that the action represents the most efficient allocation of public and private resources.

This action represents the most efficient allocation of public and private resources because the cost of the Department's administration will be absorbed by existing resources, and it will keep licensees in compliance with the changes to Title 10 of the Code of Federal Regulations mandated by the NRC.

(5) A determination of the effect of the action on competition.

This rulemaking will have no significant effect on competition in the marketplace because all participants are subject to the same requirements.

(6) A determination of the effect of the action on the cost of living in the geographical area in which the action would occur.

Cost of living in the geographical area in which the action would occur will not be affected.

(7) A determination of the effect of the action on employment in the geographical area in which the action would occur.

It is not anticipated that the action will affect employment.

(8) The source of revenue to be used for the action.

The action can be accommodated with existing resources.

(9) A conclusion as to the economic impact upon all persons substantially affected by the action, including an analysis containing a description as to which persons will bear the costs of the action and which persons will benefit directly and indirectly from the action.

The rulemaking will allow the Department to maintain compatibility with the NRC. It is not anticipated that this rulemaking will impose substantial increased costs on affected parties. The NRC estimated increased costs on all regulated small entities that can be extrapolated to less than $200,000 overall on licensed entities in Tennessee. The Department anticipates that some licensees will experience an increased amount of employee time devoted to compliance with these rules. The rulemaking will also allow for a better understanding and control of any materials being dispersed for use under a medical license by allowing a streamlined process of reporting certain medical events and certifying individuals who have specialty board recognition.

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Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: _____
Rule ID(s): _____
File Date: _____
Effective Date: _____

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission, or entity in accordance with § 4-29-121(b).

Agency/Board/Commission:	Environment and Conservation
Division:	Radiological Health
Contact Person:	Andrew Holcomb
Address:	William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 15th Floor Nashville, Tennessee
Zip:	37243
Phone:	(615) 532-3038
Email:	Andrew.Holcomb@tn.gov

Revision Type (check all that apply):

X Amendment
X New
___ Repeal

___ Content based on previous emergency rule filed on _____
___ Content is identical to the emergency rule

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	**Chapter Title**
0400-20-04	General Provisions
Rule Number	**Rule Title**
0400-20-04-.07	Notifications, Reports and Other Communications
0400-20-04-.11	Posting of Notices to Workers

Chapter Number	**Chapter Title**
0400-20-05	Standards for Protection Against Radiation
Rule Number	**Rule Title**
0400-20-05-.70	General Survey and Monitoring Requirements
0400-20-05-.115	Procedures for Receiving and Opening Packages
0400-20-05-.141	Notification of Incidents
0400-20-05-.145	Notifications, Records, and Reports of Misadministration
0400-20-05-.165	Report, Notification, and Records of a Dose to an Embryo/Fetus or a Nursing Child

Chapter Number	**Chapter Title**

0400-20-06	Use of X-Ray Apparatus
Rule Number	**Rule Title**
0400-20-06-.05	Medical X-Ray Installations
0400-20-06-.09	Appendix A

Chapter Number	**Chapter Title**
0400-20-07	Use of Radionuclides ~~In The~~ in the Healing Arts
Rule Number	**Rule Title**
0400-20-07-.05	Definitions
0400-20-07-.11	Application for License, Amendment, or Renewal
0400-20-07-.13	License Amendments
0400-20-07-.14	Notifications
0400-20-07-.15	Exemptions Regarding Specific Licenses of Broad Scope
0400-20-07-.17	Authority and Responsibilities for the Radiation Protection Program
0400-20-07-.20	Written Directives
0400-20-07-.21	Procedures for Administrations Requiring a Written Directive
0400-20-07-.23	Training for Radiation Safety Officer and Associate Radiation Safety Officer
0400-20-07-.24	Training for an Authorized Medical Physicist
0400-20-07-.25	Training for an Authorized Nuclear Pharmacist
0400-20-07-.26	Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, ~~and~~ Nuclear Pharmacist, and Authorized Nuclear Pharmacist
0400-20-07-.31	Authorization for Calibration, Transmission, and Reference Sources
0400-20-07-.39	Training for Uptake, Dilution, and Excretion
0400-20-07-.41	~~Radionuclide Contaminants~~ Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations
0400-20-07-.43	Training for Imaging and Localization
0400-20-07-.44	Use of Unsealed Radioactive Material for Which a Written Directive is Required
0400-20-07-.47	Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required
0400-20-07-.48	Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicurries)
0400-20-07-.49	Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicurries)
0400-20-07-.50	Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive
0400-20-07-.51	Use of Sealed Sources for Manual Brachytherapy
0400-20-07-.57	~~Decay of~~ Strontium-90 Sources for Ophthalmic Treatments
0400-20-07-.59	Training for Use of Manual Brachytherapy Sources
0400-20-07-.60	Training for Ophthalmic Use of Strontium-90
0400-20-07-.61	Use of Sealed Sources and Medical Devices for Diagnosis
0400-20-07-.62	Training for Use of Sealed Sources and Medical Devices for Diagnosis
0400-20-07-.63	Use of Sealed Source in a Remote Afterloader Unit, Teletheraphy Unit, or Gamma Stereotactic Radiosurgery Unit
0400-20-07-.66	Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units
0400-20-07-.77	~~Five Year~~ Full-Inspection Servicing for Teletherapy ~~Units~~ and Gamma Stereotactic Radiosurgery Units
0400-20-07-.80	Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
0400-20-07-.82	Records of Authority and Responsibilities for Radiation Protection Programs
0400-20-07-.96	Records of Safety Instruction and Training
0400-20-07-.110	Records of ~~Five Year~~ Full-Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units
0400-20-07-.114	Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations

Chapter Number	**Chapter Title**
0400-20-08	Radiation Safety Requirements for Industrial Radiography

Rule Number	Rule Title
0400-20-08-.05	Personal Radiation Safety Requirements for Radiographers and Radiographer's Assistants
0400-20-08-.12	Reporting Requirements
0400-20-08-.15	Recordkeeping Requirements

Chapter Number	Chapter Title
0400-20-10	Licensing and Registration
Rule Number	**Rule Title**
0400-20-10-.13	Special Requirements for Issuance of Specific Licenses
0400-20-10-.16	Specific Terms and Conditions of Licenses
0400-20-10-.27	Inspections
0400-20-10-.30	Packaging and Transportation of Radioactive Material
0400-20-10-.31	Fees for Licenses
0400-20-10-.34	Supplemental Fees for Calendar Year 2013
0400-20-10-.38	Appendix-Schedules

Chapter Number	Chapter Title
0400-20-12	Radiation Safety Requirements for Well Logging
Rule Number	**Rule Title**
0400-20-12-.20	Personnel Monitoring

Chapter Number	Chapter Title
0400-20-13	Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material
Rule Number	**Rule Title**
0400-20-13-.02	Background Investigations and Access Authorization Program
0400-20-13-.03	Physical Protection Requirements During Use
0400-20-13-.04	Physical Protection in Transit

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to https://sos.tn.gov/products/division-publications/rulemaking-guidelines.

Chapter 0400-20-04
General Provisions

Amendments

The table of contents for Chapter 0400-20-04 General Provisions is amended by deleting the title for Rule 0400-20-04-.07 Notifications, Reports and Other Communications in its entirety and substituting instead the following:

Notifications, Reports, and Other Communications

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

Paragraph (1) of Rule 0400-20-04-.07 Notifications, Reports, and Other Communications is amended by adding a new subparagraph (e) after subparagraph (d) to read as follows:

(e) Electronic Mail: division.radiological.health@tn.gov.

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

Rule 0400-20-04-.11 Posting of Notices to Workers is amended by deleting it in its entirety and substituting instead the following:

(1) Each licensee or registrant shall post current copies of the following documents, as applicable, in a sufficient number of places to permit workers to observe them on the way to or from any particular licensed or registered activity location to which the document applies. Documents shall be placed in a conspicuous position and replaced if removed or altered:

(a) "State Regulations for Protection Against Radiation~~;~~";

(b) Radioactive material license, license conditions, and documents incorporated into a license by reference and amendments thereto;

(c) Certified registration and amendments thereto;

(d) Registration of x-ray producing equipment;

(e) Operating and emergency procedures applicable to licensed or registered activities;

(f) Any written notice that these regulations have been violated shall be posted within ~~2~~ two working days after receipt of the documents from the Division and the licensee's or registrant's response~~, if any, shall be posted within 2 working days after dispatch from the licensee or registrant~~. These documents shall remain posted for a minimum of ~~5~~ five working days or until action correcting the violation has been completed, whichever is later~~.~~; and

(g) Form RHS 8-3 (Notice to Employees). Copies of this form may be obtained by ~~writing the Division of Radiological Health at the address given in Rule 0400-20-04-.07~~ visiting the Division website under Helpful Documents and Links at https://www.tn.gov/environment/program-areas/rh-radiological-health1/rh-helpful-links.html.

(2) Instead of posting a document specified in subparagraphs (1)(a) through (e) of ~~Rule 0400-20-04-.11~~ this rule, the licensee or registrant may post a notice that describes the document and states where it may be examined.

~~(3) Form RHS 8-3 (Notice to Employees).~~

DIVISION OF RADIOLOGICAL HEALTH

NOTICE TO EMPLOYEES

In "STATE REGULATIONS FOR PROTECTION AGAINST RADIATION", The Tennessee Department of Environment and Conservation has established standards for your protection against radiation hazards and certain provisions for the option of workers engaged in work under licenses or registrations issued by the Department.

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to–

1. Apply these regulations to work under the license or registration. Licenses and Certified Registrations contain special conditions which shall be considered in addition to these regulations.
2. Post or otherwise make available to you a copy of the regulations, licenses, registrations, and operating procedures which apply to work in which you are engaged, and explain their provisions to you.
3. Post any written notice from the Department that the regulations have been violated and response to such notice.

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the regulations, and the operating procedures which apply to the work in which you are engaged. You should observe their provisions for your own protection and protection of your co–workers.

AREAS COVERED BY THESE REGULATIONS

1. Limits on exposure to radiation and radioactive material in restricted and unrestricted areas;
2. Measures to be taken after accidental exposure;
3. Personnel monitoring, surveys and equipment;
4. Caution signs, labels and safety interlock equipment;
5. Exposure records and reports;
6. Option for workers regarding the Department's inspection; and
7. Related matters.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. The Department's regulations require that your employer give you a written report if you receive an exposure in excess of any applicable limit as set forth in the regulations or in the license. The basic limits for exposure to employees are set forth in Rules 0400-20-05-.50, 0400-20-05-.53 and 0400-20-05-.55 of the regulations. These rules specify limits on exposure to radiation and exposure to concentrations of radioactive material in air and water.
2. If you work where personnel monitoring is required and if you request information on your radiation exposures;

   a. your employer must advise you annually of your exposure to radiation; and

   b. your employer must give you a written report, following termination of your employment, of your radiation exposures.

INSPECTIONS

All licensed or registered activities are subject to inspection by representatives of the Department. In addition, any worker or representative of workers who believes that there is a violation of the regulations or the terms of the employer's license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by sending a notice of the alleged violation to the Tennessee Department of Environment and Conservation, Division of Radiological Health, L&C Annex, 3rd Floor, 401 Church Street, Nashville, Tennessee 37243–1532. The request must set forth the specific grounds for the notice, and must be signed by the worker or the representative of the workers. During inspections, Department inspectors may confer privately with workers, and any worker may bring to the attention of the inspectors any past or present condition which he believes contributed to or caused any violation as described above.

POSTING REQUIREMENT

Copies of this notice must be posted in a sufficient number of places in every establishment where employees are employed in activities registered or licensed pursuant to Chapter 0400-20-10 to permit employees working in or frequenting any portion of a restricted area to observe a copy on the way to or from their place of employment.

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

Chapter 0400-20-05
Standards for Protection Against Radiation

Amendments

The table of contents for Chapter 0400-20-05 Standards for Protection Against Radiation is amended by deleting the title for Rule 0400-20-05-.145 Notifications, Records and Reports of Misadministration in its entirety and substituting instead the following:

0400-20-05-.145 Notifications, Records, and Reports of Misadministration

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

Paragraph (4) of Rule 0400-20-05-.70 General Survey and Monitoring Requirements is amended by deleting it in its entirety and substituting instead the following:

(4) Except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities, all personnel dosimeters that require processing for determining the dose and are used to comply with these standards or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

(a) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(b) Approved for processing and evaluating dosimeters exposed to the type of radiation(s) included in the NVLAP program that most closely approximates the type of radiation(s) being monitored by the dosimeter.

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

The introductory text of paragraph (4) of Rule 0400-20-05-.115 Procedures for Receiving and Opening Packages is amended by deleting it and substituting a new introductory text to read as follows, without impacting any of its subparagraphs:

(4) The licensee shall immediately notify the final delivery carrier and the Division by telephone, ~~telegram, mailgram or~~ facsimile, or electronic mail, as set forth in Rule 0400-20-04-.07, when either removable radioactive surface contamination or external radiation levels exceed the following:

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

Part 3 of subparagraph (b) of paragraph (3) of Rule 0400-20-05-.141 Preparation and Submission of Reports is amended by deleting it in its entirety and substituting instead the following:

3. The isotopes, quantities, activity, manufacturer, model and serial number of source (if applicable), leak test results, and chemical and physical forms of the licensable material involved;

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

Rule 0400-20-05-.145 Notifications, Records and Reports of Misadministration is amended by deleting it in its entirety and substituting instead the following:

0400-20-05-.145 Notifications, Records, and Reports of Misadministration.

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

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

organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin; and

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

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

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

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

1. An administration of a wrong radioactive drug or the wrong radionuclide for a brachytherapy procedure;

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

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

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

5. A leaking sealed source.

(c) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

1. 0.5 Sv (50 rem) ~~to an organ or tissue~~ or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

2. 50 percent or more ~~of~~ the expected dose ~~expected from~~ to that site from the procedure if the administration ~~defined in~~ has been given in accordance with the written directive ~~(excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site)~~ prepared or revised before administration.

(d) A therapeutic radiation machine dose:

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

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

3. When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or

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

(2) For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(a) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;

(b) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(c) An administration that includes any of the following:

1. The wrong radionuclide;

2. The wrong individual or human research subject;

3. Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

4. A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.

~~(2)~~(3) A licensee or registrant shall report to the Division any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

~~(3)~~(4) A licensee or registrant shall notify the Division at the number given in Rule 0400-20-04-.07 no later than the next calendar day after discovery of the misadministration.

~~(4)~~(5) A licensee or registrant shall submit a written report to the Division at the address listed in Rule 0400-20-04-.07 within 15 days after discovery of the misadministration.

(a) The written report must include:

1. The licensee or registrant's name;

2. The name of the prescribing physician;

3. A brief description of the event;

4. Why the event occurred;

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

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

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

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

~~(5)~~(6) A licensee or registrant shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee or registrant either that they will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee or registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee or registrant shall notify the individual as soon as possible thereafter. The licensee or registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this rule, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee or registrant shall inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained from the licensee upon request. The licensee or registrant shall provide a written description if requested.

~~(6)~~(7) Aside from the notification requirement, nothing in this rule affects any rights or duties of licensees, registrants, and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

~~(7)~~(8) A licensee or registrant shall ~~retain~~:

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

(b) Annotate a copy of the report of a misadministration provided to the Division with:

1. The licensee's or registrant's name;

2. The names of the individuals involved;

3. The identification number, or if no other identification number is available, the social security number of the individual who is the subject of the misadministration;

4. A brief description of the event and why it occurred;

5. The effect, if any, on the individual;

6. The actions, if any, taken, or planned, to prevent recurrence; and

7. Whether the licensee or registrant notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(c) Provide a copy of the annotated report to the referring physician if other than the licensee or registrant within 15 days after discovery of the misadministration.

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

Paragraph (6) of Rule 0400-20-05-.165 Report, Notification, and Records of a Dose to an Embryo/Fetus or a Nursing Child is amended by deleting it in its entirety and substituting instead the following:

(6) A licensee or registrant shall: ~~retain~~

(a) Retain a record of a dose to an embryo/fetus or a nursing child in accordance with this rule for ~~3~~ three years~~.~~ ~~A copy of the record required shall be provided to the referring physician, if other than the licensee or registrant, no later than 15 days after the discovery of the event. The record must contain the licensee or registrant's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee or registrant notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.~~

(b) Annotate a copy of the report of the event provided to the Division with:

1. The licensee's or registrant's name;

2. The names of the individuals involved;

3. The identification number, or if no other identification number is available, the social security number of the individual who is subject of the event;

4. A brief description of the event and why it occurred;

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

6. The actions, if any, taken or planned, to prevent recurrence; and

7. Whether the licensee or registrant notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(c) Provide a copy of the annotated report to the referring physician if other than the licensee or registrant within 15 days after discovery of the event.

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

Chapter 0400-20-06
Use of X-Ray Apparatus

Amendments

Part 2 of subparagraph (b) of paragraph (2) of Rule 0400-20-06-.05 Medical X-Ray Installations is amended by deleting it in its entirety and substituting instead the follow:

2. ~~Gonadal protection, by use of gonadal shields, shall be provided and used for patients who have not passed the reproductive age, during each radiographic procedure in which the gonads are in the useful beam or proximate thereto, except for those cases in which the shield would interfere with the diagnostic procedure. The protection provided shall be at least equivalent to 0.25 millimeters of lead~~ Reserved.

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

Subparagraph (a) of paragraph (1) of Rule 0400-20-06-.09 Appendix A is amended by deleting it in its entirety and substituting instead the following:

(a) All x-ray equipment.

For x-ray equipment to which this ~~Chapter~~ chapter and ~~40 CFR~~ 21 C.F.R. §§ 1020.31 and 1020.32 are applicable, there shall be provided:

1. Adequate instructions concerning any radiological safety procedures and precautions ~~which~~ that may be necessary because of unique features of the equipment; and

2. A schedule of the maintenance necessary to keep the equipment in compliance with this ~~Chapter~~ chapter and 21 ~~CFR~~ C.F.R. §§ 1020.31 and 1020.32.

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

Amendments

The title of Chapter 0400-20-07 Use of Radionuclides In The Healing Arts is amended by deleting it its entirety and substituting instead the following:

Use of Radionuclides ~~In The~~ in the Healing Arts

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

The table of contents of Chapter 0400-20-07 Use of Radionuclides in the Healing Arts is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.19	Supervision	0400-20-07-.76	Radiation Surveys
0400-20-07-.20	Written Directives	0400-20-07-.77	~~Five-Year~~ Full-Inspection Servicing for Teletherapy ~~Units~~ and Gamma Stereotactic Radiosurgery Units
0400-20-07-.21	Procedures for Administrations Requiring a Written Directive	0400-20-07-.78	Therapy-Related Computer Systems
0400-20-07-.22	Suppliers for Sealed Sources or Devices for Medical Use	0400-20-07-.79	Reserved
0400-20-07-.23	Training for Radiation Safety Officer and Associate Radiation Safety Officer	0400-20-07-.80	Training for Use of Remote Afterloader Unit, Teletherapy Units and Gamma Stereotactic Radiosurgery Units
0400-20-07-.24	Training for an Authorized Medical Physicist	0400-20-07-.81	Other Medical Uses of Radioactive Material or Radiation from Radioactive Material
0400-20-07-.25	Training for an Authorized Nuclear Pharmacist	0400-20-07-.82	Records of Authority and Responsibilities for Radiation Protection Programs
0400-20-07-.26	Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, ~~and~~ Nuclear Pharmacist, and Authorized Nuclear Pharmacist	0400-20-07-.83	Records of Radiation Protection Program Changes
0400-20-07-.27	Recentness of Training	0400-20-07-.84	Records of Written Directives
0400-20-07-.28	Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material	0400-20-07-.85	Reserved
0400-20-07-.29	Calibration of Survey Instruments	0400-20-07-.86	Reserved
0400-20-07-.30	Determination of Dosages of Unsealed Radioactive Material for Medical Use	0400-20-07-.87	Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material
0400-20-07-.31	Authorization for Calibration, Transmission, and Reference Sources	0400-20-07-.88	Records of Radiation Survey Instrument Calibrations
0400-20-07-.32	Requirements for Possession of Sealed Sources and Brachytherapy Sources	0400-20-07-.89	Records of Dosages of Unsealed Radioactive Material for Medical Use
0400-20-07-.33	Labeling of Vials and Syringes	0400-20-07-.90	Reserved
0400-20-07-.34	Surveys of Ambient Radiation Dose Rate and Contamination	0400-20-07-.91	Records of Surveys for Ambient Radiation Exposure Rate
0400-20-07-.35	Release of Individuals Containing Radioactive Drugs or Implants	0400-20-07-.92	Records of the Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material
0400-20-07-.36	Provision of Mobile Medical Service	0400-20-07-.93	Records of ~~Administrative and Technical Requirements That Apply to the Provisions of~~ Mobile Medical Services
0400-20-07-.37	Decay-in-Storage	0400-20-07-.94	Records of Decay-in-Storage
0400-20-07-.38	Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive is Not Required	0400-20-07-.95	Records of Radionuclide Contaminants
0400-20-07-.39	Training for Uptake, Dilution, and Excretion Studies	0400-20-07-.96	Records of Safety Instruction and Training
0400-20-07-.40	Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a	0400-20-07-.97	Records of Radiation Surveys of Patients and Human Research Subjects

	Written Directive is Not Required		
0400-20-07-.41	~~Radionuclide Contaminants~~ Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations	0400-20-07-.98	Records of Brachytherapy Source Accountability
0400-20-07-.42	Reserved	0400-20-07-.99	Records of Calibration Measurements of Brachytherapy Sources
0400-20-07-.43	Training for Imaging and Localization Studies	0400-20-07-.100	Records of Decay of Strontium-90 Sources for Ophthalmic Treatments
0400-20-07-.44	Use of Unsealed Radioactive Material for Which a Written Directive is Required	0400-20-07-.101	Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
0400-20-07-.45	Safety Instruction	0400-20-07-.102	Records of Safety Procedures
0400-20-07-.46	Safety Precautions	0400-20-07-.103	Records of Dosimetry Equipment
0400-20-07-.47	Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required	0400-20-07-.104	Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations
0400-20-07-.48	Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 Millicurries)	0400-20-07-.105	Records of Periodic Spot-Checks for Teletherapy Units
0400-20-07-.49	Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 Millicurries)	0400-20-07-.106	Records of Periodic Spot-Checks for Remote Afterloader Units
0400-20-07-.50	Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive	0400-20-07-.107	Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Unit
0400-20-07-.51	Use of Sealed Sources for Manual Brachytherapy	0400-20-07-.108	Records of Additional Technical Requirements for Mobile Remote Afterloader Units
0400-20-07-.52	Surveys After Source Implant and Removal	0400-20-07-.109	Records of Surveys of Therapeutic Treatment Units
0400-20-07-.53	Brachytherapy Source Accountability	0400-20-07-.110	Records of ~~Five-Year~~ Full-Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units
0400-20-07-.54	Safety Instruction	0400-20-07-.111	Records of Leak Tests and Inventory of Sealed Sources and Brachytherapy Sources
0400-20-07-.55	Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy	0400-20-07-.112	Report of Procedures for Administrations Requiring a Written Directive
0400-20-07-.56	Calibration Measurements of Brachytherapy Sources	0400-20-07-.113	Report of a Leaking Source
0400-20-07-.57	~~Decay of~~ Strontium-90 Sources for Ophthalmic Treatments	0400-20-07-.114	Report and Notification for an Eluate Exceeding Permissible Molybdenium-99, Strontium-82, and Strontium-85 Concentrations

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

Rule 0400-20-07-.05 Definitions is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.05 Definitions.

When used in this ~~Chapter~~ 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) "Associate radiation safety officer" means an individual who:

(a) Meets the requirements in Rules 0400-20-07-.23 and 0400-20-07-.27; and

(b) Is currently identified as an associate radiation safety officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the radiation safety officer on:

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

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

~~(3)~~(4) "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)~~(5) "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)~~(6) "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)~~(7) "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)~~(8) "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)~~(9) "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)~~(10) "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)~~(11) "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)~~(12) "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)(13) "Division" means the Division of Radiological Health.

~~(13)~~(14) "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)~~(15) "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)~~(16) "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)~~(17) "Manual brachytherapy" means a type of therapy in which the brachytherapy sources (e.g., seeds, ribbons) are manually placed or inserted.

~~(17)~~(18) "Medical institution" means an organization in which more than one medical discipline is practiced.

~~(18)~~(19) "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)~~(20) "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)~~(21) "Misadministration" means an event that meets the criteria in Rule 0400-20-05-.145.

~~(21)~~(22) "Mobile medical service" means the transportation of radioactive material to and its medical use at the client's address.

(23) "Ophthalmic physicist" means an individual who:

(a) Meets the requirements in Rules 0400-20-07-.57 and 0400-20-07-.27; and

(b) Is identified as an ophthalmic physicist on a:

1. Specific medical use license issued by the U.S. Nuclear Regulatory Commission or Agreement State;

2. Permit issued by a U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee;

3. Medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; or

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

~~(22)~~(24) "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)~~(25) "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)~~(26) "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)~~(27) "Physician" means a doctor of medicine or doctor of osteopathy licensed by ~~the~~ a 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)~~(28) "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)~~(29)"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)~~(30)"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, or an associate radiation safety officer.

~~(29)~~(31)"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)~~(32)"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)~~(33)"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)~~(34)"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)~~(35)"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)~~(36)"Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

~~(35)~~(37)"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)~~(38)"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)~~(39)"Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

~~(38)~~(40)"Teletherapy," for the purpose of this ~~Chapter~~ 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)~~(41) "Temporary job site" means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.

~~(40)~~(42) "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)~~(43) "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)~~(44) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

~~(43)~~(45) "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)~~(46) "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)~~(47) "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.

Rule 0400-20-07-.11 Application for License, Amendment, or Renewal is amended by deleting it in its entirety and substituting instead the following:

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 that includes the facility diagram, equipment, and training and experience qualifications of the radiation safety officer, associate radiation safety officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); 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~~ of either:

1. A completed Form CN 0716, "Application for Radioactive Material License"; or

2. A letter containing all information required by Form CN 0716; 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) Information regarding any additional radiation safety aspects of the medical use of the material that

is not addressed in this chapter;

(b) Identification of, and commitment to follow, the applicable radiation safety program requirements in this chapter that are appropriate for the specific Rule 0400-20-07-.81 medical use; and

~~(a)~~(c) ~~The applicant shall also provide~~ Any additional 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)~~(d) An applicant or licensee shall also provide any other information requested by the Division in its review of the application.

~~(6)~~(e) 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.

Rule 0400-20-07-.13 License Amendments is amended by deleting it in its entirety and substituting instead the following:

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, ophthalmic physicist, 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, and 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~~ An individual who is identified as an authorized user, an authorized nuclear pharmacist, ~~or~~ an authorized medical physicist, or an ophthalmic 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~~ An individual who is identified as an authorized user, an authorized nuclear pharmacist, ~~or~~ an authorized medical physicist, or an ophthalmic 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 allows anyone to work as an associate radiation safety officer, or before the radiation safety officer assigns duties and tasks to an associate radiation safety officer that differ from those for which this individual is authorized on the license;

~~(d)~~(e) 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)~~(f) Before the licensee adds to or changes the areas of use identified in the application or on the license;

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

(h) Before the licensee revises procedures required by Rule 0400-20-07-.66, 0400-20-07-.72, 0400-20-07-.73, and 0400-20-07-.74, as applicable, where such revision reduces radiation safety;

~~(g)~~(i) Before the licensee changes statements, representations, and procedures ~~which~~ that are incorporated into the license; ~~and~~

~~(h)~~(j) Before the licensee releases licensed facilities for unrestricted use; and

(k) Before the licensee receives a sealed source from a different manufacturer or of a different model number than authorized by its license, unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

(2) Reserved.

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

Paragraphs (1) and (2) of Rule 0400-20-07-.14 Notifications is amended by deleting them in their entirety and substituting instead the following:

(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.~~ A licensee shall provide the Division, no later than 30 days after the date that the licensee allows an individual to work under the provisions of subparagraph (1)(b) of Rule 0400-20-07-.13 as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist the following:

(a) A copy of the board certification and, as appropriate, verification of completion of:

1. Training for the authorized medical physicist under Rule 0400-20-07-.24;

2. Any additional case experience required in item (1)(b)1(ii)(VI) of Rule 0400-20-07-.47 for an authorized user under Rule 0400-20-07-.44; or

3. Device-specific training in subparagraph (1)(c) of Rule 0400-20-07-.80 for the authorized user under Rule 0400-20-07-.63; or

(b) A copy of the U.S. Nuclear Regulatory Commission or Agreement State license, the permit issued by a U.S. Nuclear Regulatory Commission master material licensee, the permit issued by a U.S.

Nuclear Regulatory Commission or Agreement State licensee of broad scope, the permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission for each individual whom the licensee permits to work under the provisions of this rule.

(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 associate radiation safety officer, an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

(b) The licensee allows an individual qualified to be a radiation safety officer under Rule 0400-20-07-.23 and 0400-20-07-.27 to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with paragraph (3) of Rule 0400-20-07-.17;

~~(b)~~(c) The licensee's mailing address changes;

~~(c)~~(d) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in paragraph (2) of Rule 0400-20-10-.16; or

~~(d)~~(e) 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 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide or PET radioactive drug production area; or

(f) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in Rule 0400-20-07-.13. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

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

Paragraphs (3) and (4) of Rule 0400-20-07-.15 Exemptions Regarding Specific Licenses of Broad Scope is amended by deleting them in their entirety and substituting instead the following:

(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~~ identified in the application or on 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 or an ophthalmic physicist;

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

Paragraphs (2) and (3) of Rule 0400-20-07-.17 Authority and Responsibilities for the Radiation Protection Program is amended by deleting them in their entirety and substituting instead the following:

(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. A licensee's management may appoint, in writing, one or more associate radiation safety officers to support the radiation safety officer. The radiation safety officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each associate radiation safety officer. These duties and tasks are restricted to the types of use for which the associate radiation safety officer is listed on a license. The radiation safety officer may delegate duties and tasks to the associate radiation safety officer but shall not delegate the authority or responsibilities for

implementing the radiation protection program.

(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 and notifies the Division in accordance with paragraph (2) of Rule 0400-20-07-.14.

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

Paragraph (2) of Rule 0400-20-07-.20 Written Directives is amended by deleting it in its entirety and substituting instead the following:

(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 I131: 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 permanent implant brachytherapy:

1. Before implantation:

(i) The treatment site;

(ii) The radionuclide; and

(iii) The total source strength; and

2. After implantation but before the patient leaves the post-treatment recovery area:

(i) The treatment site;

(ii) The number of sources implanted,

(iii) The total source strength implanted: and

(iv) The date; or

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

1. Before implantation:

(i) ~~Treatment~~ The treatment site~~,~~;

(ii) ~~the~~ The radionuclide~~,~~; and

(iii) The dose; and

2. After implantation but before completion of the procedure:

(i) The radionuclide~~,~~;

(ii) The treatment site~~,~~;

(iii) The number of sources~~,~~; ~~and~~

(iv) The total source strength and exposure time (or the total dose); and

(v) The date.

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

Paragraph (2) of Rule 0400-20-07-.21 Procedures for Administrations Requiring a Written Directive is amended by deleting it in its entirety and substituting instead the following:

(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;

(e) Determining if a patient or medical event, as defined in Rule 0400-20-07-.114, has occurred; and

(f) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

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

Rule 0400-20-07-.23 Training for Radiation Safety Officer is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.23 Training for Radiation Safety Officer and Associate 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 or an individual assigned duties and tasks as an associate 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~~ paragraph (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.)~~ The names of board certifications that have been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page. To ~~be~~ have its certification process 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~~ five or more years of professional experience in health physics (graduate training

may be substituted for no more than ~~2~~ two years of the required experience) including at least ~~3~~ three years in applied health physics; and

3. Pass an examination administered by diplomates of the specialty board~~, which~~ that 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~~ at least two years of full-time practical training and/or supervised experience in medical physics:

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

(ii) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users under 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~~ One year of full-time radiation safety experience under the supervision of the individual identified as the radiation safety officer on a Division, U.S. Nuclear Regulatory Commission, or Agreement State license or a permit issued by a Commission master material licensee that authorizes a similar ~~type(s) of use(s)~~ type or types of use or uses of radioactive material. An associate radiation safety officer may provide supervision for those areas for which the associate radiation safety officer is authorized on a Division, U.S. Nuclear Regulatory Commission, or an Agreement State license or permit issued by a U.S. Nuclear Regulatory Commission master material licensee. The full-time radiation safety experience must ~~involving~~ involve 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; and

(b) This individual must obtain a written attestation, signed by a preceptor radiation safety officer or associate radiation safety officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation must state that the individual has satisfactorily completed the requirements of subparagraph (a) of this paragraph and paragraph (4) of this rule, and is able to independently fulfill the radiation safety-related duties as a radiation safety officer or as an associate radiation safety officer for a medical use license; 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 or as an associate radiation safety officer and who meets the requirements in ~~paragraphs~~ paragraph (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~~ a U.S. Nuclear Regulatory Commission or an Agreement State license, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by a U.S. Nuclear Regulatory Commission or an Agreement State licensee of broad scope, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual ~~has~~ as the radiation safety officer ~~responsibilities; and~~ or associate radiation safety officer, and meets the requirements in paragraph (4) of this rule; or

(c) Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the radiation safety officer and the authorized user on the same new medical use license or new medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee. The individual must also meet the requirements in paragraph (4) of this rule.

~~(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)~~(4) 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~~ a radiation safety officer, an associate radiation safety officer, an authorized medical physicist, authorized nuclear pharmacist, or an authorized user, 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.

Rule 0400-20-07-.24 Training for an Authorized Medical Physicist is amended by deleing it in its entirety and substituting instead the following:

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. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page. To ~~be recognized~~ have its certification process 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~~ two years of full-time practical training and/or supervised experience in medical physics:

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

2. In clinical radiation facilities providing high energy, external beam therapy (photons and electrons with energies greater than or equal to ~~1~~ one 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~~ that 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~~ one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use modalities for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high energy, external beam therapy and brachytherapy services and must include:

1. Performing sealed source leak tests and inventories;

2. Performing decay corrections;

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

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

(b) Has obtained written attestation that the individual has satisfactorily completed the requirements in subparagraphs (1)(a) and (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~~ is able to independently fulfill the radiation safety-related duties 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.

Rule 0400-20-07-.25 Training for an Authorized Nuclear Pharmacist is amended by deleting it in its entirety and substituting instead the following:

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. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page. To ~~be~~ have its certification process recognized, a specialty board shall require all candidates for certification to:

(a) Have graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) (previously named 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~~ that 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~~ is able to independently fulfill the radiation safety-related duties 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.

Rule 0400-20-07-.26 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized User, and Nuclear Pharmacist is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.26 Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, ~~and~~ Nuclear Pharmacist, and Authorized 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.~~ An individual identified on a U.S. Nuclear Regulatory Commission or an Agreement State license or a permit issued by a 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 as a radiation safety officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before the effective date of these rules need not comply with the training requirements of Rule 0400-20-07-.23, Rule 0400-20-07-.24, or Rule 0400-20-07-.25, respectively, except the radiation safety officers and authorized medical physicists identified in this paragraph must meet the training requirements in paragraph (4) of Rule 0400-20-07-.23 or paragraph (3) of Rule 0400-20-07-.24, as appropriate, for any material or uses for which they were not authorized prior to this date.

(2) Any individual certified by the: American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005 need not comply with the training requirements of Rule 0400-20-07-.23 to be identified as a radiation safety officer or as an associate radiation safety officer on a Division, U.S. Nuclear Regulatory Commission, or an Agreement State license or U.S. Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in Rule 0400-20-07-.24, for those materials and uses that these individuals performed on or before October 24, 2005.

~~(2)~~(4) 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~~ on or before ~~March 21, 2010~~ January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of Rules 0400-20-07-.38, 0400-20-07-.39, 0400-20-07-.40, 0400-20-07-.43, 0400-20-07-.45, 0400-20-07-.46, 0400-20-07-.47, 0400-20-07-.48, 0400-20-07-.49, 0400-20-07-.52, 0400-20-07-.53, 0400-20-07-.54, 0400-20-07-.55, 0400-20-07-.56, 0400-20-07-.58, 0400-20-07-.59, 0400-20-07-.60, 0400-20-07-.62, and 0400-20-07-.80.

(5) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the Division, the U.S. Nuclear Regulatory Commission or an Agreement State, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by a U.S. Nuclear Regulatory Commission or an Agreement State broad scope licensee, or a permit issued in accordance with a U.S. Nuclear Regulatory Commission master material license of broad scope on or before October 24, 2005, 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 for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

(a) For uses authorized under Rules 0400-20-07-.38 and 0400-20-07-.40, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in one of the following: nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(b) For uses authorized under Rule 0400-20-07-.44, a physician who was certified on or before October 24, 2005, by one of the following: the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(c) For uses authorized under Rules 0400-20-07-.51 and 0400-20-07-.63, a physician who was certified on or before October 24, 2005, in one of the following: radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or “Fellow of the Royal College of Radiology”; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(d) For uses authorized under Rule 0400-20-07-.61, a physician who was certified on or before October 24, 2005, in one of the following: radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(6) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a State of Tennessee agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the Division, need not comply with the training requirements of Rules 0400-20-07-.38, 0400-20-07-.39, 0400-20-07-.40, 0400-20-07-.43, 0400-20-07-.45, 0400-20-07-.46, 0400-20-07-.47, 0400-20-07-.48, 0400-20-07-.49, 0400-20-07-.52, 0400-20-07-.53, 0400-20-07-.54, 0400-20-07-.55, 0400-20-07-.56, 0400-20-07-.58, 0400-20-07-.59, 0400-20-07-.60, 0400-20-07-.62 and 0400-20-07-.80, when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.

~~(3)~~(7) 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.

Rule 0400-20-07-.31 Authorization for Calibration, Transmission, and Reference Sources is amended by deleting it in its entirety and substituting instead the following:

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 not exceeding 1.11 gigibecquerels (30 mCi) each, manufactured and distributed by persons specifically licensed ~~pursuant to~~ under 10 C.F.R. § 32.74, 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~~ Agreement State regulations;

(b) Sealed sources, not exceeding 1.11 ~~GBq~~ gigibecquerels (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~~ not longer than 120 days ~~or less~~ in individual amounts not to exceed ~~555 megabecquerels~~ 0.56 gigibecquerels (15 ~~millicuries~~ mCi);

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

1. 7.4 megabecquerels (200 µCi); or

2. 1,000 times the quantities in Schedule RHS 8-30 Chapter 0400-20-10; and

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

(2) Radioactive material in sealed sources authorized by this provision shall not be:

(a) Used for medical use as defined in paragraph (19) of Rule 0400-20-07-.05, except in accordance with the requirements of Rule 0400-20-07-.61; or

(b) Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this rule.

(3) A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraph (1) or (2) of this rule need not list these sources on a specific medical use license.

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

Rule 0400-20-07-.39 Training for Uptake, Dilution, and Excretion Studies is amended by deleting it in its entirety and substituting instead the following:

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~~. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page. To ~~be~~ have its certification process recognized, a specialty board shall require ~~a candidate~~ all candidates 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~~ eight hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Rule 0400-20-07-.26, this rule, Rule 0400-20-07-.43, or Rule 0400-20-07-.47, or equivalent U.S. Nuclear Regulatory Commission or ~~agreement~~ 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~~ that the individual has satisfactorily completed the requirements in part 1 of this subparagraph and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Rule 0400-20-07-.38. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements of this rule, Rule 0400-

20-07-.26, Rule 0400-20-07-.43, Rule 0400-20-07-.47, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of Rule 0400-20-07-.26, this rule, Rule 0400-20-07-.43, Rule 0400-20-07-.47, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, and that faculty member concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in part 1 of this subparagraph.

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

Rule 0400-20-07-.41 Radionuclide Contaminants is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.41 ~~Radionuclide Contaminants~~ Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

1) A licensee shall not administer to humans a radiopharmaceutical that contains:

(a) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium99m (0.15 µCi 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 µCi 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 µCi 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 licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with paragraph (1) of this rule.

~~(a)~~(3) ~~Measure~~ A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, 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~~ radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph (1) of this rule.

~~(3)~~(4) ~~A licensee who must measure radionuclide contaminant concentration~~ If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with Rule 0400-20-07-.95.

~~(4)~~(5) A licensee shall report immediately to the Division each occurrence of radionuclide contaminant concentration exceeding the limits specified in paragraph (1) of this rule at the time of generator elution, in accordance with Rule 0400-20-07-.114.

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

Rule 0400-20-07-.43 Training for Imaging and Localization Studies is amended by deleting it in its entirety and substituting instead the following:

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~~. The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page. To ~~be~~ have its certification process 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; and

(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:~~ An authorized nuclear pharmacist who meets the requirements in Rule 0400-20-07-.25 or 0400-20-07-.26 may provide the supervised work experience for item (VII) of this subpart. 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 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~~ that the individual has satisfactorily completed the requirements in part 1 of this subparagraph and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under Rules 0400-20-07-.39 and 0400-20-07-.40. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in Rule 0400-20-07-.26, this rule, 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; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rule 0400-20-07-.26, this rule, 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, and concurs with the attestation provided by the residency program director. The residency training program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in part 1 of this subparagraph.

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

Rule 0400-20-07-.44 Use of Unsealed Radioactive Material for Which a Written Directive is Required is amended by deleting it in its entirety and substituting instead the following:

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~~ radioactive material identified in item (1)(b)1(ii)(VI) of Rule 0400-20-07-.47 prepared for medical use and for which a written directive is required that is:

(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 or U.S. Nuclear Regulatory Commission 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.

Rule 0400-20-07-.47 Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required is amended by deleting it in its entirety and substituting instead the following:

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.)~~ The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit 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~~ Council on Postdoctoral Training of the American Osteopathic Association; and

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

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

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

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

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements of this rule, 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~~ from the four categories in this item. Radioactive drugs containing radionuclides in categories not included in this item are regulated under Rule 0400-20-07-.81. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:

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

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

III. Parenteral administration of any ~~beta emitter or a photonemitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or~~ radioactive drug that contains a radionuclide primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

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

2. ~~Have~~ Has 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~~ for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in this rule, Rule 0400-

20-07-.26, or equivalent Agreement State or equivalent U.S. Nuclear Regulatory Commission requirements and who has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this rule, Rule 0400-20-07-.26, or equivalent Agreement State or equivalent U.S. Nuclear Regulatory Commission requirements, who has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and who concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association, and must include training and experience specified in part 1 of this subparagraph.

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

Rule 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 Millicurries) is amended by deleting it in its entirety and substituting instead the following:

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 Millicurries).

(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 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~~ of 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~~ that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page~~)~~; or

(b) Is an authorized user under Rule 0400-20-07-.47 for uses listed in subitems (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~~ of Rule 0400-20-07-.26, Rule 0400-20-07-.47, Rule 0400-20-07-.48, Rule 0400-20-07-.49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements ~~in~~ of

subparagraph (1)(b) of Rule 0400-20-07-.47~~,~~ must also have experience ~~in~~ administering dosages as specified in subitems (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~~ three cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

~~3.~~(d) Has obtained written attestation that the individual has satisfactorily completed the requirements ~~in~~ of parts (c)1 and (c)2 of this ~~subparagraph~~ paragraph 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 subparagraph (1)(b) of Rule 0400-20-07-.47, must also have experience in administering dosages as specified in subitem (1)(b)1(ii)(VI)I or II of Rule 0400-20-07-.47~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodine I-131 for medical uses authorized under Rule 0400-20-07-.44. The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements of Rule 0400-20-07-.26, Rule 0400-20-07-.47, this rule, Rule 0400-20-07-.49, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements and who has experience in administering dosages as specified in subitem (1)(b)1(ii)(VI)I or II of Rule 0400-20-07-.47; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of Rule 0400-20-07-.26, Rule 0400-20-07-.47, this rule, Rule 0400-20-07-.49, or equivalent Agreement State requirements, who has experience in administering dosages as specified in subitem (1)(b)1(ii)(VI)I or II of Rule 0400-20-07-.47, and who concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in parts (c)1 and (c)2 of this paragraph.

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

Rule 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 Millicurries) is amended by deleting it in its entirety and substituting instead the following:

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 Millicurries).

(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~~ of parts (c)1 and (c)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~~ that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit 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, Rule 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 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~~ three 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~~ of 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~~ of Rule 0400-20-07-.26, Rule

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~~ of ~~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.

~~3.~~(d) Has obtained written attestation that the individual has satisfactorily completed the requirements ~~in~~ of parts (c)1 and (c)2 of this ~~subparagraph~~ paragraph 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 subparagraph (1)(b) of Rule 0400-20-07-.47, must also have experience in administering dosages as specified in subitem (1)(b)1(ii)(VI)I or II of Rule 0400-20-07-.47~~ is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodine I-131 for medical uses authorized under Rule 0400-20-07-.44. The attestation must be obtained from either:

1. A preceptor authorized user who meets the requirements of Rule 0400-20-07-.26, Rule 0400-20-07-.47, Rule 0400-20-07-.48, this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements and who has experience in administering dosages as specified in subitem (1)(b)1(ii)(VI)I or II of Rule 0400-20-07-.47; or

2. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of Rule 0400-20-07-.26, Rule 0400-20-07-.47, Rule 0400-20-07-.48, this rule, or equivalent Agreement State requirements, who has experience in administering dosages as specified in subitem (1)(b)1(ii)(VI)I or II of Rule 0400-20-07-.47, and who concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in parts (c)1 and (c)2 of this paragraph.

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

Rule 0400-20-07-.50 Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive is amended by deleting it in its entirety and substituting instead the following:

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 Rule 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 Rule 0400-20-07-.80, and who meets the requirements in subparagraph (d) of this paragraph~~.~~; or

(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~~ listed in subitem (1)(b)1(ii)(VI)III of Rule 0400-20-07-.47. 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, Rule 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~~ listed in subitem (1)(b)1(ii)(VI)III of Rule 0400-20-07-.47. A supervising authorized user who meets the requirements in Rule 0400-20-07-.47, this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements 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~~ in the same category or categories 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 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~~ administrations as specified in subitem (1)(b)1(ii)(VI)III of Rule 0400-20-07-.47; 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~~ obtained from either:

(i) A preceptor authorized user who meets the requirements in Rule 0400-20-07-.26, Rule 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~~ this rule, or equivalent Agreement State or U.S. Nuclear Regulatory Commission

requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in Rule 0400-20-07-.26, Rule 0400-20-07-.47, Rule 0400-20-07-.50, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in parts 1 and 2 of this subparagraph.

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

Rule 0400-20-07-.51 Use of Sealed Sources for Manual Brachytherapy is amended by deleting it in its entirety and substituting instead the following:

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 for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research to deliver therapeutic doses for medical use 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.

Rule 0400-20-07-.57 Decay of Strontium-90 Sources for Ophthalmic Treatments is amended by deleting it in its entirety and substituting instead the following:

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.~~ Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph (2) of this rule are performed by either:

(a) An authorized medical physicist; or

(b) An individual who:

1. Is identified as an ophthalmic physicist on a specific medical use license issued by the U.S. Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; or permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope medical use permittee; and

2. Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

3. Has successfully completed one year of full-time training in medical physics and an

additional year of full-time work experience under the supervision of a medical physicist; and

4. Has documented training in:

(i) The creation, modification, and completion of written directives;

(ii) Procedures for administrations requiring a written directive; and

(iii) Performing the calibration measurements of brachytherapy sources as detailed in Rule 0400-20-07-.56.

(2) The individuals identified in paragraph (1) of this rule must:

(a) 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; and

(b) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (1) of this rule will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

~~(2)~~(3) Licensees must 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.

Rule 0400-20-07-.59 Training for Use of Manual Brachytherapy Sources is amended by deleting it in its entirety and substituting instead the following:

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~~ are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page.~~)~~ To ~~be~~ have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of ~~3~~ three 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~~ Council on Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, ~~which~~ that 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~~ facility authorized to use radioactive materials under Rule 0400-20-07-.51, 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; and

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

2. Has completed ~~3~~ three 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 Agreement State or 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~~ Council 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 of this paragraph, or parts ~~(b)~~1 and 2 of this ~~paragraph~~ subparagraph and ~~has achieved a level of competency sufficient to function independently~~ is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under Rule 0400-20-07-.51. The attestation must be obtained from either:

(i) 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; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is 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 and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in parts 1 and 2 of the subparagraph.

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

Part 3 of subparagraph (b) of paragraph (1) of Rule 0400-20-07-.60 Training for ophthalmic use of strontium-90 is amended by deleting it in its entirety and substituting instead the following:

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in Rule 0400-20-07-.26, Rule 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~~ is able to independently fulfill the radiation safety-related duties 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.

Rule 0400-20-07-.61 Use of Sealed Sources for Diagnosis is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.61 Use of Sealed Sources and Medical Devices for Diagnosis.

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

(1) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(2) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(3) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration 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.

Rule 0400-20-07-.62 Training for Use of Sealed Sources for Diagnosis is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.62 Training for Use of Sealed Sources and Medical Devices 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~~ or 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~~ of subparagraphs ~~(b)~~(c) and ~~(c)~~(d) 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~~ that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State ~~will be~~ are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page~~)~~; or

(b) Is an authorized user for uses listed in Rule 0400-20-07-.40 or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements; or

~~(b)~~(c) Has completed ~~8~~ eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

1. Radiation physics and instrumentation;

2. Radiation protection;

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

4. Radiation biology; and

~~(c)~~(d) 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.

Rule 0400-20-07-.63 Use of Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.63 Use of Sealed Source in Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

(1) A licensee ~~shall~~ must only use sealed sources:

(a) As approved in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units ~~for~~ to deliver therapeutic doses for medical uses~~.~~; or

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

(b) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active investigational device exemption (IDE) application accepted by the U.S. Food and Drug Administration (FDA) provided the requirements in paragraph (1) of Rule 0400-20-07-.22 are met.

(2) A licensee may only use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(a) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but such devices must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research in accordance with an active IDE application accepted by the 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.

Paragraph (4) of Rule 0400-20-07-.66 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units is amended by deleting it in its entirety and substituting instead the following:

(4) (a) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

~~(4)~~(b) A licensee shall provide ~~instruction,~~ operational and safety instructions initially and at least annually, to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties~~,~~. The instructions shall include instruction in:

~~(a)~~1. The procedures identified in subparagraph (1)(d) of this rule; and

~~(b)~~2. The operating procedures for the unit.

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

Paragraph (7) of Rule 0400-20-07-.66 Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units is amended by deleting it in its entirety and substituting instead the following:

(7) A licensee shall retain a copy of the procedures required by ~~subparagraphs~~ subparagraph (1)(d) of this rule and part (4)(b)2 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.

Rule 0400-20-07-.77 Five Year Inspection for Teletherapy Units and Gamma Stereotactic Radiosurgery Units is amended by deleting it in its entirety and substituting instead the following:

0400-20-07-.77 ~~Five Year~~ Full-Inspection Servicing 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~~ to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not ~~to~~ exceed ~~5~~ five years~~, whichever comes first, to assure proper functioning of the source exposure mechanism~~ for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.

(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.

Rule 0400-20-07-.80 Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.is amended by deleting it in its entirety and substituting instead the following:

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 Rule 0400-20-07-.63 to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Division, the U.S. Nuclear Regulatory Commission, or an Agreement State and who meets the requirements in ~~part (b)3 and~~ subparagraph (c) of this paragraph. ~~To be recognized, a specialty board shall require all candidates for certification~~ The names of board certifications that have been recognized by the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the U.S. Nuclear Regulatory Commission's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

2. Pass an examination, administered by diplomates of the specialty board, ~~which~~ that 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~~ facility that is authorized to use radioactive materials in Rule 0400-20-07-.63, 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~~ three 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~~ Council 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~~ of part (a)1 of this paragraph, ~~or part 1 of this subparagraph, and part~~ parts 1 and 2 of this subparagraph, and subparagraph (c) of this ~~rule and has achieved a level of competency sufficient to function independently~~ paragraph and is able to independently fulfill the radiation safety-related duties 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~~ The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements of this rule, Rule 0400-20-07-.26, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements for an authorized user for each type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this rule, Rule 0400-20-07-.26, or equivalent Agreement State or U.S. Nuclear Regulatory Commission requirements, for the type(s) of therapeutic medical unit for which the individual is requesting user status, and who concurs with the attestations provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in parts 1 and 2 of this subparagraph; 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.

Rule 0400-20-07-.82 Records of Authority and Responsibilities for Radiation Protection Programs is amended by deleting it in its entirety and substituting instead the following:

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~~ five 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.

(4) For each associate radiation safety officer appointed under paragraph (2) of Rule 0400-20-07-.17, the licensee shall retain, for five years after the associate radiation safety officer is removed from the license, a copy of the written document appointing the associate radiation safety officer signed by the licensee's management.

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

Rule 0400-20-07-.96 Records of Safety Instruction and Training is amended by deleting it in its entirety and substituting instead the following:

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~~ three years. The record must include a list of the topics

covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

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

Rule 0400-20-07-.110 Records of Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units is amended by deleting it in its entirety and substituting instead the following:

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

(1) A licensee shall maintain a record of the ~~5-year inspections~~ full-inspection servicing 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.

New Rule

Rule 0400-20-07-.114 Report and Notification for an Eluate Exceeding Permissible Molybdenium-99, Strontium-82, and Strontium-85 Concentrations is added to Chapter 0400-20-07 following Rule 0400-20-07-.113 Report of a Leaking Source to read as follows:

0400-20-07-.114 Report and Notification for an Eluate Exceeding Permissible Molybdenium-99, Strontium-82, and Strontium-85 Concentrations

(1) The licensee shall notify by telephone the Division and the distributor of the generator within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in paragraph (1) of Rule 0400-20-07-.41 at the time of generator elution. The telephone report to the Division must include:

(a) The name of the manufacturer;

(b) The model number and serial number (or lot number) of the generator;

(c) The results of the measurement;

(d) The date of the measurement;

(e) Whether dosages were administered to patients or human research subjects, when the distributor was notified; and

(f) The action taken.

(2) By an appropriate method listed in Rule 0400-20-04-.07, the licensee shall submit a written report to the Division within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the:

(a) Action taken by the licensee;

(b) Patient dose assessment;

(c) Methodology used to make this dose assessment if the eluate was administered to patients or human research subjects;

(d) Probable cause and an assessment of failure in the licensee's equipment, procedures, or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and

(e) Information in the telephone report as required by 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.

Amendments

Paragraph (3) of Rule 0400-20-08-.05 Personal Radiation Safety Requirements for Radiographers and Radiographer's Assistants is amended by deleting it in its entirety and substituting instead the following:

(3) Personnel monitoring.

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

1. Pocket dosimeters shall have a range from zero to ~~2~~ two millisieverts (200 millirems) and shall be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

2. Each personnel dosimeter shall be assigned to and worn only by one individual.

3. Film badges ~~shall~~ must be replaced ~~at periods not to exceed 1 month~~ monthly and all other personnel dosimeters ~~processed and evaluated by an accredited NVLAP processor shall be replaced at periods not to exceed 3 months~~ that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

~~4. After replacement, each personnel dosimeter shall be processed as soon as possible.~~

(b) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters shall be read and the exposures recorded at the beginning and end of each shift. In accordance with Rule 0400-20-08-.15, the licensee or registrant shall maintain each record of these exposures for inspection by the Division for ~~3~~ three years after the record is made.

(c) Pocket dosimeters, or electronic personal dosimeters, shall be checked at periods not to exceed 12 months for correct response to radiation. Acceptable dosimeters shall read within plus or minus 20 percent of the true radiation exposure. In accordance with Rule 0400-20-08-.15, the licensee or registrant shall maintain each record of these exposures for inspection by the Division for ~~3~~ three years after the record is made.

(d) If an individual's pocket chamber is found to be off-scale, or if his or her electronic personal dosimeter reads greater than ~~2~~ two millisieverts (200 millirems), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter shall be sent for processing and evaluation within 24 hours. For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within 24 hours. In addition, the individual may not resume work associated with licensed material use until a determination of the individual's radiation ~~exposure~~ dose has been made. This determination shall be made by the RSO or the RSO's designee. The results of this determination shall be included in the records maintained in accordance with Rule 0400-20-08-.15.

(e) If the personnel dosimeter ~~that is~~ required by subparagraph (a) of this paragraph is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements ~~in~~ of subparagraph (a) of this paragraph is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the period for which the personnel dosimeter was lost or damaged shall be included in the records maintained in accordance with Rule 0400-20-08-.15.

(f) Dosimetry ~~reports received from the accredited NVLAP personnel dosimeter processor shall be~~

~~retained for inspection by the Division~~ results must be retained in accordance with Rule 0400-20-08-.15.

(g) Each alarm ratemeter shall:

1. Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift;

2. Be set to give an alarm signal at a preset dose rate of ~~5~~ five mSv/hr (500 mrem/hr); with an accuracy of plus or minus 20 percent of the true radiation dose rate;

3. Require special means to change the preset alarm function; and

4. Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarm ratemeter calibrations in accordance with Rule 0400-20-08-.15.

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

Subparagraph (c) of paragraph (2) of Rule 0400-20-08-.12 Reporting Requirements is amended by deleting it in its entirety and substituting instead the following:

(c) Manufacturer and model number of equipment involved in the incident as well as activity, model, and serial number of source (if applicable).

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

Subparagraph (b) of paragraph (1) of Rule 0400-20-08-.15 Recordkeeping Requirements is amended by deleting it in its entirety and substituting instead the following:

(b) Each licensee and registrant shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite~~,~~:

1. The license or registration authorizing the use of licensed material or registered equipment;

2. A copy of “State Regulations for Protection Against Radiation~~,~~”;

3. Utilization records for each radiographic exposure device dispatched from that location as required by paragraph (7) of Rule 0400-20-08-.04~~,~~;

4. Records of equipment problems identified in daily checks of equipment as required by paragraph (8) of Rule 0400-20-08-.04. The licensee or registrant shall maintain each record for ~~3~~ three years after it is made. The record shall include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was done~~.~~;

5. Records of alarm system and entrance control checks required by paragraph (9) of Rule 0400-20-08-.04, if applicable. The licensee or registrant shall maintain each record for ~~3~~ three years after it is made~~.~~;

6. Records of direct reading dosimeters such as pocket dosimeter and/or electronic personal dosimeters readings as required by paragraph (3) of Rule 0400-20-08-.05. The licensee or registrant shall maintain each record for ~~3~~ three years after it is made~~.~~;

7. Records of dosimetry reports ~~received from the accredited NVLAP personnel dosimeter processor~~ as required by paragraph (3) of Rule 0400-20-08-.05. The licensee or registrant shall maintain each record until the Division terminates the license or registration~~.~~;

8. Operating and emergency procedures required by paragraph (2) of Rule 0400-20-08-.05. The licensee or registrant shall maintain a copy of current operating and emergency procedures until the Division terminates the license or registration. ~~Superceded~~

Superseded material shall be retained for ~~3~~ three years after the change is made~~.~~;

9. Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by paragraph (4) of Rule 0400-20-08-.04. The licensee or registrant shall maintain each record for ~~3~~ three years after it is made~~.~~;

10. Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and/or electronic personal dosimeters as required by paragraph (3) of Rule 0400-20-08-.05. The licensee or registrant shall maintain each record for ~~3~~ three years after it is made~~.~~;

11. Latest survey records required by paragraph (4) of Rule 0400-20-08-.06. The licensee or registrant shall maintain the record of each exposure device survey conducted before the device is placed in storage, if that survey is the last one performed in the workday, for ~~3~~ three years after it is made~~.~~;

12. The shipping papers for the transportation of radioactive materials required by Chapter 0400-20-10~~.~~;

13. When operating under reciprocity pursuant to Rule 0400-20-10-.29, a copy of the Agreement State license authorizing the use of licensed materials; and

14. Records of estimates of exposures because of off-scale personal direct reading dosimeters or of lost or damaged personnel dosimeters until the Division terminates the license or registration.

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

Amendments

Paragraph (10) of Rule 0400-20-10-.13 Special Requirements for Issuance of Specific Licenses is amended by deleting it in its entirety and substituting instead the following:

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

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radiopharmaceuticals containing radioactive material for use by persons authorized pursuant to Chapter 0400-20-07 will be approved if:

1. The applicant satisfies the general requirements ~~specified in~~ of Rule 0400-20-10-.12;

2. The applicant submits evidence that the applicant is at least one of the following:

(i) Registered or licensed with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 ~~CFR~~ C.F.R. § 207.20(a);

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

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

(iv) Operating as a nuclear pharmacy within a Federal medical institution; or

(v) A Positron Emission Tomography (PET) drug production facility registered with a state agency.

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

4. The applicant ~~satisfies~~ commits to the following labeling requirements:

(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words “CAUTION, RADIOACTIVE MATERIAL” or “DANGER, RADIOACTIVE MATERIAL”; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half–life greater than 100 days, the time may be omitted.

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

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

1. May prepare radiopharmaceuticals for medical use, as defined in Rule 0400-20-07-.05, provided that the radiopharmaceuticals are prepared by either an authorized nuclear pharmacist, as specified in parts 2 and 4 of this subparagraph, or an individual under the supervision of an authorized nuclear pharmacist as specified in Rule 0400-20-07-.19.

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

(i) This individual qualifies as an authorized nuclear pharmacist as defined in Rule 0400-20-07-.05,

(ii) This individual meets the requirements specified in paragraph (2) of Rule 0400-20-07-.25 and Rule 0400-20-07-.27, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

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

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

4. May designate a pharmacist (as defined in Rule 0400-20-07-.05) as an authorized nuclear pharmacist if~~: (i) The~~ the individual was a nuclear pharmacist at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the ~~NRC~~ U.S. Nuclear Regulatory Commission.

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

(i) Certification by a specialty board whose certification process has been recognized by the Division, U.S. Nuclear Regulatory Commission, or an Agreement State as specified in paragraph (1) of Rule 0400-20-07-.25~~ with the written attestation signed by a preceptor as required by subparagraph (2)(b) of Rule 0400-20-07-.25~~; or

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

(iii) ~~NRC~~ U.S. Nuclear Regulatory Commission master materials licensee permit; or

(iv) The permit issued by a licensee or ~~NRC~~ U.S. Nuclear Regulatory Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorization nuclear pharmacist; or

(v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the ~~NRC~~ U.S. Nuclear Regulatory Commission; and

(vi) A copy of the state pharmacy licensure or registration~~,~~ no later than 30 days after the date that the licensee allows~~,~~ the individual to work as an authorized nuclear pharmacist under subparts 2(i) and (ii) of this subparagraph.

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

1. Perform tests before initial use, periodically and following repair~~,~~ on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument~~:~~, and make adjustments when necessary; and

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

use.

(d) A licensee shall satisfy the labeling requirements of part (a)4 of this paragraph.

~~(d)~~(e) Nothing in this rule relieves the licensee from complying with applicable FDA, other federal, and other state requirements governing radioactive drugs.

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

Paragraph (6) of Rule 0400-20-10-.16 Specific Terms and Conditions of Licenses is amended by deleting it in its entirety and substituting instead the following:

(6) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with Rule 0400-20-07-.41. The licensee shall record the results of each test and retain each record for ~~3~~ three years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in paragraph (1) of Rule 0400-20-07-.41 at the time of generator elution, in accordance with Rule 0400-20-07-.114.

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

Subparagraph (b) of paragraph (5) of Rule 0400-20-10-.27 Inspections is amended by deleting it in its entirety and substituting instead the following:

(b) The qualified individual performing the inspection shall record the results of the inspection on evaluation forms provided by the Division, one form for each facility plus an appropriate form, or forms, for each piece of equipment. The evaluation forms shall describe the compliance status of the facility and equipment~~,~~ as it exists at the time of the inspection. ~~The Division will accept computer-generated forms if these contain the same questions as Division forms contain.~~

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

Rule 0400-20-10-.27 Inspections is amended by adding a new paragraph (6) to read as follows:

(6) If a registrant who has previously employed inspection services of registered individuals, other than employees of the Division, as authorized by paragraph (4) of Rule 0400-20-10-.27, chooses to discontinue those services, then the registrant shall notify the Division 90 days prior to the end of the respective inspection cycle. Should the registrant fail to notify the Division within this time frame, a penalty consistent with T.C.A. § 68-202-212(b) may be assessed.

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

Subpart (iii) of part 2 of subparagraph (b) of paragraph (7) of Rule 0400-20-10-.30 Packaging and Transportation of Radioactive Material is amended by deleting it in its entirety and substituting instead the following:

(iii) Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of ~~Spent~~ Fuel ~~Storage and Transportation~~ Management, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 ~~CFR~~ C.F.R. § 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.

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

Subparagraph (c) of paragraph (21) of Rule 0400-20-10-.30 Packaging and Transportation of Radioactive Material is amended by deleting it in its entirety and substituting instead the following:

(c) Procedures for submitting advance notification.

1. The notification shall be made in writing to the office of each appropriate governor or governor's designee, the office of each appropriate Tribal official or Tribal official's

designee, ~~and to~~ the Director, Division of Radiological Health, and to the Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

2. A notification delivered by mail shall be postmarked at least ~~7~~ seven days before the beginning of the ~~7~~ seven-day period during which departure of the shipment is estimated to occur.

3. A notification delivered by any other means than mail shall reach the office of the governor, or of the governor's designee, ~~or~~ the Tribal official or Tribal official's designee, and ~~of~~ the Director, Division of Radiological Health, at least ~~4~~ four days before the beginning of the ~~7~~ seven-day period during which departure of the shipment is estimated to occur.

   (i) ~~A list of the names and mailing addresses of the governors' designees receiving advance notification of transportation of nuclear waste was published in the Federal Register on June 30, 1995 (60 FR 34306)~~ Reserved.

   (ii) Contact information for each state, including telephone and mailing addresses of governors and governors' designees, and participating Tribes, including telephone and mailing addresses of Tribal officials and Tribal officials' designees, is available on the ~~NRC~~ U.S. Nuclear Regulatory Commission Web site at: https://scp.nrc.gov/special/designee.pdf.

   (iii) A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of ~~Intergovernmental Liaison and Rulemaking, Office of Federal and State Materials and Environmental Management Programs~~ Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

   (iv) The licensee shall retain a copy of the notification as a record for ~~3~~ three years.

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

Subparagraph (c) of paragraph (5) of Rule 0400-20-10-.31 Fees for Licenses is amended by deleting it in its entirety and substituting instead the following:

(c) Upon receipt of an application, the Division must examine it to ~~insure~~ ensure that it is complete and advise the applicant in writing of its findings via ~~certified~~ electronic mail. ~~60~~ Sixty days will be allowed for the initial and each subsequent review per part 3 of this subparagraph.

1. If an application is determined to be incomplete, the Division must notify the applicant in writing via ~~certified~~ electronic mail of the finding with a brief explanation of the deficiencies. The application filing fee shall be retained by the Division.

2. After receiving notice from the Division that the application was incomplete, the applicant shall have 180 calendar days to correct the deficiencies. If properly corrected, the application will be processed and no additional application fee is required, except for the possibility of those above Category 8. If the deficiencies are not corrected within the ~~180 day~~ 180-day correction period, the fee will be forfeited in its entirety to the Division with no further action taken on the application by the Division. If the applicant re-applies, a new application fee must be paid in full.

3. Upon receipt of a corrected application revised pursuant to part 1 or 2 of this subparagraph, the Division shall re-evaluate the application and notify the applicant of its finding as to whether ~~or not~~ the deficiencies in the application have been ~~completed~~ corrected. The same procedure to notify an applicant as to whether ~~or not~~ the application is complete will follow the requirements specified by this subparagraph, with the exception being that the ~~180 day~~ 180-day correction period begins from the receipt of the initial application - not receipt of the revised application.

4. Any person possessing licensable quantities of unlicensed radioactive material during the

review of an application for a license for the radioactive material shall be in violation of Rule 0400-20-10-.02.

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

Rule 0400-20-10-.34 Supplemental Fees for Calendar Year 2013 is amended by deleting it in its entirety and substituting instead the following:

0400-20-10-.34 ~~Supplemental Fees for Calendar Year 2013~~ Reserved.

~~(1) Purpose~~

~~Adequate funds are required to facilitate the proper administration of The Radiological Health Service Act and The Medical Radiation Inspection Safety Act. Failure to properly administer these acts threatens the health and safety of the citizens of the state. Operating revenue for the administration of these acts is collected on a calendar year basis. Projected revenue needs of the Division in 2013 cannot be met by current registration and licensing fees. Rulemaking to increase 2013 fees cannot be completed prior to the first assessment date, January 1, 2013. Therefore, one time supplemental fees are hereby established to provide the Division with additional revenue during Calendar Year 2013. Division invoices will establish due dates for payment of these supplemental fees.~~

~~(2) Supplemental Fees Schedules~~

~~(a) In addition to the fees established in paragraph (3) of Rule 0400-20-10-.24 Registration, persons subject to registration anytime during Calendar Year 2013 shall pay a supplemental fee to be determined according to Schedule I of this paragraph:~~

~~SCHEDULE I~~

~~Class I Equipment~~	~~$20.00 per tube~~
~~Class II Equipment~~	~~$45.00 per tube~~
~~Class III Equipment~~	~~$86.00 per tube~~
~~Class IV Equipment~~	~~$90.00 per tube~~
~~Class V Equipment~~	~~$180.00 per tube~~
~~Class VI Equipment~~	~~$270.00 per tube~~
~~Class VII Equipment~~	~~$600.00 per tube~~
~~A person providing inspection services under paragraph (4) of Rule 0400-20-10-.27~~	~~$250.00~~
~~A person providing assembly/installation/servicing~~	~~$250.00~~

~~(b) In addition to the fees established in paragraphs (6) through (19) of Rule 0400-20-10-.31 Fees for Licenses, persons subject to licensure anytime during Calendar Year 2013 shall pay a supplemental fee to be determined according to Schedule II of this paragraph:~~

~~SCHEDULE II~~

~~Category GL~~	~~$200.00~~
~~Category 1~~	~~$125.00~~
~~Category 2~~	~~$250.00~~
~~Category 3~~	~~$270.00~~

~~Category 4 $450.00~~

~~Category 5 $630.00~~

~~Category 6 $1,800.00~~

~~Category 7 $1,200.00~~

~~Category 8 $3,375.00~~

~~Category 9 $4,500.00~~

~~Category 10 $4,500.00~~

~~Category 11 $6,000.00~~

~~Category 12 $75,000.00~~

~~Category 13 At least $50.00 and not greater than $125,000.00~~

~~The Category 13 supplemental fee shall be determined on a case-by-case basis. The determination shall be based on an analysis of the hazard, the scope of the difficulty encountered in the review process and the specifics of the activity, following the categories established n paragraphs (6) through (19) of Rule 0400-20-10-.31.~~

~~Category Nuclear Power Plants and Other Fuel Facilities Actual expenses that arise from emergency planning and implementation and environmental surveillance activities~~

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

The specific activity for the symbol of radionuclide “Sm-147” under the units (TBq/g) in Table A-1—A_1 and A_2 VALUES FOR RADIONUCLIDES that follows subparagraph (b) of paragraph (5) of Rule 0400-20-10-.38 Appendix-- Schedules is amended by deleting the value “$8.5X10^{-1}$” and substituting in its place the value “$8.5X10^{-10}$”~~,~~ so that as amended the entry for “Sm-147” shall read as follows:

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	~~$8.5x10^{-1}$~~ $8.5x10^{-10}$	$2.3X10^{-8}$

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

Amendments

Paragraph (1) of Rule 0400-20-12-.20 Personnel Monitoring is amended by deleting it in its entirety and substituting instead the following:

(1) The licensee or registrant shall not permit an individual to act as a logging supervisor or logging assistant unless that person wears~~,~~ a personnel dosimeter at all times during the handling of ~~sources of radiation, a personnel dosimeter that is processed and evaluated by an accredited National Voluntary Accreditation Program (NVLAP) processor~~ licensed radioactive materials. Each personnel dosimeter shall be assigned to and worn by only one individual. Film badges shall be replaced at least monthly and other personnel dosimeters that require replacement must be replaced at least quarterly. ~~After replacement, each personnel dosimeter shall be promptly processed~~ All personnel dosimeters must be evaluated at least quarterly, or promptly after replacement, whichever is more frequent.

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

Amendments

Part 2 of subparagraph (b) of paragraph (2) of Rule 0400-20-13-.02 Background Investigations and Access Authorization Program is amended by deleting it in its entirety and substituting instead the following:

2. Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee to the ATTN: Director, Tennessee Division of Radiological Health at the address prescribed in Rule 0400-20-04-.07. The fingerprints of the named reviewing official must be taken by a law enforcement agency, federal or state agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a state to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every ten years in accordance with subparagraph (3)(c) of this rule.

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

Subparagraph (c) of paragraph (4) of Rule 0400-20-13-.02 Background Investigations and Access Authorization Program is amended by deleting it in its entirety and substituting instead the following:

(c) Procedures for processing of fingerprint checks.

1. For the purpose of complying with this chapter, licensees shall use an appropriate method listed in 10 ~~CFR~~ C.F.R. § 37.7 to submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop ~~TWB-05 B32M~~ T-07D04M, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by ~~writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 1-630-829-9565, or by email to FORMS.Resource@nrc.gov~~ emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at ~~http://www.nrc.gov/site-help/e-submittals.html~~ https://www.nrc.gov/security/chp.html.

2. Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the ~~Security Branch, Division of Facilities and Security at 301-492-3531~~ Division of Physical and Cyber Security Policy by e-mailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The Commission publishes the amount of the fingerprint check application fee on the ~~NRC's~~ U.S. Nuclear Regulatory Commission's public Web site. (To find the current fee amount, go to the ~~Electronic Submittals page at http://www.nrc.gov/site-help/esubmittals.html and see the link for the Criminal History Program under Electronic Submission Systems~~ Licensee Criminal History Records Checks & Firearms Background Check information page at https//www.nrc.gov/security/chp.html and see the link for How do I determine how much to pay for the request?).

3. The Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

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

Subparagraph (d) of paragraph (2) of Rule 0400-20-13-.03 Physical Protection Requirements During Use is amended by deleting it in its entirety and substituting instead the following:

(d) Protection of information.

1. Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

2. Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan, ~~and~~ implementing procedures, and the list of individuals who have been approved for unescorted access.

3. Before granting an individual access to the security plan, ~~or~~ implementing procedures, or the list of individuals who have been approved for unescorted access, licensees shall:

   (i) Evaluate an individual's need to know the security plan, ~~or~~ implementing procedures, or the list of individuals who have been approved for unescorted access; and

   (ii) If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in parts (3)(a)2 through 7 of Rule 0400-20-13-.02.

4. Licensees need not subject the following individuals to the background investigation elements for protection of information:

   (i) The categories of individuals listed in parts (5)(a)1 through 13 of Rule 0400-20-13-.02; or

   (ii) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in parts (3)(a)2 through 7 of Rule 0400-20-13-.02, has been provided by the security service provider.

5. The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan, ~~or~~ implementing procedures, or the list of individuals who have been approved for unescorted access.

6. Licensees shall maintain a list of persons currently approved for access to the security plan, ~~or~~ implementing procedures, or the list of individuals who have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, ~~or~~ implementing procedures, or the list of individuals who have been approved for unescorted access or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than ~~7~~ seven working days, and take prompt measures to ensure that the individual is unable to obtain the security plan, ~~or~~ implementing procedures, or the list of individuals who have been approved for unescorted access.

7. When not in use, the licensee shall store its security plan, ~~and~~ implementing procedures, and the list of individuals who have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

8. The licensee shall retain as a record for ~~3~~ three years after the document is no longer needed:

   (i) A copy of the information protection procedures; and

(ii) The list of individuals approved for access to the security plan, ~~or~~ implementing procedures, or the list of individuals who have been approved for unescorted access.

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

Part 1 of subparagraph (a) of paragraph (4) of Rule 0400-20-13-.04 Physical Protection in Transit is amended by deleting it in its entirety and substituting instead the following:

1. The notification must be made to the Division and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the ~~NRC~~ U.S. Nuclear Regulatory Commission's Web site at https://scp.nrc.gov/special/designee.pdf. ~~A list of the contact information is also available upon request from the Director, Division of Materials Safety, State, Tribal, and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Notifications to the NRC must be to the NRC's Director, Division of Security Policy, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The notification to the NRC may be made by email to RAMQC_SHIPMENTS@nrc.gov or by fax to 301-816-5151~~ Notifications to the Division should be in accordance with the methods set out in 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.

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Commissioner on 10/10/2023, and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 07/12/2023

Rulemaking Hearing(s) Conducted on: (add more dates). 09/07/2023

Date: October 10, 2023

Signature:

Name of Officer: David W. Salyers, P.E.

Title of Officer: Commissioner

Agency/Board/Commission: Commissioner of the Department of Environment and Conservation

Rule Chapter Number(s): 0400-20-04, 0400-20-05, 0400-20-06, 0400-20-07, 0400-20-08, 0400-20-10, 0400-20-12, and 0400-20-13

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Jonathan Skrmetti
Attorney General and Reporter

Date

Department of State Use Only

Filed with the Department of State on:

Effective on:

Tre Hargett
Secretary of State

Public Hearing Comments

One copy of a document that satisfies T.C.A. § 4-5-222 must accompany the filing.

During the comment period, the Department received four written comments from one commenter and there were no comments received at the rulemaking hearing.

1. Comment: A commenter pointed out that the first sentence in subparagraph (3)(c) of Rule 0400-20-07-.23 does not agree with its federal analog at 10 C.F.R. § 35.50 and contains a typographical error. The word “license” should be “licensee.”

   Response: The Commissioner agrees, and the typographical error has been corrected.

2. Comment: A commenter made the Department aware that the American Council on Pharmaceutical Education as cited in subparagraph (1)(a) of Rule 0400-20-07-.25 has changed its name to Accreditation Council for Pharmacy Education and recommended the name be updated.

   Response: The Commissioner agrees, and the name has been changed as suggested.

3. Comment: A commenter pointed out that paragraph (5) of Rule 0400-20-07-.26 does not agree with its federal analog at 10 C.F.R. § 35.57(b)(2) that correctly identifies that permits were not issued “by” but “in accordance with” a Commission master material license of broad scope on or before October 25, 2005. The commenter recommends that the Department make this correction to paragraph (5) of Rule 0400-20-07-.26.

   Response: The Commissioner agrees, and the paragraph was revised as suggested.

4. Comment: A commenter pointed out that the purpose of amending Rule 0400-20-07-.41 is to align the rule with 10 C.F.R. § 35.204. However, the current language in paragraph (2) was replaced in its entirety with the federal analog in 10 C.F.R. § 35.204(b), and the federal analog to 10 C.F.R. § 35.204(c) was intended to be retained and amended as paragraph (3) with the remaining paragraphs renumbered. The commenter suggested that the Rule 0400-20-07-.41 be revised as originally intended.

   Response: The Commissioner agrees, and the rule was revised as suggested.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

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

The bulk of this rulemaking focuses on the medical use of radioactive materials. The affected medical organizations could include dentists, physicians, and medical facilities licensed to use radioactive materials in their practice. Many of these organizations are small businesses. Using the Nuclear Regulatory Commission's (NRC) Regulatory Analysis, the average initial implementation cost per licensee is $1,100 and the estimated average annual cost per licensee is $100.

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

This rule requires no additional reporting, no additional recordkeeping, and no other administrative costs to remain in compliance with the proposed rule. No additional professional skills are necessary for preparation of reports or records as a result of this rule.

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

This rule provides a positive effect on impacted businesses by ensuring that all licensed businesses are adequately trained to use nuclear materials in the performance of practices in a manner that minimizes undue exposure to themselves and to their clients. These rules should increase consumer's confidence in the health and safety practices of their caregivers.

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

The Department is not aware of a less burdensome, less intrusive, or less costly alternative method of achieving the objectives of this rule, because this rule substantially codifies existing federal law. Tennessee is an Agreement state with the NRC and desires to remain an Agreement State.

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

The amended rules, when effective, will make the Department's rules comparable to the Conference of Radiation Control Program Directors Suggested State Regulations (SSRs): Part G - Use of Radionuclides in the Healing Arts. In addition, the rulemaking references 10 C.F.R. part 35 – Medical Use of Byproduct Material. These rules are necessary for Agreement States to align with federal regulations to remain an Agreement State the same as other states.

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

Exemption of small businesses from any part of the requirements proposed in these rules would pose a potential health risk to persons being exposed to radioactive materials during processing or transportation. In addition, small businesses are required to adhere to licensing standards in the same manner as larger businesses. The consequences of not adopting these rules could affect the State of Tennessee status as an NRC Agreement State.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228, “On any rule and regulation proposed to be promulgated, the proposing agency shall state in a simple declarative sentence, without additional comments on the merits or the policy of the rule or regulation, whether the rule or regulation may have a projected financial impact on local governments. The statement shall describe the financial impact in terms of increase in expenditures or decrease in revenues.”

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

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The new rule and amendments bring the regulations of the Division of Radiological Health into compliance with changes that the U.S. Nuclear Regulatory Commission (NRC) has made to Title 10 of the Code of Federal Regulations. This compatibility is required for Tennessee to maintain its status as an Agreement State. The rulemaking amends Chapters 0400-20-04, 0400-20-05, 0400-20-06, 0400-20-07, 0400-20-08, 0400-20-10, 0400-20-12, and Chapter 0400-20-13 to update regulatory requirements to:

- Establish separate requirements for identifying and reporting medical events involving permanent implant brachytherapy.
- Amend training and experience requirements in multiple sections to remove the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State.
- Change the requirements for measuring the molybdenum-99 (Mo-99) concentration for elutions of Mo-99/Technetium-99m (Tc-99m) generators and add requirements for reporting and notification of a generator eluate exceeding permissible Mo-99, strontium-82 (Sr-82), or strontium-85 (Sr-85) concentrations.
- Allow licensees to appoint a qualified individual with expertise in certain uses of byproduct material to be named on a license to serve as an associate radiation safety officer (ARSO).
- Remove text requiring processing and evaluation by National Voluntary Laboratory Accreditation Program processor.
- Change in Sm-147 value in Table A-1.
- Add Social Security Number fraud prevention measures.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

The rulemaking is pursuant to Tennessee Code Annotated section 68-202-206 authorizing the Commissioner to promulgate rules and regulations for implementation of the Radiological Health Service Act. In addition, 10 C.F.R. part 150 defines activity in Agreement States as well as the regulatory authority of the Nuclear Regulatory Commission within Agreement States.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

No representatives of any potentially affected company or organization have urged adoption or rejection of these amendments.

(D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

The Department is not aware of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

This rulemaking is not likely to increase or decrease state or local government revenue or expenditures.

(F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Andrew Holcomb
Division of Radiological Health
Department of Environment and Conservation
(615) 532-3038
Andrew.Holcomb@tn.gov

(G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Alli Williamson
Legislative Liaison
Office of General Counsel

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

William R. Snodgrass Tennessee Tower
312 Rosa L. Parks Avenue, 2nd Floor
Nashville, Tennessee 37243
(629) 401-9485
Alli.F.Williamson@tn.gov

(I) Any additional information relevant to the rule proposed for continuation that the committee requests.

(1) A description of the action proposed, the purpose of the action, the legal authority for the action and the plan for implementing the action.

The action proposed is the adoption of the rules contained herein amending Chapters 0400-20-04, 0400-20-05, 0400-20-06, 0400-20-07, 0400-20-08, 0400-20-10, 0400-20-12, and 0400-20-13 to maintain compatibility with federal regulations that is required for Tennessee to maintain its status as an Agreement State. These rules are implemented pursuant to Tennessee Code Annotated section 68-202-206 authorizing the Commissioner to promulgate rules and regulations for implementation of the Radiological Health Service Act.

(2) A determination that the action is the least-cost method for achieving the stated purpose.

This rulemaking is the least-cost method to achieve the stated purpose. As an Agreement State, the Department is required to maintain a degree of compatibility with the Nuclear Regulatory Commission (NRC) regulations. Therefore, our rulemaking is not allowed a high degree of latitude to make significant changes.

(3) A comparison of the cost-benefit relation of the action to nonaction.

These rule amendments are being promulgated to meet legislative and regulatory requirements as an Agreement State with the NRC. The cost of these rules is anticipated to be the work hours dedicated to making the rulemaking effective. If the rules are not promulgated, the absence of legislative compatibility could affect our status as an Agreement State via heightened oversight which would necessitate many avoidable work hours dedicated to the oversight requirements. Based on this comparison, the benefits of moving forward with this rulemaking outweigh the costs.

(4) A determination that the action represents the most efficient allocation of public and private resources.

This action represents the most efficient allocation of public and private resources because the cost of the Department's administration will be absorbed by existing resources, and it will keep licensees in compliance with the changes to Title 10 of the Code of Federal Regulations mandated by the NRC.

(5) A determination of the effect of the action on competition.

This rulemaking will have no significant effect on competition in the marketplace because all participants are subject to the same requirements.

(6) A determination of the effect of the action on the cost of living in the geographical area in which the action would occur.

Cost of living in the geographical area in which the action would occur will not be affected.

(7) A determination of the effect of the action on employment in the geographical area in which the action would occur.

It is not anticipated that the action will affect employment.

(8) The source of revenue to be used for the action.

The action can be accommodated with existing resources.

(9) A conclusion as to the economic impact upon all persons substantially affected by the action, including an analysis containing a description as to which persons will bear the costs of the action and which persons will benefit directly and indirectly from the action.

The rulemaking will allow the Department to maintain compatibility with the NRC. It is not anticipated that this rulemaking will impose substantial increased costs on affected parties. The NRC estimated increased costs on all regulated small entities that can be extrapolated to less than $200,000 overall on licensed entities in Tennessee. The Department anticipates that some licensees will experience an increased amount of employee time devoted to compliance with these rules. The rulemaking will also allow for a better understanding and control of any materials being dispersed for use under a medical license by allowing a streamlined process of reporting certain medical events and certifying individuals who have specialty board recognition.