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

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 material 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.

§ 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 of 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 B 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 individual 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 an 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.

§ 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.

§ 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 the 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.

§ 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

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 x 10¹⁷ 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.

§ 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.

§ 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 operator 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 instructed 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. Tests may be oral.

§ 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 location 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.

§ 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 shall 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 the 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 range 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 μ Sv) 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 μ Sv) per hour.

§ 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 method 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 $0.005~\mu Ci~(200~Bq)$ 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

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 140°F) 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 terminates 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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