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

Part VII. Use of Radionuclides in the Healing Arts

Article 1. Purpose and Scope

12VAC5-481-1660. 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.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006.

Article 2. General Information

12VAC5-481-1670. General requirements.

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 12VAC5-481-204 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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 otherwis in the public interest.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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, an ophthalmic physicist, 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, an associate radiation safety officer, an ophthalmi physicist, 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

Article 3. General Administrative Requirements

12VAC5-481-1700. Authority and responsibilities for the radiation protection programs and changes.

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.

The licensee, through the RSO, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more associate radiation safety officers to support the RSO. The RSO, with written agreement of the licensee's management, must assign the specific duties and tasks to each associate RSO. These duties and tasks are restricted to the types of use for which the associate radiation safety officer is listed on a license. The RSO may delegate duties and tasks to the associate radiation safety officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

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.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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;

6. For permanent implant brachytherapy:

a. Before implantation: treatment site, the radionuclide, and the total source strength; and

b. After implantation but before the patient leaves the post-treatment recovery area: treatment site, number of sources implanted, total source strength implanted, and the date; or

7. 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) and date.

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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

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. A licensee shall retain a copy of the procedures required by this section in accordance with 12VAC5-481-2070. 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;

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 C and 12VAC5-481-2060;

5. Determining if a medical event, as defined in 12VAC5-481-2080, has occurred; and

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

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-1750. Training for radiation safety officer and associate radiation safety officer.

Except as provided in 12VAC5-481-1780, licensees shall require an individual fulfilling the responsibilities of the radiation safety officer (RSO) or an individual assigned duties and tasks as an associate radiation safety officer as provided in 12VAC5-481-1700 to be an individual who:

1. Is certified by a specialty board who has been recognized by the agency, the NRC, or an agreement state and who meets the requirements of subdivision 5 of this section. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to (i) hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science; (ii) have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of th required experience) including at least three years in applied health physics; and (iii) pass an examination administered by diplomate of the specialty board that evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

2. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from a accredited college or university; has two years of full-time practical training or supervised experience in medical physics (i) under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the agency, NRC, or an agreement state or (ii) in clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in 12VAC5-481-1780, 12VAC5-481-1940, or 12VAC5-481-1980; and has passed an examination administered by diplomates of the specialty board that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

3. 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;

(4) Radiation biology; and

(5) 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 an NRC master material licensee that authorizes similar types of uses of radioactive material. An associate radiation safety officer may provide supervision for those areas for which the associate radiation safety officer is

authorized on an agency, NRC, or another agreement state license or permit issued by an NRC master material licensee. The full-time radiation safety experience must involve 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; and

c. This individual must obtain a written attestation signed by a preceptor radiation safety officer or associate radiation safety officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a radiation safety officer or an associate radiation safety officer. The written attestation must state that the individual has satisfactorily completed the requirements in subdivisions 3 a, 3 b, and 5 of this section and is able to independently fulfill the radiation safety-related duties as a radiation safety officer or has an associate radiation safety officer for a medical use licensee; or

4. 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 agency, NRC or an agreement state under subdivision 1 of 12VAC5-481-1760 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 or an associate radiation safety officer and who meets the requirements in subdivision 5 of this section; or

b. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist (i) identified on an agency, NRC, or another agreement state license; a permit issued by a NRC master material licensee; a permit issued by an agency, NRC, or another agreement state board scope licensee; or a permit issued by a NRC master material license board scope permittee; (ii) has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has RSO or associate radiation safety officer responsibilities; and (iii) meets subdivision 5 of this section; or

c. Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as a radiation safety officer and the authorized user on the same new medical use license or new medical use permit issued by a NRC master material license. The individual must also meet the requirements in subdivision 5 of this section.

5. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a RSO, an associate radiation safety officer, 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

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 agency, NRC, or an agreement state and who meets the requirements of subdivision 3 of this section. The name of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

b. Have two years of full-time practical training or supervised experience in medical physics (i) under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the agency, the NRC, or an agreement state; or (ii) in clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in 12VAC5-481-1780, 12VAC5-481-2018, or 12VAC5-481- 2040; and

c. Pass an examination, administered by diplomates of the specialty board that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

2. 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 th agency, the NRC, or another Agreement state and has completed one year of full-time training in medical physics and an additional yea 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 completin either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type 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 2 and 3 of this section; and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation shall be signed by a preceptor authorized medical physicist who meets the requirements in 12VAC5-481-1760, 12VAC5-481-1780, or equivalent NRC or agreement state requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022; Errata, 38:10 VA.R. 902 January 3, 2022.

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, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

b. Hold a current, active license to practice pharmacy;

c. Provide evidence of having acquired at least 4000 hours of training or experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

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

2. 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 2 of this section and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

12VAC5-481-1780. Training for experienced radiation safety officer, teletherapy or medical physicist, authorized medical physicist, nuclear pharmacist, authorized nuclear pharmacist, and authorized user.

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

1. An individual identified on an agency, NRC, or agreement state 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 as a RSO, a teletherapy or medical physicist, AMP, a nuclear pharmacist, or an ANP on or before January 14, 2019, need not comply with the training requirements of 12VAC5-481-1750, 12VAC5-481-1760, or 12VAC5-481-1770, respectively, except the RSO and AMP identified in this subdivision must meet the training requirements in subdivision 5 of 12VAC5-481-1750 or subdivision 3 of 12VAC5-481-1760, as appropriate, for any material or uses for which they were not authorized prior to this date.

2. An individual certified by the American Board of Health Physics in Comprehensive Health Physics, American Board of Radiology, American Board of Nuclear Medicine, American Board of Science in Nuclear Medicine, Board of Pharmaceutical Specialties in Nuclear

Pharmacy, American Board of Medical Physics in Radiation Oncology Physics, Royal College of Physicians and Surgeons of Canada in Nuclear Medicine, American Osteopathic Board of Radiology, or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of 12VAC5-481-1750 to be identified as an RSO or as an associate RSO on an agency, NRC, or another agreement state license or NRC master material permit for those materials and uses that these individuals performed on or before October 24, 2005. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in 12VAC5-481-1760 for those materials and uses that these individuals performed on or before October 24, 2005.

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 on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of 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 license broad scope permittee on or before October 24, 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 for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

a. For uses authorized under 12VAC5-481-1900 or 12VAC5-481-1920, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the

American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

b. For uses authorized under 12VAC5-481-1950, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

c. For uses authorized under 12VAC5-481-2010 or 12VAC5-481-2040, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

d. For uses authorized under 12VAC5-481-2020, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

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 requirement 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.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

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.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

Article 4. General Technical Requirements

12VAC5-481-1800. Possession, use, and calibration of instruments used to measure the activity of unsealed radioactive material.

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.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-1810. (Repealed.)

Statutory Authority

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; repealed, Virginia Register Volume 32, Issue 24, eff. August 25, 2016.

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%.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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 o 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 µCi) or 1000 times the quantities in 12VAC5-481-3730.

5. Technetium-99m in amounts as needed.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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 supplied 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 µCi (185 Bq) of radioactive material in the sample.

D. If the leak test reveals the presence of 0.005 µCi (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 µCi (3.7 MBq) or less of beta or gamma-emitting material;

4. Containing 10 µCi (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 conduc a semi-annual physical inventory of all such sources in its possession.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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 materia 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.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

Article 5. Unsealed Byproduct Material – Written Directive Not Required

12VAC5-481-1900. Use of unsealed radioactive material for uptake, dilution, and excretion 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 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.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

a. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in subdivisions 3 a (1) through 3 a (2) (f) of this section; and

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

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 that the individual has satisfactorily completed the requirements in subdivision 3 a of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 12VAC-481-1900. The attestation must be obtained from either:

(1) 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; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1940, or 12VAC5-481-1980 or equivalent NRC or other agreement state requirements and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subdivision 3 a of this section.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

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.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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. A licensee that uses molybdenum-99/technetium-99m for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with subsection A of this section.

C. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-82 to demonstrate compliance with subsection A of this section.

D. If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-82 concentrations, the license shall retain a record of each measurement in accordance with 12VAC5-481-2070 K.

E. The licensee shall report any measurement that exceeds the limits in subsection A of this section at the time of generator elution in accordance with 12VAC5-481-2080 D.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

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, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

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. An authorized nuclear pharmacist who meets the requirements of 12VAC5-481-1770 or 12VAC5-481-1780 may provide the supervised work experience in subdivision 3 a (2) (g) of this section. Work experience must involve:

(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 that the individual has satisfactorily completed the requirements in subdivision 3 a of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 12VAC5-

481-1900 and 12VAC5-481-1920. The attestation must be obtained from either:

(1) A preceptor 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; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this section, 12VAC5-481-1780, or 12VAC5-481-1980 and subdivision 3 a (2) (g), or equivalent NRC or other agreement state requirements and concurs with the attestation provided by the residency program director. The residency training must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specific in subdivision 3 a of this section.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

Article 6. Unsealed Byproduct Material - Written Directive Required

12VAC5-481-1950. Use of unsealed radioactive material for which a written directive is required.
Licensees may use any unsealed radioactive material identified in subdivision 2 b (7) of 12VAC5-481-1980 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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, the agency, or an agreement state and who meets the requirements in subdivision 2 b (7) of this section. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page; 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 o 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 from the three categories in this subdivision 2 b (7). Radioactive drugs containing radionuclides in categories not included in this subdivision are regulated under 12VAC5-481-2060.Thi work experience must involve a minimum of three cases in each of the following categories (experience with at least three cases in subdivision 2 b (7) (b) of this section also satisfies the requirements of subdivision 2 b (7) (a) of this section) for which the individual is requesting authorized user status.

(a) 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;

(b) Oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131;

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

3. Who has obtained written attestation that the individual has satisfactorily completed the requirements in subdivision 2 b of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 12VAC5-481-1950. The written attestation shall be obtained from either:

a. A preceptor AU who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements and has experience in administering dosages in the same dosage category (i.e., subdivision 2 b (7) of this section) as the individual requesting authorized user status; or

b. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements; has experience in administering dosages in the same dosage category as the individual requesting the authorized user status; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include the training and experience specified in subdivision 2 b of this section.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022; Errata, 38:10 VA.R. 902 January 3, 2022.

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 includes all of the requirements of subdivision 3 of this section and has been recognized by the NRC, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Licensee Toolkit Web page; or

2. Who is an AU under 12VAC5-481-1980 for uses listed in subdivision 2 b (7) (a) and (b) 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) (a) or subdivision 2 b (7) (b) 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 subdivision 3 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to

1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 12VAC5-481-1950. The attestation mus be obtained from either:

a. A preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, 12VAC5-481-2000, or equivalent NRC or other agreement state requirements and has experience in administering dosages as specified in subdivision 2 b (7) (a) or (b) of 12VAC5-481-1980; or

b. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, 12VAC5-481-2000, or equivalent NRC or other agreement state requirements, has experience in administering dosages as specifie in 12VAC5-481-1980 2 b (7) (a) or (b), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education o the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subdivision 3 of this section.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

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 process includes all of the requirements in subdivision 3 of this section and has been recognized by the NRC, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

2. Who is an AU under 12VAC5-481-1980 for uses listed in subdivision 2 b (7) (b) 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, 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) (b) 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 subdivision 3 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under 12VAC5-481-1950. The written attestation must be obtained by either:

(1) A preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, 12VAC5-481-1980, or equivalent NRC or other Agreement state requirements and has experience in administering dosages as specified in subdivision 2 b (7) (b) of 12VAC5-481-

1980; or

(2) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this section, 12VAC5-481-1780, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements; has experience in administering dosages as specified in 12VAC5-481-1980 2 b (7) (b); and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience as specified in this subdivision 3.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

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) (c) of 12VAC5-481-1980 or equivalent NRC or other Agreement state requirements; or

2. Who is an AU under 12VAC5-481-2018, 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, the agency, or an agreement state under 12VAC5-481-2018 or 12VAC5-481-2040 and who meets the requirements in subdivision 4 of this section;

4. Who has:

a. Completed 80 hours of classroom and laboratory training applicable to parenteral administrations. 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, o equivalent NRC or other Agreement state requirements in the parenteral administration listed in 12VAC5-481-1980 2 b (7) (c). A supervising AU who meets the requirements in this section, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements shall have experience in administering dosages in the same category 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; and

(6) Administering dosages to patients or human research subjects that include at least three cases of the parenteral administration as specified in 12VAC5-481-1980 2 b (7) (c); and

5. Obtained a written attestation that the individual has satisfactorily completed the requirements in subdivision 4 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation shall be obtained from either:

a. 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 this section, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements shall have experience in administering dosages in the same category as the individual requesting authorized user status; or

b. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of this section, 12VAC5-481-1780, 12VAC5-481-1980, or equivalent NRC or other agreement state requirements; has experience in administering dosages in the same dosage categor

as the individual requesting authorized user status; and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council of Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subdivision 4 of this section.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 24, Issue 18, eff. June 12, 2008; amended, Virginia Register Volume 32, Issue 24, eff. August 25, 2016; Errata 37:14 VA.R. 2151 March 1, 2021; Volume 37, Issue 25, eff. January 14, 2022; Erata 38:11 VA.R. 902 January 3, 2022.

Article 7. Manual Brachytherapy

12VAC5-481-2010. Use of sources for manual brachytherapy.

Licensees shall use only brachytherapy sources:

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

2. In research to deliver therapeutic doses for medical use 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

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 accoun 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016.

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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016.

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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016.

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, licensee 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016.

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 thi 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2016. Strontium-90 sources for ophthalmic treatments.

A. Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in subsection B of this section are performed by either:

1. An authorized medical physicist; or

2. An individual who:

a. Is identified as on ophthalmic physicist on a specific medical use license issued the agency, NRC, or another agreement state; permit issued by an agency, NRC, or another agreement state broad scope licensee; medical use permit issued by a NRC master material licensee; or permit issued by a NRC master material broad scope medical use permittee;

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

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

d. Has documented training in the following:

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

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

(3) Performing the calibration measurements of brachytherapy sources as detailed in 12VAC5-481-2015.

B. The individuals who are identified in subsection A of this section must:

1. Calculate the activity of each strontium-90 sources that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 12VAC5-481-2015; and

2. Assist the licensee in developing, implementing, and maintaining written procedures to provide a high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in subsection A of this section will observe treatments, review the treatment methodology, calculate treatment time for prescribed dose, and review records to verify that the administrations were in accordance with the written directive.

C. Licensees must retain a record of the activity of each strontium-90 source in accordance with 12VAC5-481-2070 P.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016; amended, Virginia Register Volume 37, Issue 25, eff. January 14, 2022; Errata, 38:10 VA.R. 902 January 3, 2022.

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.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016.

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 authorize 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, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

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

2. Who has:

a. Completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherap 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 facility authorized to use radioactive material under

12VAC5-481-2010, 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 that the individual has satisfactorily completed the requirements in subdivision 2 of 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. This attestation must be obtained from either:

a. A preceptor authorized user who meets the requirements in this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements; or

b. A residency program director who affirms in writing that the attestation represents the residency program faculty where at least one faculty member is an authorized user who meets the requirement in this section, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specific in subsection 2 of this section.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016; amended, Virginia Register Volume 37, Issue 25, eff. January 14, 2022.

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 is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016; amended, Virginia Register Volume 37, Issue 25, eff. January 14, 2022.

Article 8. Sealed Sources for Diagnosis

12VAC5-481-2020. Use of sealed sources for diagnosis.

A. Licensees shall use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

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

C. Sealed sources and devices for diagnostic medical uses may be used 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

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 whose certification process includes all of the requirements in subdivisions 3 and 4 of this section and whose certification has been recognized by the NRC, the agency, or an agreement state. The names of board certifications that have been recognized by the NRC or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

2. Is an authorized user for uses listed under 12VAC5-481-1920 or equivalent NRC or other agreement state requirements; or

3. 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

4. Has completed training in the use of the device for the uses requested.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

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

12VAC5-481-2040. Training requirements and use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

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, the agency, or an agreement state and who meets the requirements in subdivision 4 of this section. The names of board certifications that have been recognized by the agency, NRC, or an agreement state are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

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

b. Pass an examination administered by diplomates of the specialty board that tests knowledge and competence radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and

external beam therapy; 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 that is authorized for subsections B and C of this section, 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 subdivisions 2 a, 2 b, 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 either:

a. 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; or

b. A residency program director who affirms in writing that the attestation of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in this subsection, 12VAC5-481-1780, or equivalent NRC or other agreement state requirements for the type of therapeutic medical unit for which the individual is requesting authorized user status and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or

the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in subdivisions 2 a and 2 b of this subsection.

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.

C. Licensees shall use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

1. As approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry but must be used in accordance with radiation safety conditions and limitations described 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022; Errata, 38:10 VA.R. 902 January 3, 2022.

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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 24, 2016.

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 remove 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016.

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 th 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 contacte 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. Safety instruction and training.

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

b. Licensees shall provide instruction initially and at least annually to all individuals who operate the unit, as appropriate to the individual's assigned duties, in the procedures identified in subdivision 1 d of this subsection and 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.

6. Licensees shall retain a record of individuals receiving instruction required by subdivision 4 of this subsection in accordance with 12VAC5-481-2070 L.

7. Licensees shall retain a copy of the procedures required by subdivisions 1 d and 4 b of this subsection in accordance with 12VAC5-481-2070 R.

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 irradiatior

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 an 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 th 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016; amended, Virginia Register Volume 37, Issue 25, eff. January 14, 2022.

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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016.

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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016.

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 th 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 AMI 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 soor 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016.

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 mad 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2048. Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.

A. Licensees shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed five years for each teletherapy unit and shall not exceed seven years for each gamma stereotactic radiosurgery unit.

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.

C. Licensees shall keep a record of the inspection and servicing in accordance with 12VAC5-481-2070 X.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016; amended, Virginia Register Volume 37, Issue 25, eff. January 14, 2022.

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 plannin system.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 32, Issue 24, eff. August 25, 2016.

Article 10. Training and Experience Requirements

12VAC5-481-2050. (Repealed.)

Statutory Authority

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; repealed, Virginia Register Volume 24, Issue 18, eff. June 12, 2008.

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

12VAC5-481-2060. Other medical uses of radioactive material or radiation from radioactive materials.
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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

Article 12. Records

12VAC5-481-2070. 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.

3. For each associate radiation safety officer, the licensee shall retain for five years after the associate radiation safety officer is removed from the license, a copy of the written document appointing the associate radiation safety officer signed by licensee's 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 th 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 stontrium-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 and the operational and safety instructions required by 12VAC5-481-2013 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 strontrium-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, eac source exposure indicator light, and the viewing and intercom system and doors; the name of the individual who performed the periodi 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 time linearity and accuracy; the calculated on-off error; a determination of trunnion centricity; the difference between the anticipated outpu 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 full-inspection servicing 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.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

Article 13. Reports

12VAC5-481-2080. Reports.
A. Report and notification of a medical event.

1. Licensees shall report any event as a medical event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, 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 or the wrong radionuclide for a brachytherapy procedure;

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

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

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

(5) A leaking sealed source.

c. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem (0.5 Sv) or more of the dose expected to that site if the administration had been given in accordance with the written directive prepared or revised before administration and 50% or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

2. For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material, excluding sources that were implanted in the correct site but migrated outside the treatment site, that result in the total source strength administered differing by 20% or more from the total source strength documented in the post-implantation portion of the written directive or the total source strength administered outside of the treatment site exceeding 20% of the total source strength documented in the post-implantation of the written directive or an administration involving any of the following: wrong radionuclide the wrong individual or human research subject, sealed sources implanted directly into a location discontiguous from the treatment site as documented in the post-implantation portion of the written directive, or a leaking sealed source resulting in a dose that exceeds 50 rem (0.5 Sv) to an organ or tissue.

3. 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 or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

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

5. 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.

6. 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) Identification number, or if no other identification number is available, the social security number 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) Identification number, or if no other identification number is available, the social security number 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) o 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.

D. Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.

1. Licensees shall notify the agency and the distributor of the generator by telephone within seven calendar days after discovery that an eluate exceeded the permissible concentration listed in 12VAC5-481-1930 A at the time of generator elution. The telephone report to the agency must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the distributor was notified; and the action taken.

2. By an appropriate method listed in 12VAC5-481-150, the licensee shall submit a written report to the agency within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report shall include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; the probable cause and assessment of failure in the licensee's equipment, procedure, or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by subdivision 1 of this subsection.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022.

Part XII. Licensing and Radiation Safety Requirements for Irradiators

Article 1. Purpose and Scope

12VAC5-481-2660. Purpose and scope.

A. This part contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This part also contains radiation safety requirements for operating irradiators. The requirements of this part are in addition to other requirements of this chapter. In particular, the provisions of Parts III (12VAC5-481-380, et seq.), IV (12VAC5-481-600, et seq.), X (12VAC5-481-2250 et seq.), and XIII (12VAC5-481-2950, et seq.) of this chapter apply to applications and licenses subject to this part. Nothing in this part relieves licensees from complying with other applicable federal, state, and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

B. This part applies to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are underwater. Irradiators whose dose rates exceed 500 rad (5 gray) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this part.

C. This part does not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiators.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

Article 2. Specific Licensing Requirements

12VAC5-481-2670. Application for a specific license.

A person, as defined in 12VAC5-481-10, may file an application for a specific license authorizing the use of sealed sources in an irradiator. Each application shall be sent to the agency along with the appropriate fee prescribed in 12VAC5-490.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2680. Specific licenses for irradiators.

A. The agency will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in subsection B of this section and includes the information, as appropriate, from subsections C through I of this section.

B. The applicant shall satisfy the general requirements specified in 12VAC5-481-450 and the requirements contained in this part.

C. The application shall describe the training provided to the irradiator operators including:

1. Classroom training;

2. On-the-job training or simulator training;

3. Safety reviews;

4. Means employed by the applicant to test each operator's understanding of the agency regulations and licensing requirements and the irradiator operating and emergency procedures; and

5. Minimum training and experience of personnel who may provide training.

D. The application shall include the outline of the written operating and emergency procedures listed in the 12VAC5-481-2840 that describes the radiation safety aspects of the procedures.

E. The application shall describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety

responsibilities or authorities. In particular, the application shall specify who, within the management structure, has the authority to stop unsafe operations. The application shall also describe the training and experience required for the position of radiation safety officer.

F. The application shall include a description of the access control systems required by 12VAC5-481-2730, the radiation monitors required by 12VAC5-481-2760, the method of detecting leaking sources required by 12VAC5-481-2870 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

G. If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the agency. The description shall include:

1. Instruments to be used;

2. Methods of performing the analysis; and

3. Pertinent experience of the individual who analyzes the samples.

H. If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading shall be done by an organization specifically licensed by the agency, NRC, or another agreement state to load or unload irradiator sources.

I. The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by 12VAC5-481-2880.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2690. Commencement of construction.

Commencement of construction of a new irradiator may occur prior to the submission to the agency of both an application for a license for the irradiator and the fee required by 12VAC5-490. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license. Commencement of construction, as defined in 12VAC5-481-10, may include non-construction activities if the activity has a reasonable nexus to radiological safety and security.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2700. Applications for exemptions.

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

B. Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements in this part. The agency will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that it is likely to provide an adequate level of safety for workers and the public.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2710. Request for written statements.

A. After the filing of an application, the agency may request further information necessary to enable the agency to determine whether the application shall be granted or denied.

B. Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the agency's request submit written statements to enable the agency to determine whether the license shall be modified, suspended, or revoked.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

Article 3. Design and Performance Requirements for Irradiators

12VAC5-481-2720. Performance criteria for sealed sources.

A. Sealed sources installed after July 1, 1993, shall:

1. Have a certificate of registration issued by the NRC or another agreement state;

2. Be doubly encapsulated;

3. Use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

4. Be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other materia with equivalent resistance if the sources are for use in irradiator pools; and

5. In prototype testing of the sealed source, have been leak tested and found leak-free after each of the tests described in subsections B through G of this section.

B. The test source shall be held at -40°C for 20 minutes, 600°C for one hour, then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

C. The test source shall be twice subjected for at least five minutes to an external pressure (absolute) of 2 million newtons per square meter.

D. A 2-kilogram steel weight (2.5. centimeters in diameter) shall be dropped from a height of 1 meter onto the test source.

E. The test source shall be subjected three times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source shall be vibrated for 30 minutes at each resonant frequency found.

F. A 50-gram weight and a pin (0.3 centimeter pin diameter) shall be dropped from a height of 1 meter onto the test source.

G. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source shall be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2730. Access control.

A. Each entrance to a radiation room at a panoramic irradiator shall have a door or other physical barrier to prevent inadvertent entry o personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It shall not be possible to move the sources out of their shielded position if the door or barrier is open Opening the door or barrier while the sources are exposed shall cause the sources to return promptly to their shielded position. The personnel entrance door or barrier shall have a lock that is operated by the same key used to move the sources. The doors and barriers shall not prevent any individual in the radiation room from leaving.

B. In addition, each entrance to a radiation room at a panoramic irradiator shall have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed shall cause the sources to return to their fully shielded position and shall also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm shall also alert at least one other individual who is onsite of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

C. A radiation monitor shall be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor shall be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, shall activate the alarm described in subsection of this section. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

D. Before the sources move from their shielded position in a panoramic irradiator, the source control shall automatically activate conspicuous visible and audible alarms to alert personnel in the radiation room that the sources will be moved from their shielded position. The alarms shall give individuals enough time to leave the room before the sources leave the shielded position.

E. Each radiation room at a panoramic irradiator shall have a clearly visible and readily accessible control that would allow an individua in the room to make the sources return to their fully shielded position.

F. Each radiation room of a panoramic irradiator shall contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

G. Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of ar underwater irradiator shall be posted as required by 12VAC5-481-860. Radiation postings for panoramic irradiators shall comply with the posting requirements of 12VAC5-481-860, except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

H. If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it shall not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

I. Underwater irradiators shall have a personnel access barrier around the pool which shall be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There shall be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm shall alert an individual (not necessarily on site) who is prepared to respond or summon assistance.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2740. Shielding.

A. The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 2 mrem (0.02 mSv) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate shall be averaged over an area not to exceed 100 square cm having no linear dimension greater than 20 centimeters. Areas where the radiation dose rate exceeds 2 mrem (0.02 mSv) per hour shall be locked, roped off, or posted.

B. The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 2 mrem (0.02 mSv) per hour when the sources are in the fully shielded position.

C. The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator may not exceed 2 mrem (0.02 mSv) per hour and at 5 centimeters from the shield may not exceed 20 mrem (0.2 mSv) per hour.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2750. Fire protection.

A. The radiation room at panoramic irradiator shall have heat and smoke detectors. The detectors shall activate an audible alarm. The alarm shall be capable of alerting a person who is prepared to summon assistance promptly. The sources shall automatically become fully shielded if a fire is detected.

B. The radiation room at a panoramic irradiator shall be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room shall have a shut-off valve to control flooding into unrestricted areas.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2760. Radiation monitors.

A. Irradiators with automatic product conveyor systems shall have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm shall sound and product conveyors shall stop automatically. The alarm shall be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from this requirement.

B. Underwater irradiators that are not in a shielded radiation room shall have a radiation monitor over the pool to detect abnormal radiation levels. The monitor shall have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The alarm shall be capable of alerting an individual who is prepared to respond promptly.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2770. Control of source movement.

A. The mechanism that moves the sources of a panoramic irradiator shall require a key to actuate. Actuation of the mechanism shall cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key shall be attached to a portable radiation survey meter by a chain or cable. The lock for source control shall be designed so that the key may not be removed if the sources are in an unshielded position. The door to th radiation room shall require the same key.

B. The console of a panoramic irradiator shall have source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

C. The control console of a panoramic irradiator shall have a control that promptly returns the sources to the shielded position.

D. Each control for a panoramic irradiator shall be clearly marked as to its function.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2780. Irradiator pools.

A. For licenses initially issued after July 1, 1993, irradiator pools shall have a method to safely store the sources during repairs of the pool and either:

1. Have a watertight stainless steel liner or a liner metallurgically compatible with other components in the pools; or

2. Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination.

B. For licenses initially issued after July 1, 1993, irradiator pools shall have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons shall have siphon breakers to prevent siphoning of pool water.

C. A means shall be provided to replenish water losses from the pool.

D. A visible indicator shall be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

E. Irradiator pools shall be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

F. A physical barrier, such as a railing or cover, shall be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

G. If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 2 mrem (0.02 mSv) per hour.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2790. Source rack protection.

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack shall be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2800. Power failures.

A. If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources shall automatically return to the shielded position.

B. The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

C. During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2810. Design requirements.

A. For all irradiators, licensees shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by 12VAC5-481-2760 A. Licensees shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person.

B. For panoramic irradiators:

1. Licensees shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entrance ways to meet the radiation shielding requirements of 12VAC5-481-2740. If the irradiator will use more than 5 million curies (2×10^{17} Bq) of activity, licensees shall evaluate the effects of heating of the shielding walls by the irradiator sources.

2. Licensees shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

3. Licensees shall verify from the design and logic diagram that the access control system will meet the requirements of 12VAC5-481-2730.

4. Licensees shall verify that the number, locations, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. Licensees shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

5. Licensees shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

6. Licensees shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

7. Licensees shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources.

8. Licensees shall review the design of the mechanism that moves the sources to assure that the likelihood of a struck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

9. For panoramic irradiators to be built in seismic areas, licensees shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source or local building codes, if current.

D. For pool irradiators:

1. Licensees shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of 12VAC5-481-2780 C, and that metal components are metallurgically compatible with other components in the pool.

2. Licensees shall verify that the design of the water purification system is adequate to meet the requirements of 12VAC5-481-2780 E. The system shall be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

3. Licensees shall verify that there are no crevices on the source or between the source and the source holders that would promote corrosion on a critical area of the source.

4. If licensees use radiation monitors to detect contamination under 12VAC5-481-2870 B, they shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2820. Construction monitoring and acceptance testing.

A. For all irradiators, licensees shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 12VAC5-481-2760 A.

B. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in 12VAC5-481-2790 are met for protection of the source rack and the mechanism that moves the rack; testing

shall include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

C. For panoramic irradiators:

1. Licensees shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

2. Licensees shall monitor the construction of the foundations to verify that their construction meets design specifications.

3. Licensees shall test the movement of the source racks for proper operation prior to source loading; testing shall include source rack lowering due to simulated loss of power.

4. Licensees shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

5. Licensees shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. Licensees shall test the operability of the fire extinguishing system.

6. Licensees shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

7. For panoramic irradiators that use a computer system to control the access control system, licensees shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

8. Licensees shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

D. For pool irradiators:

1. Licensees shall verify that the pool meets design specifications and shall test the integrity of the pool. Licensees shall verify that outlets and pipes meet the requirements of 12VAC5-481-2780 B.

2. Licensees shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

3. Licensees shall verify the proper operation of the radiation monitors and the related alarm if used to meet 12VAC5-481-2870 B.

E. For underwater irradiators, licensees shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by 12VAC5-481-2760 B.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

Article 4. Operation of Irradiators

12VAC5-481-2830. Training.

A. Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall be instructed in:

1. The fundamentals of radiation protection applied to irradiators, including the differences between external radiation and radioactive contamination, units of radiation dose, agency dose limits, why large radiation doses shall be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator;

2. The requirements of Part X (12VAC5-481-2250 et seq.) and Part XII (12VAC5-481-2660 et seq.) of this chapter that are relevant to the irradiator;

3. The operation of the irradiator;

4. Those operating and emergency procedures listed in 12VAC5-481-2840 that the individual is responsible for performing; and

5. Case histories of accidents or problems involving irradiators.

B. Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

C. Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that the individual is to perform.

D. Licensees shall conduct safety reviews for irradiator operators at least annually. Licensees shall give each operator a brief written test on the information. Each safety review shall include, to the extent appropriate, each of the following:

1. Changes in operating and emergency procedures since the last review;

2. Changes in regulations and license conditions since the last review;

3. Reports on recent accidents, mistakes, or problems that have occurred at irradiators;

4. Relevant results of inspections of operator safety performance;

5. Relevant results of the facility's inspection and maintenance checks; and

6. A drill to practice an emergency or abnormal event procedure.

E. Licensees shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. Licensees shall discuss the results of the evaluation with the operato and shall instruct the operator on how to correct mistakes or deficiencies observed.

F. Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators or for the radiation safety officer, shall be instructe and tested in precautions they shall take to avoid radiation exposure, procedures or parts of procedures listed in 12VAC5-481-2840 that they are expected to perform or comply with, and their proper response to alarms required in this part. Tests may be oral.

G. Individuals who shall be prepared to respond to alarms required by 12VAC5-481-2730 B and I, 12VAC5-481-2750 A, 12VAC5-481-2760, and 12VAC5-481-2870 B shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Test may be oral.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2840. Operating and emergency procedures.

A. Licensees shall have and follow written operating procedures for:

1. Operation of the irradiator, including entering and leaving the radiation room;

2. Use of personnel dosimeters;

3. Surveying the shielding of panoramic irradiators;

4. Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

5. Leak testing of sources;

6. Inspection and maintenance checks required by 12VAC5-481-2880;

7. Loading, unloading, and repositioning sources if the operations will be performed by the licensee; and

8. Inspection of movable shielding required by 12VAC5-481-2730, if applicable.

B. Licensees shall have and follow written emergency or abnormal event procedures appropriate for the irradiator type for:

1. Sources stuck in the unshielded position;

2. Personnel overexposures;

3. A radiation alarm from the product exit portal monitor or pool monitor;

4. Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;

5. A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

6. A prolonged loss of electrical power;

7. A fire alarm or explosion in the radiation room;

8. An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

9. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical locatio of the facility; and

10. The jamming of automatic conveyor systems.

C. Licensees may revise operating and emergency procedures without agency approval only if all of the following conditions are met:

1. The revisions do not reduce the safety of the facility;

2. The revisions are consistent with the outline or summary of procedures submitted with the license application;

3. The revisions have been reviewed and approved by the radiation safety officer; and

4. The users or operators are instructed and tested on the revised procedures before they are put into use.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2850. Personnel monitoring.

A. Irradiator operators shall wear a personnel dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter must be capable of detecting high energy photons in the normal and accident dose ranges (see 12VAC5-481-750). Each personnel dosimeter shall be assigned to and worn by only one individual. Film badges shall be processed at least monthly, and other personnel dosimeters that require replacement shall be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

B. Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this subsection, a check of their response to radiation shall be done at least annually. Acceptable dosimeters shall read within plus or minus 30% of the true radiation dose.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016; Volume 37, Issue 25, eff. January 14, 2022; Errata, 38:4 VA.R. 478 October 11, 2021.

12VAC5-481-2860. Radiation surveys.

A. A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator shall be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators sha be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding shall be performed at intervals not to exceed three years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

B. If the radiation levels specified in 12VAC5-481-2740 are exceeded, the facility shall be modified to comply with the requirements in 12VAC5-481-2740.

C. Portable radiation survey meters shall be calibrated at least annually to an accuracy of plus or minus 20% for the gamma energy of th sources in use. The calibration shall be done at two points on each scale or for digital instruments at one point per decade over the rang that will be used. Portable radiation survey meters shall be of a type that does not saturate and read zero at high radiation dose rates.

D. Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming shall be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations shall not exceed those specified in Table 2, Column 2 or Table 3 of Appendix B to 10 CFR Part 20.

E. Before releasing resins for unrestricted use, they shall be monitored in an area with a background level less than 0.05 mrem (0.5 μSv) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used shall be capable of detecting radiation levels of 0.05 mrem (0.5 μSv) per hour.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2870. Detection of leaking sources.

A. Each dry-source-storage sealed source shall be tested for leakage at intervals not to exceed six months using a leak test kit or metho approved by the agency, NRC, or another agreement state. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test shall be capable of detecting the presence of 0.005 μCi (200 Bq) of radioactive material and shall be performed by a person approved by the agency, the NRC, or another agreement state to perform the test.

B. For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within the six months before the transfer. Water from the pool shall be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis shall be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels shall activate an alarm. The alarm set-point shall be set as low as practical, but high enough to avoid

false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

C. If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an agency, the NRC, or another agreement state licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination shall be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an agency, the NRC, or another agreement state licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2 of Appendix B to 10 CFR Part 20. (See 12VAC5-481-1110 for reporting requirements.)

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 25, Issue 2, eff. November 1, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2880. Inspection and maintenance.

A. Licensees shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

1. Operability of each aspect of the access control system required by 12VAC5-481-2730;

2. Functioning of the source position indicator required by 12VAC5-481-2770 B;

3. Operability of the radiation monitor for radioactive contamination in pool water required by 12VAC5-481-2870 B using a radiation check source, if applicable;

4. Operability of the over-pool radiation monitor at underwater irradiators as required by 12VAC5-481-2760 B;

5. Operability of the product exit monitor required by 12VAC5-481-2760 A;

6. Operability of the emergency source return control required by 12VAC5-481-2770 C;

7. Leak-tightness of systems through which pool water circulates (visual inspection);

8. Operability of the heat and smoke detectors and extinguisher system required by 12VAC5-481-2750 (but without turning extinguishers on);

9. Operability of the means of pool water replenishment required by 12VAC5-481-2780 C;

10. Operability of the indicators of high and low pool water levels required by 12VAC5-481-2780 D;

11. Operability of the intrusion alarm required by 12VAC5-481-2730 I, if applicable;

12. Functioning and wear of the system, mechanisms, and cables used to raise and lower sources;

13. Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 12VAC5-481-2790;

14. Amount of water added to the pool to determine if the pool is leaking;

15. Electrical wiring on required safety systems for radiation damage; and

16. Pool water conductivity measurements and analysis as required by 12VAC5-481-2890 B.

B. Malfunctions and defects found during inspection and maintenance checks shall be repaired without undue delay.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2890. Pool water purity.

A. Pool water purification system shall be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, licensees shall take prompt actions to lower pool water conductivity and shall take corrective actions to prevent future recurrences.

B. Licensees shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters shall be calibrated at least annually.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2900. Attendance during operation.

A. Both an irradiator operator and at least one other individual who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds shall be present on site:

1. Whenever the irradiator is operated using an automatic product conveyor system; and

2. Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

B. At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in 12VAC5-481-2830 G shall be on site.

C. At an underwater irradiator, an irradiator operator shall be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they shall have received the training described in 12VAC5-481-2830 F and G. Static irradiations may be performed without a person present at the facility.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2910. Entering and leaving the radiation room.

A. Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to the fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

B. Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

1. Visually inspect the entire radiation room to verify that no one else is in it; and

2. Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

C. During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by 12VAC5-481-2760 B is operating with backup power.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2920. Irradiation of explosive or flammable materials.

A. Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the agency. Authorization will not be granted unless the licensee can demonstrate that denotation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures to personnel.

B. Irradiation of more than small quantities of flammable material (flash point below 140ºF) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the agency. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures to personnel.

Statutory Authority
§ 32.1-229 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

Article 5. Records

12VAC5-481-2930. Records and retention periods.

Licensees shall maintain the following records at the irradiator for the periods specified:

1. A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the agency terminates the license for documents not superseded.

2. Records of each individual's training, tests, and safety reviews provided to meet the requirements of 12VAC5-481-2830 until three years after the individual terminates work.

3. Records of the annual evaluations of the safety performance of irradiator operators required by 12VAC5-481-2830 E for three years after the evaluations.

4. A copy of the current operating and emergency procedures required by 12VAC5-481-2840 until superseded or the agency terminate the license. Records of the radiation safety officer's review and approval of changes in procedures as required by 12VAC5-481-2840 C retained for three years from the date of the change.

5. Evaluations of personnel dosimeters required by 12VAC5-481-2850 until the agency terminates the license.

6. Records of radiation surveys required by 12VAC5-481-2860 for three years from the date of the survey.

7. Records of radiation survey meter calibrations required by 12VAC5-481-2860 and pool water conductivity meter calibrations required by 12VAC5-481-2890 B until three years from the date of calibration.

8. Records of the results of leak tests required by 12VAC5-481-2870 A and the results of contamination checks required by 12VAC5-481-2870 B for three years from the date of each test.

9. Records of inspection and maintenance checks required by 12VAC5-481-2880 for three years.

10. Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.

11. Records of receipt, transfer, and disposal, of all licensed sealed sources as required by 12VAC5-481-571 and 12VAC5-481-3100.

12. Records on the design checks required by 12VAC5-481-2810 and the construction control checks as required by 12VAC5-481-2820 until the license is terminated. The records shall be signed and dated. The title or qualification of the person signing shall be included

13. Records related to decommissioning of the irradiator as required by 12VAC5-481-450 C.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

12VAC5-481-2940. Reports.

A. In addition to the reporting requirements in this chapter, licensees shall report the following events:

1. Source stuck in an unshielded position;

2. Any fire or explosion in a radiation room;

3. Damage to the source racks;

4. Failure of the cable or drive mechanism used to move the source racks;

5. Inoperability of the access control system;

6. Detection of radiation source by the product exit monitor;

7. Detection of radioactive contamination attributable to licensed radioactive material;

8. Structural damage to the pool liner or walls;

9. Abnormal water loss or leakage from the source storage pool (greater than the design parameters); and

10. Pool water conductivity exceeding 100 microsiemens per centimeter.

B. The reports shall include a telephone report within 24 hours as described in 12VAC5-481-1100 and a written report within 30 days as described in 12VAC5-481-1110.

Statutory Authority

§ 32.1-229 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 22, Issue 25, eff. September 20, 2006; amended, Virginia Register Volume 24, Issue 18, eff. June 12, 2008; Volume 32, Issue 24, eff. August 25, 2016.

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