

Virginia Administrative Code
Title 12. Health
Agency 5. Department of Health
Chapter 481. Virginia Radiation Protection Regulations

12VAC5-481-1660. Purpose and Scope.

Part VII. Use of Radionuclides in the Healing Arts

Article 1. Purpose and Scope

Part VII ([12VAC5-481-1660](#) et seq.) of this chapter establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of Part VII ([12VAC5-481-1660](#) et seq.) of this chapter are in addition to, and not in substitution for, others in these regulations. The requirements and provisions of these regulations apply to applicants and licensees subject to Part VII ([12VAC5-481-1660](#) et seq.) of this chapter unless specifically exempted.

12VAC5-481-1670. General Requirements.

Article 2. General Information

A. Licensees may conduct research involving human research subjects only if it uses the radioactive materials specified on its license for the uses authorized on its license.

B. If the research is conducted, funded, supported, or regulated by another agency that has implemented a policy for protection of human subjects, the licensee shall, before conducting research:

1. Obtain review and approval of the research from an authorized review board; and
2. Obtain informed consent, in writing, from the human research subject.

C. If the research will not be conducted, funded, supported, or regulated by another agency that has implemented an appropriate protection policy, licensees shall, before conducting research, apply for and receive a specific license amendment to its medical use license. The amendment request shall include a written commitment that licensees will, before conducting research:

1. Obtain review and approval of the research from an authorized review board; and
2. Obtain informed consent, in writing, from the human research subject.

D. Nothing in this section relieves licensees from complying with other requirements of this part.

E. Nothing in this part relieves licensees from complying with applicable FDA, federal, and other state requirements governing radioactive drugs or devices.

F. When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern.

G. Licensees shall continue to comply with any license condition that requires it to implement procedures required by [12VAC5-481-2043](#) and [12VAC5-481-2046](#) until there is a license amendment or renewal that modifies the license condition.

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

12VAC5-481-1680. Licensing and Exemptions.

A. A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only in accordance with a specific license issued by the agency, the NRC, or another agreement state, or as allowed in subsection B of this section.

B. A specific license is not needed for an individual who:

1. Receives, possesses, uses, or transfers radioactive material in accordance with this part under the supervision of an authorized user as provided in [12VAC5-481-1710](#) , unless prohibited by license condition; or
2. Prepares unsealed radioactive material for medical use in accordance with this part under the supervision of an authorized nuclear pharmacist or authorized user as provided in [12VAC5-481-1710](#) , unless prohibited by license condition.

C. An application shall be signed by the applicant's or licensee's management.

D. An application for a license for medical use of radioactive material as described in [12VAC5-481-1900](#) , [12VAC5-481-1920](#) , [12VAC5-481-1950](#) , [12VAC5-481-2010](#) , [12VAC5-481-2020](#) , [12VAC5-481-2040](#) B, and [12VAC5-481-2060](#) shall be made by:

1. Filing a completed and signed application for medical use; and
2. Submitting procedures required by [12VAC5-481-2043](#) and [12VAC5-481-2046](#) , as applicable.

E. A request for a license amendment or renewal shall be made by:

1. Submission of a license amendment may be completed by submitting in letter format including all necessary documentation;
2. Submission for a license renewal shall be completed by submitting a completed and signed renewal application for medical use; and

3. Submitting procedures required by [12VAC5-481-2043](#) and [12VAC5-481-2046](#) , as applicable.

F. In addition to the requirements in subsections D and E of this section, submittal of a license application or amendment for medical use of radioactive material as described in [12VAC5-481-2060](#) shall also include information regarding any radiation safety aspects of the medical use of the material that is not otherwise addressed in this part, including but not limited to, the following specific information:

1. Radiation safety precautions and instructions;
2. Training and experience of proposed users;
3. Methodology for measurement or dosages or doses to be administered to patients or human research subjects;
4. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and
5. Any other information requested by the agency in its review of the application.

G. An applicant that satisfies the requirements specified in [12VAC5-481-470](#) may apply for a specific license of broad scope. Licensees possessing a Type A specific license of broad scope for medical use, issued under [12VAC5-481-470](#) , are exempt from:

1. The provisions of subsection E of this section regarding the need to file an amendment to the license for medical use of radioactive material, as described in [12VAC5-481-2060](#);
2. Additions to or changes in any authorized user, authorized nuclear pharmacist, or authorized medical physicist;
3. Additions to or changes in the areas of use at the addresses identified in the application or on the license;
4. The provisions of [12VAC5-481-1690](#) A;
5. The provisions of [12VAC5-481-1690](#) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;
6. The provisions of [12VAC5-481-1690](#) B 5;
7. The provisions of [12VAC5-481-1740](#) .

H. The agency shall issue a license for medical use of radioactive material if:

1. The applicant has filed the appropriate application form in accordance with the instructions in this subsection and subsections D, F, G, and I of this section;
2. The applicant has paid any applicable fee as provided in [12VAC5-490](#) ;
3. The agency finds the applicant equipped and committed to observe the safety standards established by the agency in this part for the protection of the public health and safety; and

4. The applicant meets the requirements of [12VAC5-481-450](#) .

I. The agency shall issue a license for mobile medical service if the applicant:

1. Meets the requirements of subsection H of this section and [12VAC5-481-1880](#); and
2. Assures that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with [12VAC5-481-1870](#) .

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

12VAC5-481-1690. Notifications.

A. Licensees shall provide the agency the following information 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:

1. A copy of (i) the board certification, (ii) the written attestation signed by a preceptor, and (iii) the NRC or another agreement state license;
2. The permit issued by a NRC master material licensee;
3. The permit issued by a broad scope licensee;
4. The permit issued by a NRC master material broad scope permittee; or
5. 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 NRC.
6. For individuals permitted to work within the 30-day time frame, the licensee shall also provide, as appropriate, verification of completion of:
 - a. Any additional case experience required in [12VAC5-481-1980](#) 2 b (7) for an authorized user under [12VAC5-481-1950](#) ;
 - b. Any additional training required in [12VAC5-481-2040](#) A 4 for an authorized user under [12VAC5-481-2040](#) A; or
 - c. Any additional training required in [12VAC5-481-1760](#) A 3 for an authorized medical physicist.

B. A licensee shall notify the agency no later than 30 days after:

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

2. The licensee permits an authorized user or an individual qualified to be a radiation safety officer, under [12VAC5-481-1750](#) and [12VAC5-481-1790](#) , to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer in accordance with [12VAC5-481-1700](#) C;

3. The licensee's mailing address changes;

4. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in [12VAC5-481-500](#) B; or

5. The licensee has added to or changed the areas of use identified in the application or on the license where radioactive material is used in accordance with either [12VAC5-481-1900](#) or [12VAC5-481-1920](#) 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/PET radioactive drug production area.

C. The licensee shall send the documents required in this section to the appropriate address identified in [12VAC5-481-150](#) .

12VAC5-481-1700. Authority and Responsibilities for the Radiation Protection Programs and Changes.

Article 3. General Administrative Requirements

A. In addition to the radiation protection program requirements of [12VAC5-481-630](#) , the licensee's management or designee shall approve, in writing:

1. Requests for a license application, renewal, or amendment before submittal to the agency;
2. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, or an authorized medical physicist; and
3. Radiation protection program changes that do not require a license amendment and are permitted under subsection F of this section.

B. The licensee's management shall appoint a radiation safety officer (RSO) who agrees, in writing, to be responsible for implementing the radiation protection program. This written document shall establish the authority, duties, and responsibilities of the RSO. Licensees, through the RSO, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. Licensees shall provide the RSO sufficient authority, organization freedom, time, resources, and management prerogative to:

1. Identify radiation safety problems;
2. Initiate, recommend, or provide corrective actions;
3. Stop unsafe operations; and
4. Verify implementation of corrective actions.

C. For up to 60 days each year, licensees may permit an authorized user or an individual qualified to be a RSO, under [12VAC5-481-1750](#) and [12VAC5-481-1790](#) , to function as a temporary radiation safety officer, as provided in subsection G if the licensee takes the actions required in subsections B, E, G, and H of this section and notifies the agency in accordance with [12VAC5-481-1690](#) B.

D. Licensees may simultaneously appoint more than one temporary RSO in accordance with subsection C of this section, if needed to ensure that the temporary RSO satisfies the requirements to be a RSO for each of the different types of uses of radioactive material permitted by the licensee.

E. Licensees that are authorized for two or more different types of uses of radioactive material under Articles 6, 7, and 9 of this part, or two or more types of units under [12VAC5-481-2040](#) B, shall establish a Radiation Safety Committee (RSC) to oversee all uses of radioactive material permitted by the license. The RSC shall include an authorized user for each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor a RSO. The RSC may include other members the licensee considers appropriate.

F. A licensee may revise its radiation protection program without agency approval if:

1. The revision does not require a license amendment under [12VAC5-481-450](#) or [12VAC5-481-1680](#) ;
2. The revision is in compliance with this chapter and the license;
3. The revision has been reviewed and approved by the RSO and licensee management; and
4. The affected individuals are instructed on the revised program before the changes are implemented.

12VAC5-481-1710. Supervision.

A. Licensees that permit the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user, as allowed by [12VAC5-481-1680](#) B 1, shall:

1. In addition to the requirements in [12VAC5-481-2270](#) , instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations, and license conditions with respect to the use of radioactive material; and
2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, written directive procedures, regulations, and license conditions with respect to the medical use of radioactive material.

B. Licensees that permit the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by [12VAC5-481-1680](#) B 2, shall:

1. In addition to the requirements in [12VAC5-481-2270](#) , instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

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

C. Licensees that permit supervised activities under subsections A and B of this section are responsible for the acts and omissions of the supervised individual.

12VAC5-481-1720. Written Directives.

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

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive shall be documented as soon as possible in writing in the patient's record. A written directive shall be prepared within 48 hours of the oral directive.

B. The written directive shall contain the patient or human research subject's name and the following information:

1. For any administration of quantities greater than 30 μCi (1.11 MBq) of sodium iodide (I-131): the dosage;
2. For an administration of a therapeutic dosage of unsealed radioactive material other than sodium iodide (I-131): the radioactive drug, dosage, and route of administration;
3. For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;
4. For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;
5. For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
6. For all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders:
 - a. Before implantation: treatment site, the radionuclide, and dose; and
 - b. After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

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

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision shall be documented as soon as possible in the patient's record. A revised written directive shall be signed by the authorized user within 48 hours of the oral revision.

12VAC5-481-1730. Procedures for Administrations Requiring a Written Directive.

For any administration requiring a written directive, licensees shall develop, implement, and maintain written directive procedures to provide high confidence that the patient's or human research subject's identity is verified before each administration and each administration is in accordance with the written directive. At a minimum, the procedures required by this section shall address the following items that are applicable to the licensee's use of radioactive material:

1. Verifying the identity of the patient or human research subject;
2. Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;
3. Checking both manual and computer-generated dose calculations; and
4. Verifying that all computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by [12VAC5-481-2040](#) B and [12VAC5-481-2060](#).

12VAC5-481-1740. Suppliers for Sealed Sources or Devices for Medical Use.

For medical use, licensees may only use the following:

1. Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under this part or equivalent requirements of the NRC or another agreement state;
2. Sealed sources or devices non-commercially transferred from another medical use licensee;
3. Teletherapy sources manufactured and distributed in accordance with a license issued under Part III ([12VAC5-481-380](#) et seq.) of this chapter or equivalent requirements of the NRC or another agreement state.

12VAC5-481-1750. Training for Radiation Safety Officer.

Except as provided in [12VAC5-481-1780](#), licensees shall require an individual fulfilling the

responsibilities of the radiation safety officer (RSO) as provided in [12VAC5-481-1700](#) to be an individual who:

1. Is certified by a specialty board who has been recognized by the NRC; or
2. Has completed a structured educational program consisting of provisions, as follows:
 - a. 200 hours of classroom and laboratory training in the following areas:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;
 - (3) Radiation biology; and
 - (4) Radiation dosimetry; and
 - b. One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on an agency, NRC, or another agreement state license or permit issued by a master material licensee that authorizes similar types of uses of radioactive material involving the following:
 - (1) Shipping, receiving, and performing related radiation surveys;
 - (2) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
 - (3) Securing and controlling radioactive material;
 - (4) Using administrative controls to avoid mistakes in the administration of radioactive material;
 - (5) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
 - (6) Using emergency procedures to control radioactive material; and
 - (7) Disposing of radioactive material; or
3. Meets the following qualifications:
 - a. Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the NRC under [12VAC5-481-1760](#) A 1 and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as RSO and who meets the requirements in subdivisions 4 and 5 of this section; or
 - b. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO responsibilities; and meets subdivisions 4 and 5 of this section; and

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 RSO, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the types of use for which the licensee is seeking approval; and

5. Has obtained written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in subdivisions 1, 2, or 3; and 4 of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a RSO for a medical use licensee.

12VAC5-481-1760. Training for an Authorized Medical Physicist.

Except as provided in [12VAC5-481-1780](#), licensees shall require the authorized medical physicist (AMP) to be an individual who:

1. Is certified by a specialty board whose certification process has been recognized by the NRC, or
2. Meets the following requirements:
 - a. Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, health physics, other physical science, engineering, or applied mathematics from an accredited college or university or an equivalent training program approved by the agency, the NRC, or another agreement state and has completed one year of full-time training in medical physics and an additional year of full-time practical experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the types of use for which the individual is seeking authorization. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one million electron volts) and brachytherapy services and shall 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
3. Has training for the types of use 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 types of use for which the individual is seeking authorization; and

4. Has obtained written attestation that the individual has satisfactorily completed the requirements of subdivisions 1 or 2; and 3 of this section; and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in [12VAC5-481-1760](#) , [12VAC5-481-1780](#) , or equivalent requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

12VAC5-481-1770. Training for an Authorized Nuclear Pharmacist.

Except as provided in [12VAC5-481-1780](#) , licensees shall require the authorized nuclear pharmacist (ANP) to be a pharmacist who:

1. Is certified by a specialty board whose certification process has been recognized by the NRC; or
2. Meets the following requirements:
 - a. Has completed 700 hours in a structured educational program consisting:
 - (1) 200 hours of classroom and laboratory training in the following areas:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity;
 - (d) Chemistry of byproduct material for medical use; and
 - (e) Radiation biology; and
 - (2) Supervised practical experience in a nuclear pharmacy involving:
 - (a) Shipping, receiving, and performing related radiation surveys;
 - (b) 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-emitting or beta-emitting radionuclides;
 - (c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
 - (d) Using administrative controls to avoid medical events in the administration of radioactive material; and
 - (e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
3. Has obtained written attestation, signed by a preceptor ANP, that the individual has satisfactorily completed the requirements in subdivision 1 or 2 of this section and has

achieved a level of competency sufficient to function independently as an ANP.

12VAC5-481-1780. Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Nuclear Pharmacist, and Authorized User.

A. The following applies to individuals with experience as a radiation safety officer (RSO), teletherapy or medical physicist (AMP), or authorized nuclear pharmacist (ANP):

1. An individual identified as an RSO, AMP, or ANP on a specific license or a permit issued by the agency, the NRC, or another agreement state; broad scope licensee or master material license permit; or by a master material license permittee of broad scope that authorizes medical use or the practice of nuclear pharmacy before October 24, 2002, need not comply with the training requirements of [12VAC5-481-1750](#) , [12VAC5-481-1760](#) , or [12VAC5-481-1770](#) , respectively.
2. An individual identified as an RSO, AMP, or ANP on a license or a permit issued by the agency, NRC, or another agreement state broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002, and April 29, 2005, need not comply with the training requirements of [12VAC5-481-1750](#) , [12VAC5-481-1760](#) , or [12VAC5-481-1770](#) , respectively.
3. An RSO, AMP, or ANP, who used only accelerator-produced radioactive materials or discrete sources of radium-226, or both, for medical uses 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 NRC, need not comply with the training requirements of [12VAC5-481-1750](#) , [12VAC5-481-1760](#) , or [12VAC5-481-1770](#) , respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this subdivision, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this part.

B. The following applies to experienced authorized users (AU):

1. Physicians, dentists, or podiatrists identified as AUs for the medical use of radioactive material on a license issued by the agency, the NRC, or another agreement state; a permit issued by an NRC master material licensee; a permit issued by an agency, NRC, or other agreement state broad scope licensee; or a permit issued by an NRC master material license broad scope permittee before October 24, 2002, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Articles 5 ([12VAC5-481-1900](#) et seq.) through 9 ([12VAC5-481-2040](#) et seq.) of this part.
2. Physicians, dentists, or podiatrists identified as AUs for the medical use of radioactive material on a license issued by the agency, the NRC, or another agreement state; a permit

issued by an NRC master material licensee; a permit issued by an agency, NRC, or other agreement state broad scope licensee; or a permit issued by an NRC master material licensee broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002, and April 29, 2005, need not comply with the training requirements of Articles 5 ([12VAC5-481-1900](#) et seq.) through 9 ([12VAC5-481-2040](#) et seq.) of this part.

3. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials or discrete sources of radium-226, or both, for medical uses performed 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, need not comply with the training requirements of Articles 5 ([12VAC5-481-1900](#) et seq.) through 9 ([12VAC5-481-2040](#) et seq.) of this part 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 subdivision, qualifies as an AU for those materials and uses performed before these dates for purposes of this chapter.

C. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.

12VAC5-481-1790. Recentness of Training.

The training and experience specified in this article and Articles 5 ([12VAC5-481-1900](#) et seq.), 6 ([12VAC5-481-1950](#) et seq.), 7 ([12VAC5-481-2010](#) et seq.), 8 ([12VAC5-481-2020](#) et seq.), and 9 ([12VAC5-481-2040](#) et seq.) of this part shall have been obtained within the seven years preceding the date of the application or the individual shall have had related continuing education and experience since the required training and experience was completed.

12VAC5-481-1800. Possession, Use, and Calibration of Instruments Used to Measure the Activity of Unsealed Radioactive Material.

Article 4. General Technical Requirements

A. For direct measurements performed in accordance with [12VAC5-481-1820](#) , licensees shall possess and use instrumentation to measure the activity of unsealed radioactive material before it is administered to each patient or human research subject.

B. Licensees shall test the instrumentation required by subsection A of this section in accordance with nationally recognized standards or the manufacturer's instructions.

12VAC5-481-1810. (Repealed.)

12VAC5-481-1820. Determination of Dosages of Unsealed Radioactive Material for Medical Use.

A. Licensees shall determine and record the activity of each dosage before medical use.

B. For a unit dosage, this determination shall be made by:

1. Direct measurement of the radioactivity; or

2. A decay correction based on activity or activity concentration determined by:

a. A manufacturer or preparer licensed under [12VAC5-481-480](#) I or equivalent NRC or other agreement state requirements;

b. An agency, NRC, or another agreement state licensee for use in research in accordance with Radioactive Drug Research Committee-approved protocol or Investigational New Drug (IND) protocol accepted by FDA; or

c. A PET radioactive drug producer licensed under [12VAC5-481-440](#) H or equivalent NRC or other agreement state requirements.

C. For other than unit dosages, this determination shall be made by:

1. Direct measurement of radioactivity;

2. Combination of measurement of radioactivity and mathematical calculations; or

3. Combination of volumetric measurements and mathematical calculations, based on the measurement made by:

a. A manufacturer or preparer licensed under [12VAC5-481-480](#) I or equivalent NRC or other agreement state requirements; or

b. A PET radioactive drug producer licensed under [12VAC5-481-440](#) H or equivalent NRC or other agreement state requirements.

D. Unless otherwise directed by the authorized user, licensees may not use a dosage if the dosage does not fall within the prescribed dosage range or the dosage differs from the prescribed dosage by more than 20%.

12VAC5-481-1830. Authorization for Calibration, Transmission, and Reference Sources.

Any person authorized by [12VAC5-481-1680](#) for medical use of radioactive material may receive, possess, and use any of the following radioactive material for check, calibration, transmission, and reference use:

1. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under [12VAC5-481-480](#) or equivalent NRC or other agreement state regulations.

2. Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under [12VAC5-481-480](#) or equivalent NRC or other agreement state regulations, providing the redistributed sealed sources are in the original packaging and shielding and

are accompanied by the manufacturer's approved instructions.

3. Any radioactive material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

4. Any radioactive material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 μ Ci) or 1000 times the quantities in [12VAC5-481-3730](#).

5. Technetium-99m in amounts as needed.

12VAC5-481-1840. Requirements for Possession of Sealed Sources and Brachytherapy Sources.

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

B. Licensees in possession of a sealed source shall:

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

2. Test the source for leakage at intervals not to exceed six months or at other intervals approved by the NRC or another agreement state in the Sealed Source and Device Registry.

C. To satisfy the leak test requirements of this section, licensees shall measure the sample so that the leak test can detect the presence of 0.005 μ Ci (185 Bq) of radioactive material in the sample.

D. If the leak test reveals the presence of 0.005 μ Ci (185 Bq) or more of removable contamination, the licensee shall:

1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in Parts III ([12VAC5-481-380](#) et seq.) and IV ([12VAC5-481-600](#) et seq.) of this chapter; and

2. File a report within five days of the leak test in accordance with [12VAC5-481-2080](#) C.

E. Licensees need not perform a leak test on the following sources:

1. Containing only radioactive material with a half-life of less than 30 days;

2. Containing only radioactive material as a gas;

3. Containing 100 μ Ci (3.7 MBq) or less of beta or gamma-emitting material;

4. Containing 10 μ Ci (0.37 MBq) or less of alpha-emitting material;

4. Seeds of iridium-192 encased in nylon ribbon; and

5. Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within six months before

the date of use or transfer.

F. Licensees in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession.

12VAC5-481-1850. Labeling of Vials and Syringes.

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

12VAC5-481-1860. Surveys of Ambient Radiation Exposure Rate.

A. In addition to the surveys required by Part IV ([12VAC5-481-600](#) et seq.) of this chapter, licensees shall survey with a radiation detection survey instrument at the end of each day of use. Licensees shall survey all areas where unsealed radioactive material requiring a written directive was prepared for use or administered.

B. Licensees do not need to perform the surveys required by subsection A of this section in an area where patients or human research subjects are confined when they cannot be released under [12VAC5-481-1870](#).

12VAC5-481-1870. Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material.

A. Licensees may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 500 mrem (5 mSv).

B. Licensees shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonable achievable if the total effective dose equivalent to any other individual is likely to exceed 100 mrem (1 mSv). If the total effective dose equivalent to a nursing infant or child could exceed 100 mrem (1 mSv), assuming there were no interruption of breast-feeding, the instructions shall also include:

1. Guidance on the interruption or discontinuation of breast-feeding; and
2. Information on the potential consequences, if any, on failure to follow guidance.

12VAC5-481-1880. Provision of Mobile Medical Service.

A. The mobile medical service shall be licensed if the service receives, uses, or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

B. Licensees providing mobile medical service shall:

1. Obtain a letter signed by the management of each client for whom services are rendered that permits the use of radioactive material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;
2. Inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered;
3. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this subdivision shall include a constancy check;
4. Check survey instruments for proper operation with a dedicated check source before use at each client's address; and
5. Before leaving a client's address, survey all areas of use for dose rate and removable contamination to ensure compliance with the requirements in Part IV ([12VAC5-481-600](#) et seq.) of this chapter.

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

12VAC5-481-1890. Decay-In-Storage.

Licensees may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it:

1. Monitors material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
2. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.

12VAC5-481-1900. Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required.

Article 5. Unsealed Byproduct Material – Written Directive Not Required

Except for quantities that require a written directive under [12VAC5-481-1720](#) , licensees may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

1. Obtained from a manufacturer or preparer licensed under [12VAC5-481-480](#) I or equivalent NRC or other agreement state regulations or a PET radioactive drug producer licensed under [12VAC5-481-440](#) H or equivalent NRC or other agreement state

requirements;

2. Excluding PET radionuclides, prepared by (i) an ANP; (ii) a physician who is an AU and who meets the requirements specified in [12VAC5-481-1940](#) or [12VAC5-481-1980](#) and [12VAC5-481-1940](#) 3 a 1; or (iii) an individual under supervision, as specified in [12VAC5-481-1710](#);
3. Obtained from and prepared by an agency, NRC, or another agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigation New Drug (IND) protocol accepted by FDA; or
4. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigation New Drug (IND) protocol accepted by FDA for use in research.

12VAC5-481-1910. Training for Uptake, Dilution, and Excretion Studies.

Except as provided in [12VAC5-481-1780](#) , licensees shall require an authorized user of unsealed radioactive material for the uses authorized under [12VAC5-481-1900](#) to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC and who meets the requirements in subdivision 3 b of this section;
2. Who is an authorized user under [12VAC5-481-1940](#) , [12VAC5-481-1980](#) , or equivalent NRC or other agreement state requirements; or
3. Who has:
 - a. 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 shall include the following:
 - (1) Classroom and laboratory training in the following areas:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity;
 - (d) Chemistry of radioactive material for medical use; and
 - (e) Radiation biology; and
 - (2) Work experience under the supervision of an authorized user who meets the requirements in this section, [12VAC5-481-1780](#) , [12VAC5-481-1940](#) , [12VAC5-481-1980](#) , or equivalent NRC or other agreement state requirements, involving:
 - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

- (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
 - (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (f) Administering dosages of radioactive drugs to patients or human research subjects; and
- b. Obtained written attestation, signed by a preceptor authorized user who meets the requirements in this section, [12VAC5-481-1780](#) , [12VAC5-481-1940](#) , or [12VAC5-481-1980](#) , or equivalent NRC or other agreement state requirements, that the individual has satisfactorily completed the requirements in subdivisions 1 a or 3 a of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under [12VAC5-481-1900](#) .

12VAC5-481-1920. Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive Is Not Required.

Except for quantities that require a written directive under [12VAC5-481-1720](#) , licensees may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

1. Obtained from a manufacturer or preparer licensed under [12VAC5-481-480](#) I or equivalent NRC or other agreement state requirements or a PET radioactive drug producer licensed under [12VAC5-481-440](#) H or equivalent NRC or other agreement state requirements;
2. Excluding production of PET radionuclides, prepared by an ANP; a physician who is an authorized user (AU) and who meets the requirements specified in [12VAC5-481-1940](#) , or [12VAC5-481-1980](#) and [12VAC5-481-1940](#) 3 a (1) (g); or an individual under the supervision, as specified in [12VAC5-481-1710](#) , of an ANP or a physician who is an AU;
3. Obtained from and prepared by an agency, NRC, or another agreement state licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an IND protocol accepted by FDA; or
4. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA.

12VAC5-481-1930. Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations.

A. Licensees may not administer to humans a radiopharmaceutical that contains:

1. More than 0.15 μCi of molybdenum-99 per mCi of technetium-99m (0.15 kBq of molybdenum-99 per MBq of technetium-99m); or
2. More than 0.02 μCi of strontium-82 per mCi of rubidium-82 chloride (0.02 kBq of strontium-82 per MBq of rubidium-82 chloride injection) or more than 0.2 μCi of strontium-85 per mCi of rubidium-82 (0.2 kBq of strontium-85 per MBq of rubidium-82 chloride injection).

B. To demonstrate compliance with subsection A of this section, the licensee preparing the radioactive drug from the radionuclide generator shall:

1. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;
2. Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems, not to exceed before the first patient use of the day for a strontium/rubidium-82 generator.

12VAC5-481-1940. Training for Imaging and Localization Studies.

Except as provided in [12VAC5-481-1780](#), licensees shall require an authorized user (AU) of unsealed radioactive material for the uses authorized under [12VAC5-481-1920](#) to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC and who meets the requirements in subdivision 3 b of this section;
2. Who is an AU under [12VAC5-481-1980](#) and meets the requirements in subdivision 3 a (2) (g) of this section, or equivalent NRC or other agreement state requirements; or
3. Who has:
 - a. 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 shall include at a minimum:
 - (1) Classroom and laboratory training in the following areas:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity;
 - (d) Chemistry of radioactive material for medical use; and
 - (e) Radiation biology; and
 - (2) Work experience, under the supervision of an authorized user who meets the

requirements in this section, [12VAC5-481-1780](#) , or [12VAC5-481-1980](#) and subdivision 3 a (2) (g) of this section, or equivalent NRC or other agreement state requirements, involving:

- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (b) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (d) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
 - (e) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;
 - (f) Administering dosages of radioactive drugs to patients or human research subjects; and
 - (g) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
- b. Obtained written attestation, signed by a preceptor authorized user who meets the requirements in this section, [12VAC5-481-1780](#) , or [12VAC5-481-1980](#) and subdivision 3 a (2) (g), or equivalent NRC or other agreement state requirements, that the individual has satisfactorily completed the requirements in subdivisions 1 a or 3 a of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under [12VAC5-481-1900](#) and [12VAC5-481-1920](#) .

12VAC5-481-1950. Use of Unsealed Radioactive Material for Which a Written Directive Is Required.

Article 6. Unsealed Byproduct Material - Written Directive Required

Licensees may use any unsealed radioactive material prepared for medical use and for which a written directive is required that is:

1. Obtained from a manufacturer or preparer licensed under [12VAC5-481-480](#) I or equivalent NRC or other agreement state requirements or a PET radioactive drug producer licensed under [12VAC5-481-440](#) H or equivalent NRC or another agreement state requirements;
2. Excluding production of PET radionuclides, prepared by an ANP; a physician who is an authorized user (AU) and who meets the requirements specified in [12VAC5-481-1940](#) or

[12VAC5-481-1980](#); or an individual under the supervision, as specified in [12VAC5-481-1710](#) , of an ANP or the physician who is an AU;

3. Obtained from and prepared by an agency, NRC, or another agreement state licensee for use in research in accordance with an investigational new drug (IND) protocol accepted by U.S. Food and Drug Administration (FDA); or

4. Prepared by the licensee for use in research in accordance with an IND protocol accepted by FDA.

12VAC5-481-1960. Safety Instruction.

In addition to the requirements of [12VAC5-481-2270](#) , licensees shall provide radiation safety instruction initially and at least annually to personnel caring for patients or human research subjects who cannot be released under [12VAC5-481-1870](#) . To satisfy this requirement, the instruction shall be commensurate with the duties of the personnel and include:

1. Patient or human research subject control;

2. Visitor control, including:

a. Routine visitation to hospitalized individuals in accordance with [12VAC5-481-720](#) A 1; and

b. Visitation authorized in accordance with [12VAC5-481-720](#) C;

3. Contamination control;

4. Waste control; and

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

12VAC5-481-1970. Safety Precautions.

A. For each patient or human research subject who cannot be released under [12VAC5-481-1870](#) , licensees shall:

1. Quarter the patient or the human research subject either in:

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

b. A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under [12VAC5-481-1870](#);

2. Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign;

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

4. Either monitor material and items removed from the patient's or human research

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

B. Licensees shall notify the RSO, or his designee, and an AU as soon as possible if the patient or human research subject has a medical emergency or dies.

12VAC5-481-1980. Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required.

Except as provided in [12VAC5-481-1780](#), licensees shall require an authorized user (AU) of unsealed radioactive material for the uses authorized under [12VAC5-481-1950](#) to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC; or
2. Who 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 shall include:
 - a. Classroom and laboratory training in the following areas:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;
 - (4) Chemistry of radioactive material for medical use; and
 - (5) Radiation biology; and
 - b. Work experience under the supervision of an AU who meets the requirements in this section, [12VAC5-481-1780](#), or equivalent NRC or another agreement state requirements. A supervising AU, who meets the requirements of this subdivision 2 shall also have experience in administering dosages in the same dosage category or categories (i.e., subdivision 2 b (7) of this section) as the individual requesting authorized user status. The work experience shall involve:
 - (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (2) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
 - (3) Calculating, measuring, and safely preparing patient or human research subject dosages;

(4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;

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

(6) (Reserved.)

(7) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each categories for which the individual is requesting authorized user status. These categories are oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide I-131, for which a written directive is required; oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131; parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; or parenteral administration of any other radionuclide, for which a written directive is required.

3. Who has obtained written attestation that the individual has satisfactorily completed the requirements in either subdivisions 1 and 2 b (7) of this section or subdivision 2 of this section and has achieved a level of competency sufficient to function independently as an AU for the medical uses authorized under [12VAC5-481-1950](#) . The written attestation shall be signed by a preceptor AU who meets the requirements in this section, [12VAC5-481-1780](#) , or equivalent NRC or other agreement state requirements. The preceptor AU, who meets the requirements in subdivision 2 of this section shall have experience in administering dosages in the same dosage category or categories (i.e., subdivision 2 b (7) of this section) as the individual requesting authorized user status.

12VAC5-481-1990. Training for the Oral Administration of Sodium Iodide (I-131) Requiring a Written Directive in Quantities Less Than or Equal to 33 Mci (1.22 Gbq).

Except as provided in [12VAC5-481-1780](#) , licensees shall require an authorized user (AU) for the oral administration of sodium iodide (I-131) requiring a written directive in quantities less than or equal to 33 mCi (1.22 GBq) to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC; or

2. Who is an AU under [12VAC5-481-1980](#) for uses listed in subdivision 2 b (7) of [12VAC5-481-1980](#) , [12VAC5-481-2000](#) , or equivalent NRC or other agreement state requirements; or

3. Who has:

a. 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 shall include:

(1) Radiation physics and instrumentation;

- (2) Radiation protection;
- (3) Mathematics pertaining to the use and measurement of radioactivity;
- (4) Chemistry of byproduct material for medical use; and
- (5) Radiation biology; and

b. Work experience under the supervision of an AU who meets the requirements in this section, [12VAC5-481-1780](#) , [12VAC5-481-1980](#) , [12VAC5-481-2000](#) , or equivalent NRC or another agreement state requirements. A supervising AU who meets the requirements in subdivision 2 of [12VAC5-481-1980](#) shall also have experience in administering dosages as specified in subdivision 2 b (7) of [12VAC5-481-1980](#) . The work experience shall involve:

- (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (4) Using administrative controls to prevent a medical event involving the use of byproduct material;
- (5) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
- (6) Administering dosages to patients or human research subjects, that includes at least three cases involving the oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide (I-131); and

4. Obtained written attestation that the individual has satisfactorily completed the requirements in subdivisions 1 and 3 b of this section or subdivision 3 of this section and has achieved a level of competency sufficient to function independently as an AU for medical uses authorized under [12VAC5-481-1950](#) . The written attestation shall be signed by a preceptor AU who meets the requirements in this section, [12VAC5-481-1780](#) , [12VAC5-481-1980](#) , [12VAC5-481-2000](#) , or equivalent NRC or other agreement state requirements. A preceptor AU who meets the requirement in subdivision 2 of [12VAC5-481-1980](#) shall also have experience in administering dosages as specified in subdivision 2 b (7) of [12VAC5-481-1980](#) .

12VAC5-481-2000. Training for the Oral Administration of Sodium Iodide (I-131) Requiring a Written Directive in Quantities Greater Than 33 Mci (1.22 Gbq).

Except as provided in [12VAC5-481-1780](#) , licensees shall require an authorized user (AU) for the oral administration of sodium iodide (I-131) requiring a written directive in quantities

greater than 33 mCi (1.22 GBq) to be a physician:

1. Who is certified by a medical specialty board whose certification has been recognized by the NRC;

2. Who is an AU under [12VAC5-481-1980](#) for uses listed in subdivision 2 b (7) of [12VAC5-481-1980](#) or equivalent NRC or other agreement state requirements; or

3. Who has:

a. 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 shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

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

(5) Radiation biology; and

b. Work experience, under the supervision of an AU who meets the requirements in this section, [12VAC5-481-1780](#) , [12VAC5-481-1980](#) , [12VAC5-481-1990](#) , or equivalent NRC or other agreement state requirements. A supervising AU who meets the requirements in subdivision 2 of [12VAC5-481-1980](#) shall also have experience in administering dosages as specified in subdivision 2 b (7) of [12VAC5-481-1980](#) . The work experience shall involve:

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

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

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

(4) Using administrative controls to prevent a medical event involving the use of radioactive material;

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

(6) Administering dosages to patients or human research subjects that includes at least three cases involving the oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide (I-131); and

c. Obtained written attestation that the individual has satisfactorily completed the requirements in subdivisions 1 and 3 b of this section or subdivision 3 of this section

and has achieved a level of competency sufficient to function independently as an AU for medical uses authorized under [12VAC5-481-1950](#) . The written attestation shall be signed by a preceptor AU who meets the requirements in this section, [12VAC5-481-1780](#) , [12VAC5-481-1980](#) , [12VAC5-481-1990](#) , or equivalent NRC or other agreement state requirements. A preceptor AU who meets the requirements in subdivision 2 of [12VAC5-481-1980](#) shall also have experience in administering dosages as specified in subdivision 2 b (7) of [12VAC5-481-1980](#) .

12VAC5-481-2001. Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.

Except as provided in [12VAC5-481-1780](#) , licensees shall require an authorized user (AU) for the parenteral administration requiring a written directive to be a physician:

1. Who is an AU under [12VAC5-481-1980](#) for uses listed in subdivision 2 b (7) of [12VAC5-481-1980](#) or equivalent NRC or other agreement state requirements;
2. Who is an AU under [12VAC5-481-2010](#) , [12VAC5-481-2040](#) , or equivalent NRC or other agreement state requirements and who meets the requirements in subdivision 4 of this section; or
3. Who is certified by a medical specialty board whose certification process has been recognized by the NRC; or
4. Who has:
 - a. 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 or parenteral administration of any other radionuclide for which a written directive is required. The training shall include:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;
 - (4) Chemistry of radioactive material for medical use; and
 - (5) Radiation biology; and
 - b. Work experience under the supervision of an AU who meets the requirements in this section, [12VAC5-481-1780](#) , [12VAC5-481-1980](#) , or equivalent NRC or other agreement state 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 or parenteral administration of any other radionuclide for which a written directive is required. A supervising AU who meets the requirements in [12VAC5-481-1980](#) shall have experience in administering dosages as specified in subdivision 2 b (7) of [12VAC5-481-1980](#) . The work experience shall involve:

- (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (2) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (4) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
- (6) Administering dosages to patients or human research subjects that include at least three cases involving the parenteral administration for which a written directive is required of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV or at least three cases involving the parenteral administration of any other radionuclide for which a written directive is required; and

5. Obtained a written attestation that the individual has satisfactorily completed the requirements in subdivision 2 or 3; and subdivision 4 b of this section or subdivision 4 of this section, and has achieved a level of competency sufficient to function independently as an AU for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation shall be signed by a preceptor AU who meets the requirements in this section, [12VAC5-481-1780](#) , [12VAC5-481-1980](#) , or equivalent NRC or other agreement state requirements. A preceptor AU who meets the requirements in [12VAC5-481-1980](#) shall have experience in administering dosages as specified in subdivision 2 b (7) of [12VAC5-481-1980](#) .

12VAC5-481-2010. Use of Sources for Manual Brachytherapy.

Article 7. Manual Brachytherapy

Licensees shall use only brachytherapy sources for therapeutic medical uses:

1. As approved in the Sealed Source and Device Registry; or
2. In research in accordance with an active Investigational Device Exemption application accepted by the U.S. Food and Drug Administration provided the requirements of [12VAC5-481-1740](#) are met.

12VAC5-481-2011. Surveys After Source Implant and Removal.

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

B. Immediately after removing the last temporary implant source from a patient or a human

research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

C. A licensee shall retain a record of the surveys required by subsections A and B of this section in accordance with [12VAC5-481-2070](#) O.

12VAC5-481-2012. Brachytherapy Sources Accountability.

A. Licensees shall maintain accountability at all times for all brachytherapy sources in storage or use.

B. As soon as possible after removing sources from a patient or a human research subject, licensees shall return brachytherapy sources to a secure storage area.

12VAC5-481-2013. Safety Instruction.

A. In addition to the requirements of [12VAC5-481-2270](#), licensees shall provide radiation safety instruction initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under [12VAC5-481-1870](#).

B. To satisfy this requirement, the instruction shall be commensurate with the duties of the personnel and include:

1. Size and appearance of the brachytherapy sources;
2. Safe handling and shielding instructions;
3. Patient or human research subject control;
4. Visitor control, including both:
 - a. Routine visitation of hospitalized individuals in accordance with [12VAC5-481-720](#) A 1; and
 - b. Visitation authorized in accordance with [12VAC5-481-720](#) C; and
5. Notification of the RSO, or his designee, and an AU if the patient or the human research subject has a medical emergency or dies. The licensee shall also notify the agency if it is possible that any individual could receive exposures in excess of regulatory limits as a result of the deceased's body.

12VAC5-481-2014. Safety Precautions.

A. For each patient or human research subject who is receiving brachytherapy and cannot be released under [12VAC5-481-1870](#), licensees shall:

1. Not quarter the patient or human research subject in the same room as an individual who is not receiving brachytherapy;
2. Visibly post the patient's or human research subject's room with a "Radioactive

Materials" sign; and

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

B. Licensees shall have applicable emergency response equipment available near each treatment room to respond to a source that becomes:

1. Dislodged from the patient; and
2. Lodged within the patient following removal of the source applicators.

C. Licensees shall notify the RSO, or his designee, and an AU as soon as possible if the patient or human research subject has a medical emergency or dies.

12VAC5-481-2015. Calibration Measurements of Brachytherapy Sources.

A. Before the first medical use of a brachytherapy source, licensees shall have:

1. Determined the source output or activity using a dosimetry system that meets the requirements of [12VAC5-481-2044](#) ;
2. Determined source positioning accuracy with applicators; and
3. Used published protocols currently accepted by nationally recognized bodies to meet the requirements of subdivision 1 and 2 of this subsection.

B. Instead of a licensee making its own measurements as required in subsection A of this section, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with subsection A of this section.

C. A licensee shall mathematically correct the outputs or activities determined in subsection A of this section for physical decay at intervals consistent with 1.0% physical decay.

12VAC5-481-2016. Decay of Strontium-90 Sources for Ophthalmic Treatments.

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 shall be based on the activity determined under [12VAC5-481-2015](#) .

12VAC5-481-2017. Therapy-Related Computer Systems.

Licensees shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

1. The source-specific input parameters required by the dose calculation algorithm;
2. The accuracy of dose, dwell time, and treatment time calculations at representative

points;

3. The accuracy of isodose plots and graphic displays; and
4. The accuracy of the software used to determine sealed source positions from radiographic images.

12VAC5-481-2018. Training for Use of Manual Brachytherapy Sources.

Except as provided in [12VAC5-481-1780](#) , licensees shall require an authorized user of a manual brachytherapy source for uses authorized under [12VAC5-481-2010](#) to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC; or
2. Who has:
 - a. Completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:
 - (1) 200 hours of classroom and laboratory training in the following areas:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection;
 - (c) Mathematics pertaining to the use and measurement of radioactivity; and
 - (d) Radiation biology; and
 - (2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in this subsection, [12VAC5-481-1780](#) , or equivalent NRC or another agreement state requirements at a medical institution, involving:
 - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (b) Checking survey meters for proper operation;
 - (c) Preparing, implanting, and removing brachytherapy sources;
 - (d) Maintaining running inventories of material on hand;
 - (e) Using administrative controls to prevent a medical event involving the use of radioactive material;
 - (f) Using emergency procedures to control radioactive material; and
 - b. Completed three years of supervised clinical experience in radiation oncology, under an AU who meets the requirements in this section, [12VAC5-481-1780](#) , or equivalent NRC or another agreement state requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of

Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by subdivision 2 a (2) of this section.

3. Who has obtained written attestation, signed by a preceptor AU who meets the requirements in this section, [12VAC5-481-1780](#) , or equivalent NRC or other agreement state requirements, that the individual has satisfactorily completed the requirements in this section and has achieved a level of competency sufficient to function independently as an AU of manual brachytherapy sources for the medical uses authorized in [12VAC5-481-2010](#) .

12VAC5-481-2019. Training for Ophthalmic Use of Strontium-90.

Except as provided in [12VAC5-481-1780](#) , licensees shall require the AU of strontium-90 for ophthalmic radiotherapy to be a physician:

1. Who is an authorized user (AU) under [12VAC5-481-2018](#) or equivalent NRC or other agreement state requirements; or

2. Who has:

a. Completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

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

(4) Radiation biology; and

b. Clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training shall involve:

(1) Examination of each individual to be treated;

(2) Calculation of the dose to be administered;

(3) Administration of the dose; and

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

c. Obtained written attestation, signed by a preceptor AU who meets the requirements in [12VAC5-481-1780](#) , [12VAC5-481-2018](#) , this section, or equivalent NRC or other agreement state requirements, that the individual has satisfactorily completed the requirements in this subdivision 2 and has achieved a level of competency sufficient to function independently as an AU of strontium-90 for ophthalmic use.

12VAC5-481-2020. Use of Sealed Sources for Diagnosis.

Article 8. Sealed Sources for Diagnosis

Licensees shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

12VAC5-481-2030. Training for Use of Sealed Sources for Diagnosis.

Except as provided by [12VAC5-481-1780](#) , licensees shall require the authorized user of a diagnostic sealed source for use in a device authorized under [12VAC5-481-2020](#) to be a physician, dentist, or podiatrist who:

1. Is certified by a specialty board that has been recognized by the NRC; or
2. Has completed eight hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training shall include:
 - a. Radiation physics and instrumentation;
 - b. Radiation protection;
 - c. Mathematics pertaining to the use and measurement of radioactivity; and
 - d. Radiation biology; and
3. Has completed training in the use of the device for the uses requested.

12VAC5-481-2040. Training Requirements and Use of a Sealed Source in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.

Article 9. Photon Emitting Remote Afterloader Units, Teletherapy Units, and Stereotactic Radiosurgery Units

A. Except as provided in [12VAC5-481-1780](#) , licensees shall require an authorized user (AU) of a sealed source in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units to be a physician:

1. Who is certified by a medical specialty board whose certification process has been recognized by the NRC; or
2. Who has:
 - a. Completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:
 - (1) 200 hours of classroom and laboratory training in the following areas: radiation physics and instrumentation; radiation protection; mathematics pertaining to the use and measurement of radioactivity; and radiation biology; and
 - (2) 500 hours of work experience, under the supervision of an AU who meets the requirements in this section, [12VAC5-481-1780](#) , or equivalent NRC or another

agreement state requirements at a medical institution, involving: reviewing full calibration measurements and periodic spot-checks; preparing treatment plans and calculating treatment doses and times; using administrative controls to prevent a medical event involving the use of radioactive material; implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console; checking and using survey meters; and selecting the proper dose and knowing how it is to be administered; and

b. Completed three years of supervised clinical experience in radiation therapy under an AU who meets the requirements in this section, [12VAC5-481-1780](#), or equivalent NRC or another agreement state requirements as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by this subdivision.

3. Who has obtained written attestation that the individual has satisfactorily completed the requirements in (i) subdivision 1 or 2 of this subsection and (ii) subdivisions 3 and 4 of this subsection and has achieved a level of competency sufficient to function independently as an AU of each type of therapeutic medical unit for which the individual is requesting AU status. The written attestation shall be signed by a preceptor AU who meets the requirements in this subsection, [12VAC5-481-1780](#), or equivalent NRC or another agreement state requirements for an AU for each type of therapeutic medical unit for which the individual is requesting AU status.

4. Who has received training in device operation, safety procedures, and clinical use for the types 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 AU or authorized medical physicist, as appropriate, who is authorized for the types of use for which the individual is seeking authorization.

B. Licensees shall use sealed sources in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

1. As approved in the Sealed Source and Device Registry; or

2. In research in accordance with an active Investigational Device Exemption application accepted by the U.S. Food and Drug Administration provided the requirements of [12VAC5-481-1740](#) are met.

12VAC5-481-2041. Surveys Required.

A. Radiation surveys.

1. In addition to the survey requirements in [12VAC5-481-750](#), licensees shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source in the shielded position do not exceed the levels

stated in the Sealed Source and Device Registry.

2. The licensee shall make the survey required by subdivision 1 of this subsection at installation of a new source and following repairs to the source shielding, the source driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the source.

B. Patient surveys. Before releasing a patient or human research subject from licensee control, a licensee shall survey the patient or human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source has been removed from the patient or human research subject and returned to the safe shielded position.

12VAC5-481-2042. Installation, Maintenance, Adjustment, and Repair.

A. Only a person specifically licensed by the agency, the NRC, or another agreement state shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source shielding, the source driving unit, or other electronic or mechanical components that could expose the source, reduce the shielding around the source, or compromise the radiation safety of the unit or the source.

B. Except for low dose-rate remote afterloader unit, only a person specifically licensed by the agency, the NRC, or another agreement state shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

C. For a low dose-rate remote afterloader unit, only a person specifically licensed by the agency, the NRC, or another agreement state or an authorized medical physicist shall install, replace, relocate, or remove a sealed source contained in the unit.

12VAC5-481-2043. Safety Procedures and Instructions, and Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

A. Safety procedures and instructions.

1. Licensees shall:

- a. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
- b. Permit only individuals approved by the authorized user (AU), the authorized medical physicist (AMP), or the RSO to be present in the treatment room during treatment with sources;
- c. Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and

d. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source in the shielded position, or remove the patient or human research subject from the radiation field with controls from the outside the treatment room. These procedures shall include:

- (1) Instructions for responding to equipment failure and the names of the individuals responsible for implementing corrective actions;
- (2) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
- (3) The names and telephone numbers of the authorized user (AU), the authorized medical physicist (AMP), and the RSO to be contacted if the unit or the console operates abnormally.

2. A copy of the procedures required by subdivision 1 d of this subsection shall be physically located at the unit console.

3. Licensees shall post instructions at the unit console to inform the operator of:

- a. The location of the procedures required by subdivision 1 d of this subsection; and
- b. The names and telephone numbers of the AU, the AMP, and the RSO to be contacted if the unit or console operates abnormally.

4. Licensees shall provide instruction and document initially and at least annually to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:

- a. The procedures identified in subdivision 1 d of this subsection; and
- b. The operating procedures for the unit.

5. Licensees shall ensure that operators, authorized users, and authorized medical physicists participate in drills of the emergency procedures initially and at least annually and document the exercise.

B. Safety procedures for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

1. Licensees shall control access to the treatment room by a door at each entrance.

2. Licensees shall equip each entrance to the treatment room with an electrical interlock system that will:

- a. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
- b. Cause the source to be shielded when an entrance door is opened; and
- c. Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off console is reset at the console.

3. Licensees shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.
4. Except for low-dose remote afterloader units, licensees shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.
5. For licensed activities where sources are placed within the patient's or human research subject's body, licensees shall only conduct treatments that allow for expeditious removal of a decoupled or jammed source.
6. In addition to the requirements specified in subdivisions 1 through 5 of this subsection, licensees shall:
 - a. For medium dose-rate and pulsed dose-rate remote afterloader units, require:
 - (1) An AMP and either an AU or a physician under the supervision of an AU who has been trained to the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the units; and
 - (2) An AMP and either an AU or an individual under the supervision of an AU who has been trained to remove the source applicators in the event of an emergency involving the unit to be immediately available during the continuation of all patient treatments involving the unit.
 - b. For high dose-rate remote afterloader units, require:
 - (1) An AU and an AMP to be physically present during the initiation of all patient treatments involving the unit; and
 - (2) An AMP and either an AU or a physician under the supervision of an AU who has been trained in the operation and emergency response for the unit to be physically present during continuation of all patient treatments involving the unit.
 - c. For gamma stereotactic radiosurgery units, require an AU and an AMP to be physically present throughout all patient treatments involving the unit.
 - d. Notify the RSO, or his designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.
7. Licensees shall have applicable emergency response equipment available near each treatment room to respond to a source that:
 - a. Remains in the unshielded position; or
 - b. Lodges within the patient following completion of the treatment.

12VAC5-481-2044. Dosimetry Equipment.

- A. Except for low dose-rate remote afterloader sources where the source output or activity is

determined by the manufacturer, licensees shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met.

1. The system shall have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration; or
2. The system shall have been calibrated within the previous four years. 18 to 30 months after that calibration, the system shall have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison shall indicate that the calibration factor of the licensee's system had not changed by more than 2.0%. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

B. Licensees shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with subsection A of this section. This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in subsection A of this section.

12VAC5-481-2045. Full Calibration Measurements.

A. Teletherapy units.

1. Licensees authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:
 - a. Before the first medical use of the unit;
 - b. Before medical use under the following conditions:
 - (1) Whenever spot-check measurements indicate that the output differs by more than 5.0% from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - (2) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and
 - (3) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 - c. At intervals not exceeding one year.

2. To satisfy the requirement of subdivision 1 of this subsection, full calibration measurements shall include determination of:

- a. The output within plus or minus 3.0% for the range of field sizes and for the distance or range of distances used for medical use;
- b. The coincidence of the radiation field and the field indicated by the light beam localizing device;
- c. The uniformity of the radiation field and its dependence on the orientation of the useful beam;
- d. Timer accuracy and linearity over the range of use;
- e. On-off error; and
- f. The accuracy of all distance measuring and localization devices in medical use.

3. Licensees shall use the dosimetry system described in [12VAC5-481-2044](#) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subdivision 2 a of this subsection may be made using a dosimetry system that indicates relative dose rates.

4. Licensees shall make full calibration measurements required by subdivision 1 of this subsection in accordance with published protocols accepted by nationally recognized bodies.

5. Licensees shall mathematically correct the outputs determined in subdivision 2 a of this subsection for physical decay for intervals not exceeding one month for cobalt-60, six months for cesium-137, or at intervals consistent with 1.0% decay for all other nuclides.

6. Full calibration measurements required by subdivision 1 of this subsection and physical decay corrections required by subdivision 5 of this subsection shall be performed by the authorized medical physicist (AMP).

B. Remote afterloader units.

1. Licensees authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

- a. Before the first medical use of the unit;
- b. Before medical use under the following conditions:
 - (1) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
 - (2) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly;
- c. At intervals not exceeding one quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days;

and

d. At intervals not exceeding one year for low dose-rate remote afterloader units.

2. To satisfy the requirement of subdivision 1 of this subsection, full calibration measurements shall include, as applicable, determination of:

- a. The output within plus or minus 5.0%;
- b. Source positioning accuracy to within plus or minus 1 millimeter;
- c. Source retraction with backup battery upon power failure;
- d. Length of the source transfer tubes;
- e. Timer accuracy and linearity over the typical range of use;
- f. Length of the applicators; and
- g. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

3. Licensees shall use the dosimetry system described in [12VAC5-481-2044](#) to measure the output.

4. Licensees shall make full calibration measurements required by subdivision 1 of this subsection in accordance with published protocols accepted by nationally recognized bodies.

5. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in subdivision 2 of this subsection, licensees shall perform an autoradiograph of the sources to verify inventory and source arrangement at intervals not exceeding one calendar quarter.

6. For low dose-rate remote afterloader units, licensees may use measurements provided by the source manufacturer that are made in accordance with subdivisions 1 through 5 of this subsection.

7. Licensees shall mathematically correct the outputs determined in subdivision 2 a of this subsection for physical decay at intervals consistent with 1.0% physical decay.

8. Full calibration measurements required by subdivision 1 of this subsection and physical decay corrections required by subdivision 7 of this subsection shall be performed by the AMP.

C. Gamma stereotactic radiosurgery units.

1. Licensees authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

- a. Before the first medical use of the unit;
- b. Before medical use under the following conditions:

(1) Whenever spot-check measurements indicate that the output differs by more than 5.0% from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(2) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(3) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

c. At intervals not exceeding one year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

2. To satisfy the requirement of subdivision 1 of this subsection, full calibration measurements shall include determination of:

a. The output within plus or minus 3.0%;

b. Relative helmet factors;

c. Isocenter coincidence;

d. Timer accuracy and linearity over the range of use;

e. On-off error;

f. Trunnion centricity;

g. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

h. Helmet microswitches;

i. Emergency timing circuits; and

j. Stereotactic frames and localizing devices (trunnions).

3. Licensees shall use the dosimetry system described in [12VAC5-481-2044](#) to measure the output for one set of exposure conditions. The remaining radiation measurements required in subdivision 2 a of this subsection may be made using a dosimetry system that indicates relative dose rates.

4. Licensees shall make full calibration measurements required by subdivision 1 of this subsection in accordance with published protocols accepted by nationally recognized bodies.

5. Licensees shall mathematically correct the outputs determined in subdivision 2 a of this subsection at intervals not exceeding one month for cobalt-60 and at intervals consistent with 1.0% physical decay for all other radionuclides.

6. Full calibration measurements required by subdivision 1 of this subsection and physical

decay corrections required by subdivision 5 of this subsection shall be performed by the AMP.

12VAC5-481-2046. Periodic Spot-Checks.

A. Periodic spot-checks for teletherapy units.

1. Licensees authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

- a. Timer accuracy and timer linearity over the range of use;
- b. On-off error;
- c. The coincidence of the radiation field and the field indicated by the light beam localizing device;
- d. The accuracy of all distance measuring and localization devices used for medical use;
- e. The output for one typical set of operating conditions measured with the dosimetry system described in [12VAC5-481-2044](#); and
- f. The difference between the measurement made in subdivision 1 e of this subsection and the anticipated output, expressed as a percentage of the anticipated output (i.e. the value obtained at last full calibration corrected mathematically for physical decay).

2. Licensees shall perform measurements required by subdivision 1 of this subsection in accordance with written procedures established by the authorized medical physicist (AMP). That individual need not actually perform the spot-check measurements.

3. Licensees shall have the AMP review the results of each spot-check within 15 days. The shall notify the licensee as soon as possible in writing of the results of each spot-check.

4. Licensees authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

- a. Electrical interlocks at each teletherapy room entrance;
- b. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam on-off mechanism);
- c. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
- d. Viewing and intercom systems;
- e. Treatment room doors from inside and outside the treatment room; and
- f. Electrically assisted treatment room doors with the teletherapy unit electrical power

turned off.

5. If the results of the checks required in subdivision 4 of this subsection indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

B. Periodic spot-checks for remote afterloader units.

1. Licensees authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

a. Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day;

b. Before each patient treatment with a low dose-rate remote afterloader unit; and

c. After each source installation.

2. Licensees shall perform the measurements required by subdivision 1 of this subsection in accordance with written procedures established by the AMP. That individual need not actually perform the spot-check measurements.

3. Licensees shall have the authorized medical physicist review the results of each spot-check within 15 days. The AMP shall notify the licensee as soon as possible in writing of the results of each spot-check.

4. To satisfy the requirements of subdivision 1 of this subsection, spot-checks shall, at a minimum, assure proper operation of:

a. Electrical interlocks at each remote afterloader unit room entrance;

b. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

c. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

d. Emergency response equipment;

e. Radiation monitors used to indicate the source position;

f. Timer accuracy;

g. Clock (date and time) in the unit's computer; and

h. Decayed sources activity in the unit's computer.

5. If the results of the checks required in subdivision 4 of this subsection indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

C. Periodic spot-checks for gamma stereotactic radiosurgery units.

1. Licensees authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

- a. Monthly;
- b. Before the first use of the unit on a given day; and
- c. After each source installation.

2. Licensees shall:

- a. Perform the measurements required by subdivision 1 of this subsection in accordance with written procedures established by the AMP. That individual need not actually perform the spot-check measurements.
- b. Have the AMP review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

3. To satisfy the requirements of subdivision 1 a of this subsection, spot-checks shall, at a minimum:

a. Assure proper operation of:

- (1) Treatment table retraction mechanisms, using backup battery power or hydraulic backups with the unit off;
- (2) Helmet microswitches;
- (3) Emergency timing circuits; and
- (4) Stereotactic frames and localizing devices (trunnions).

b. Determine the following:

- (1) The output for one typical set of operating conditions measured with the dosimetry system described in [12VAC5-481-2044](#) ;
- (2) The difference between the measurement made in subdivision 3 b (1) of this subsection and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);
- (3) Source output against computer calculation;
- (4) Timer accuracy and linearity over the range of use;
- (5) On-off error; and
- (6) Trunnion centricity.

4. To satisfy the requirements of subdivisions 1 b and 1 c of this subsection, spot-checks

shall assure proper operation of:

- a. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
- b. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
- c. Viewing and intercom systems;
- d. Timer termination;
- e. Radiation monitors used to indicate room exposures; and
- f. Emergency off buttons.

5. A licensee shall arrange for the repair of any system identified in subdivision 3 of this subsection that is not operating properly as soon as possible.

6. If the results of the checks required in subdivision 4 of this subsection indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

12VAC5-481-2047. Additional Technical Requirements for Mobile Remote Afterloader Units.

A. Licensees providing mobile remote afterloader service shall:

1. Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and
2. Account for all sources before departure from a client's address of use.

B. In addition to the periodic spot-checks required by [12VAC5-481-2046](#), licensees authorized to use a mobile remote afterloader for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks shall be made to verify the operation of:

1. Electrical interlocks on treatment area access points;
2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
3. Viewing and intercom systems;
4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;
5. Radiation monitors used to indicate room exposures;
6. Source positioning (accuracy); and
7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

C. In addition to the requirements for checks in subsection B of this section, licensees shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

D. If the results of the checks required in subsection B of this section indicate the malfunction of any system, licensees shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

12VAC5-481-2048. Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

A. Licensees shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

B. This inspection and servicing may only be performed by person specifically licensed to do so by the agency, the NRC, or another agreement state.

12VAC5-481-2049. Therapy-Related Computer Systems.

Licensees shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing shall include, as applicable, verification of:

1. The source-specific input parameters required by the dose calculation algorithm;
2. The accuracy of dose, dwell time, and treatment time calculations at representative points;
3. The accuracy of isodose plots and graphic displays;
4. The accuracy of the software used to determine sealed source positions from radiographic images; and
5. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

12VAC5-481-2050. (Repealed.)

Article 10. Training and Experience Requirements

12VAC5-481-2060. Other Medical Uses of Radioactive Material or Radiation from Radioactive Materials.

Article 11. Other Medical Uses of Byproduct Material or Radiation from Byproduct Material

Licensees may use radioactive material or a radiation source approved for medical use that is not specifically addressed in Articles 3 ([12VAC5-481-1700](#) et seq.) through 9 ([12VAC5-481-](#)

[2040](#) et seq.) of this part if:

1. The applicant or licensee has submitted the information required by [12VAC5-481-1680](#); and
2. The applicant or licensee has received written approval from the agency in a license or license amendment and uses the material in accordance with this chapter and specific conditions the agency considers necessary for the medical use of the material.

12VAC5-481-2070. Records.

Article 12. Records

A. Records of authority and responsibilities for radiation protection programs.

1. Licensees shall retain a record of actions taken by the licensee's management in accordance with [12VAC5-481-1700](#) for five years. The record shall include a summary of the actions taken and a signature of licensee management.
2. Licensees shall retain a copy of both authority, duties, and responsibilities of the RSO as required by [12VAC5-481-1700](#) and a signed copy of each RSO's agreement to be responsible for implementing the radiation safety program, as required by [12VAC5-481-1700](#), for the duration of the license. The records shall include the signature of the RSO and licensee management.

B. Records of radiation protection program changes. Licensees shall retain a record of each radiation protection program change made in accordance with [12VAC5-481-1700](#) F for five years. The record shall include a copy of the old and new procedures, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

C. Records of written directives. Licensees shall retain a copy of each written directive as required by [12VAC5-481-1720](#) for three years.

D. Records for procedures for administrations requiring written directive. Licensees shall retain a copy of the procedures required by [12VAC5-481-1730](#) for the duration of the license.

E. Records of dosages of unsealed radioactive material for medical use. Licensees shall maintain a record of dosage determinations required by [12VAC5-481-1820](#) for three years. The record shall contain the radiopharmaceutical; the patient's or human research subject's name or identification number if one has been assigned; the prescribed dosage, the determined dosage, or a notation that the total activity is less than 30 μCi (1.1 MBq); the date and time of dosage determination; and the name of the individual who determined the dosage.

F. Records of leak tests and inventory of sealed sources and brachytherapy sources.

1. Licensees shall retain records of leak tests required by [12VAC5-481-1840](#) for three years. The records shall include the model number, and the serial number, if one has been assigned, of each source tested; the identity of each source by radionuclide and its

estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

2. Licensees shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by [12VAC5-481-1840](#) for three years. The inventory records shall contain the model number of each source, and serial number of each source if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

G. Records of surveys for ambient radiation exposure rate. Licensees shall retain a record of each survey required by [12VAC5-481-1860](#) for three years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

H. Records of the release of individuals containing unsealed radioactive material or implants containing radioactive material.

1. Licensees shall retain a record signed by the authorized user of the basis for authorizing the release of an individual in accordance with [12VAC5-481-1870](#) for three years after the date of release if the total effective dose equivalent is calculated by:

- a. Using the retained activity rather than the activity administered;
- b. Using an occupancy factor less than 0.25 at 1 meter;
- c. Using the biological or effective half-life; or
- d. Considering the shielding by tissue.

2. Licensees shall retain a record for three years after the date of release of the instruction required by [12VAC5-481-1870](#) that were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 500 mrem (5 mSv).

I. Records of mobile medical services.

1. Licensees shall retain a copy of each letter that permits the use of radioactive material at the client's address, as required by [12VAC5-481-1880](#). Each letter shall clearly delineate the authority and responsibility of the licensee and the client and shall be retained for three years after the last provision of service.

2. Licensees shall retain the record of each survey required by [12VAC5-481-1880](#) for three years. The record shall include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

J. Records of decay-in-storage. Licensees shall maintain records of the disposal of licensed materials, as required by [12VAC5-481-1890](#) for three years. The record shall include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who

performed the survey.

K. Records of molybdenum-99, strontium-82 and strontium-85 concentrations. Licensee shall maintain a record of molybdenum-99 concentration or strontium-82 and strontium-85 concentration tests required by [12VAC5-481-1930](#) for three years. The record shall include:

1. For each measured elution of technetium-99m, the ratio of measures expressed as microcuries of molybdenum-99 per millicurie of technetium-99m or kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m, the time and date of the measurement, and the name of the individual who made the measurement; or
2. For each measured elution of rubidium-82, the ratio of the measures expressed as microcurie of strontium-82 per millicurie of rubidium-82 or kilobecquerel of strontium-82 per megabecquerel of rubidium-82, microcurie of strontium-85 per millicurie of rubidium-82 or kilobecquerel of strontium-85 per megabecquerel of rubidium-82, the time and date of the measurement, and the name of the individual who made the measurement.

L. Records of safety instruction. Licensees shall maintain a record of safety instructions and training required by [12VAC5-481-1960](#) and [12VAC5-481-1970](#) for three years. Each record shall include a list of topics covered, the date of the instruction or training, the names of the attendees, and the names of the individuals who provided the instruction.

M. Records of surveys after source implant and removal. Licensees shall maintain a record of the surveys required by [12VAC5-481-2011](#) and [12VAC5-481-2041](#) for three years. Each record shall include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

N. Records of brachytherapy source accountability.

1. Licensee shall maintain a record of brachytherapy source accountability required by [12VAC5-481-2012](#) for three years.
2. For temporary implants, the record shall include the number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use and the number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.
3. For permanent implants, the record shall include the number and activity of sources removed from storage, the date they were removed from storage, the name of the individual who removed them from storage, the number and activity of sources not implanted, the date they were returned to storage, the name of the individual who returned them to storage, and the number and activity of sources permanently implanted in the patient or human research subject.

O. Records of calibration measurements of brachytherapy sources. Licensees shall maintain a record of the calibrations of brachytherapy sources required by [12VAC5-481-2015](#) for three years after the last use of the source. The record shall include the date of the calibration; the manufacturer's name, model number and serial number for the source and the instruments

used to calibrate the source; the source output or activity; the source positioning accuracy within the applicators; and the name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

P. Records of decay of strontium-90 sources for ophthalmic treatments. Licensees shall maintain a record of the activity of a strontium-90 source required by [12VAC5-481-2016](#) for the life of the source. The record shall include the date and initial activity of the source as determined under [12VAC5-481-2016](#), and for each decay calculation, the date and the source activity as determined under [12VAC5-481-2016](#) and the signature of the authorized medical physicist.

Q. Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Licensees shall retain a record of the installation, adjustment, maintenance, and repair of remote afterloaders units, teletherapy units, and gamma stereotactic radiosurgery units as required by [12VAC5-481-2042](#) for three years. For each installation, adjustment, maintenance, and repair, the record shall include the date, description of the service, and names of the individuals who performed the work.

R. Records of safety procedures. Licensees shall retain a copy of the procedures required by [12VAC5-481-2043](#) until the licensee no longer possesses the remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

S. Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. Licensees shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with [12VAC5-481-2044](#) for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date; the manufacturer's name, model numbers, and serial numbers of the instruments that were calibrated, intercompared, or compared as required by [12VAC5-481-2044](#); the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and the names of the individuals who performed the calibration, intercomparison, or comparison.

T. Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. Licensees shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by [12VAC5-481-2045](#) for three years. The record shall include the date of calibration; the manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit, the source, and the instruments used to calibrate the unit; the results and an assessment of the full calibrations; the results of the autoradiograph required for low dose-rate remote afterloader units; and the signature of the authorized medical physicist who performed the full calibration.

U. Records of periodic spot-checks for teletherapy units, remote afterloader units, and gamma stereotactic radiosurgery units.

1. Licensees shall retain a record of each periodic spot-check for teletherapy units, remote

afterloader units, and gamma stereotactic radiosurgery units required by [12VAC5-481-2046](#) for three years. The record shall include:

a. For each teletherapy unit; the date of the spot-check, the manufacturer's name, model number, and serial number, source, and instrument used to measure the output of the teletherapy unit; an assessment of timer linearity and constancy; the calculated on-off error; a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; the determined accuracy of each distance measuring and localization device; the difference between the anticipated output and the measured output; notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the record of the spot-check.

b. For each remote afterloader unit: the date of the spot-check, the manufacturer's name, model and serial number for the remote afterloader unit and source; an assessment of timer accuracy; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the record of the spot-check.

c. For each gamma stereotactic radiosurgery unit: the date of the spot-check, the manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit; an assessment of timer linearity and accuracy; the calculated on-off error; a determination of trunnion centricity; the difference between the anticipated output and the measured output; an assessment of source output against computer calculations; notations indicating the operability of radiation monitors; helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems; timer termination, treatment table retraction mechanism, and stereotactic frames and localizing device (trunnions); the name of the individual who performed the periodic spot-check; and the signature of the authorized medical physicist who reviewed the record of the spot-check.

2. Licensees shall retain a copy of the procedures required by [12VAC5-481-2046](#) A 2, [12VAC5-481-2046](#) B, and [12VAC5-481-2046](#) C 2 until the licensee no longer possesses the teletherapy unit, remote afterloader unit, or gamma stereotactic radiosurgery unit.

V. Records of additional technical requirements for mobile remote afterloader units.

Licensees shall retain a record of each check for mobile remote afterloader units required by [12VAC5-481-2047](#) for three years. The record shall include the date of the check, the manufacturer's name, model number, and serial number of the remote afterloader unit; notations accounting for all sources before the licensee departs from a facility; notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer

tubes, and transfer tube applicator interfaces; source positioning accuracy; and the signature of the individual who performed the check.

W. Records of surveys of therapeutic treatment units. Licensees shall maintain a record of radiation surveys of treatment units made in accordance with [12VAC5-481-2041](#) for the duration of use of the unit. The record shall include the date of the measurements, the manufacturer's name, model number, and serial number of the treatment unit; source and instrument used to measure radiation levels; each dose rate measured around the source while the unit is in the off position and the average of all measurements; and the signature of the individual who performed the test.

X. Records of five-year inspection for teletherapy and gamma stereotactic radiosurgery units. Licensees shall maintain a record of the five-year inspections for teletherapy and gamma stereotactic radiosurgery required by [12VAC5-481-2048](#) for the duration of use of the unit. The record shall include the inspector's radioactive materials license number, the date of inspection, the manufacturer's name, model number, and serial number of both the treatment unit and source, a list of components inspected and serviced, the type of service, and the signature of the inspector.

12VAC5-481-2080. Reports.

Article 13. Reports

A. Report and notification of a medical event.

1. Licensees shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material results in:

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

(1) The total dose delivered differs from the prescribed dose by 20% or more;

(2) The total dosage delivered differs from the prescribed dosage by 20% 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% or more.

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

(1) An administration of a wrong radioactive drug containing radioactive material;

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

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

3. Licensees shall notify the agency by telephone no later than the next calendar day after discovery of the medical event.

4. By an appropriate method listed in [12VAC5-481-150](#), licensees shall submit a written report to the agency within 15 days after discovery of the medical event.

a. The written report shall include:

(1) The licensee'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 individuals who received the administration;

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

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

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

5. Licensees shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. Licensees are 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, licensees shall notify the individual as soon as possible thereafter.

Licensees may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this subdivision, the notification of the

individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, licensees 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. Licensees shall provide such a written description if requested.

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

7. Licensees shall:

a. Annotate a copy of the report provided to the agency with the:

(1) Name of the individual who is the subject of the event; and

(2) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

b. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

B. Report and notification of a dose to an embryo/fetus or a nursing child.

1. Licensees shall report any dose to an embryo/fetus that is greater than 500 mrem (5 mSv) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

2. Licensees shall report any dose to a nursing child that is a result of an administration of radioactive material to a breast-feeding individual that:

a. Is greater than 5 mSv (500 rem) total effective dose equivalent; or

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

3. Licensees shall notify the agency by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in accordance with subdivision 1 or 2 in this subsection.

4. By an appropriate method listed in [12VAC5-481-150](#), licensees shall submit a written report to the agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in subdivision 1 or 2 of this subsection.

a. The written report shall include

(1) The licensee's name;

(2) The name of the prescribing physician;

(3) A brief description of the event;

- (4) Why the event occurred;
- (5) The effect, if any, on the embryo/fetus or the nursing child;
- (6) What actions, if any, have been taken or are planned to prevent recurrence; and
- (7) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

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

5. Licensees shall provide notification of the event to the referring physician and also notify the pregnant individual or mother, both hereafter referred to as "mother," no later than 24 hours after discovery of an event that would require reporting under subdivisions 1 or 2 of this subsection, unless the referring physician personally informs the licensee either that the mother will be informed or that, based on medical judgment, telling the mother would be harmful. Licensees are not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, licensees shall make the appropriate notifications as soon as possible thereafter. Licensees may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subdivision, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, licensees shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. Licensees shall provide such a written description if requested.

6. Licensees shall:

a. Annotate a copy of the report provided to the agency with the:

(1) Name of the pregnant individual or the nursing child who is the subject of the event; and

(2) Social security number or other identification number, if one has been assigned, of the pregnant individual or the nursing child who is the subject of the event; and

b. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

C. Report of a leaking source.

1. Licensees shall file a report within five days if a leak test required by [12VAC5-481-1840](#) reveals the presence of 0.005 μCi (185 Bq) or more of removable contamination.

2. The report shall be filed with the agency by an appropriate method listed in [12VAC5-481-150](#). The written report shall include:

a. The model number and serial number, if assigned, of the leaking source;

- b. The radionuclide and its estimated activity;
- c. The results of the test;
- d. The date of the test; and
- e. The action taken.