25 TEXAS ADMINISTRATIVE CODE

§289.258

Licensing and Radiation Safety Requirements for Irradiators

Texas Regulations for Control of Radiation

(revisions effective May 1, 2008 are shown as shaded text)

§289.258. Licensing and Radiation Safety Requirements for Irradiators.

(a) Purpose. This section contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive material in irradiators that irradiate objects or materials using gamma radiation. This section also contains radiation safety requirements for operating irradiators.

(b) Scope.

(1) In addition to the requirements of this section, all licensees, unless otherwise specified, are subject to the requirements of §289.201 of this title (relating to General Provisions for Radioactive Material), §289.202 of this title (relating to Standards for Protection Against Radiation from Radioactive Material), §289.203 of this title (relating to Notices, Instructions, and Reports to Workers; Inspections), §289.204 of this title (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services), §289.205 of this title (relating to Hearing and Enforcement Procedures), §289.252 of this title (relating to Licensing of Radioactive Material), and §289.257 of this title (relating to Packaging and Transportation of Radioactive Material). Nothing in this section relieves the licensee from complying with other applicable federal, state and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(2) The requirements in this section apply 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 under water. Irradiators whose dose rates exceed 500 rads (5 grays) per hour at 1 meter (m) from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this section.

(3) The requirements in this section do 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) irradiations.

(c) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Annually--At intervals not to exceed 390 days.

(2) Doubly encapsulated sealed source--A sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

(3) Category I self-contained, dry-source irradiator--An irradiator in which the sealed source is completely contained in a dry container constructed of solid materials and is shielded at all times, and in which human access to the sealed source and the volume undergoing irradiation is not physically possible in its designed configuration.

(4) Irradiator--A facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 500 rads (5 grays) per hour exist at 1 m from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

(5) Irradiator operator--An individual who has successfully completed the training and testing described in subsection (s) of this section and is authorized by the terms of the license to operate the irradiator without the presence of a supervisor who has completed the requirements of subsection (s)(1)-(3) of this section.

(6) Onsite--A physical presence within the building housing the irradiator or on property controlled by the licensee that is contiguous with the building housing the irradiator.

(7) Panoramic dry-source-storage irradiator--An irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

(8) Panoramic irradiator--An irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

(9) Panoramic wet-source-storage irradiator--An irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

(10) Pool irradiator--Any irradiator in which the sources are stored or used in a pool of water, including panoramic wet-source-storage irradiators and underwater irradiators.

(11) Product conveyor system--A system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

(12) Radiation room--A shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

(13) Seismic area--Any area where the probability of horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the United States Geological Survey.

(14) Underwater irradiator--An irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

(d) Application for a specific license. Applications for specific licenses shall be filed in accordance with §289.252(d) of this title.

(e) Specific licenses for irradiators.

(1) 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 this section.

(2) The applicant shall satisfy the general requirements specified in §289.252 of this title and the requirements contained in this section.

(3) The application shall describe the training provided to irradiator operators including:

(A) classroom training;

(B) on-the-job or simulator training;

(C) safety reviews;

(D) means employed by the applicant to test each operator's understanding of the agency's rules and licensing requirements and the irradiator operating, safety, and emergency procedures; and

(E) minimum training and experience of personnel who may provide training.

(4) The application shall include a copy of the written operating, safety, and emergency procedures as outlined in subsection (t) of this section that describes the radiation safety aspects of the procedures.

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

(6) The application shall include a description of the access control systems required by subsection (i) of this section, the radiation monitors required by subsection (l) of this section, the method of detecting leaking sources required by subsection (w) of this section, including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(7) If the applicant intends to perform and analyze leak tests 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 at least the following:

(A) instruments to be used;

(B) methods of performing the analysis; and

(C) pertinent experience of the individual who analyzes the samples.

(8) 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 a person specifically authorized by the agency, the United States Nuclear Regulatory Commission (NRC), an agreement state, or a licensing state to load or unload irradiator sources.

(9) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by subsection (x) of this section.

(f) Start of construction. The applicant may not begin construction of a new irradiator prior to the submission to the agency of both an application for a license for the irradiator and the fee required by §289.204 of this title. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work; purchase of a site; site surveys or soil testing; site preparation; site excavation; construction of warehouse or auxiliary structures; and other similar tasks. Any construction 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 with respect to the requirements of the Texas Radiation Control Act (Act), rules, and orders issued in accordance with the Act.

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(g) Applications for exemptions. Any applications 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 of this section. The agency will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

(h) Performance criteria for sealed sources.

(1) Cesium-137 shall not be used in any irradiator other than a Category I self-contained, dry-source irradiator as defined in subsection (c) of this section.

(2) Sealed sources. Sealed sources installed after August 1, 1996, shall meet the following requirements:

(A) have been evaluated in accordance with §289.252(v) of this title;

(B) be doubly encapsulated;

(C) 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;

(D) 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

(E) have been leak tested and found leak-free in prototype testing of the sealed source after each of the tests described in paragraphs (3)-(8) of this subsection.

(3) Temperature. The test source shall be held at -40 degrees Celsius for 20 minutes, 600 degrees Celsius for one hour, and then be subjected to thermal shock test with a temperature drop from 600 degrees Celsius to 20 degrees Celsius within 15 seconds.

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

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

(6) Vibration. The test source shall be subjected three times for ten 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.

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

(8) Bend. 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 2,000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

(i) Access control requirements in addition to the requirements of §289.202(u) of this title.

(1) 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 the 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.

(2) 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 make at least one other individual who is onsite aware of the entry. That individual shall be trained on how to respond to the alarm and be prepared to promptly render or summon assistance.

(3) 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 paragraph (2) of this subsection. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

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(4) 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 people 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 and to operate the control described in paragraph (5) of this subsection before the sources leave the shielded position.

(5) Each radiation room at a panoramic irradiator shall have a clearly visible and readily accessible control that allows an individual in the room to return the sources to their fully shielded position.

(6) 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.

(7) 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 have a sign bearing the radiation symbol and the words, "CAUTION (or DANGER), RADIOACTIVE MATERIAL." Panoramic irradiators shall also have a sign stating "CAUTION (or DANGER), HIGH RADIATION AREA," as defined in §289.201(b) of this title, or "GRAVE DANGER, VERY HIGH RADIATION AREA," as defined in §289.201(b) of this title, whichever is applicable, but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

(8) 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. The 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.

(9) Underwater irradiators shall have a personnel access barrier around the pool that 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 onsite) who is prepared to respond or summon assistance.

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(j) Shielding.

(1) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 2 millirems (mrem) (0.02 millisievert (mSv)) per hour at any location 30 centimeters (cm) 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 centimeters (cm^2) having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 2 mrem (0.02 mSv) per hour shall be locked, roped off, or posted.

(2) The radiation dose at 30 cm 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.

(3) The radiation dose rate at 1 m from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 2 mrem (0.02 mSv) per hour and at 5 cm from the shield may not exceed 20 mrem (0.2 mSv) per hour.

(k) Fire protection.

(1) The radiation room at a 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.

(2) 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. If water is used, the system for the radiation room shall have a shut-off valve to control flooding into unrestricted areas.

(l) Radiation monitors.

(1) 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 the requirements of this paragraph.

(2) 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 audible alarm may have a manual shut-off. The alarm shall be capable of alerting an individual who is prepared to respond promptly.

(m) Control of source movement.

(1) 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.

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

(3) The control console of a panoramic irradiator shall have a control that when activated, shall return the source to its fully shielded position within its normal transit time.

(4) Each control for a panoramic irradiator shall be clearly marked as to its function.

(n) Irradiator pools.

(1) For licenses initially issued after August 1, 1996, irradiator pools shall either:

(A) have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

(B) be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

(2) For licenses initially issued after August 1, 1996, irradiator pools shall have no outlets more than 0.5 m below the normal low water level that could allow water to drain out of the pool. Pipes that have openings more than 0.5 m below the normal low water level and that could act as siphons shall have siphon breakers to prevent the siphoning of pool water.

(3) A means shall be provided to replenish water losses from the pool.

(4) 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.

(5) 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.

(6) 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.

(7) 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.

(o) 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 carrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

(p) Power failures.

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

(2) The lock on the door of the radiation room of a panoramic irradiator shall not be deactivated by a power failure.

(3) 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.

(q) Design requirements for irradiators. The following are design requirements for irradiators that have construction beginning after August 1, 1996.

(1) Shielding. For panoramic irradiators, the licensee 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 subsection (j) of this section. If the irradiator will use more than 5 million curies (2×10^{17} becquerels) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

(2) Foundations. For panoramic irradiators, the licensee 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) Pool integrity. For pool irradiators, the licensee 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 subsection (n)(2) of this section, and that metal components are metallurgically compatible with other components in the pool.

(4) Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of subsection (n)(5) of this section. The system shall be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

(5) Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by subsection (l)(1) of this section. The licensee 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. For pool irradiators, if the licensee uses radiation monitors to detect contamination in accordance with subsection (w)(2) of this section, the licensee 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.

(6) Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee 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. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

(7) Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of subsection (i) of this section.

(8) Fire protection. For panoramic irradiators, the licensee 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. The licensee 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.

(9) Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if power is lost for more than 10 seconds.

(10) Seismic. For panoramic irradiators to be built in seismic areas, the licensee 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 such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

(11) Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

(r) Construction monitoring and acceptance testing requirements. The following are construction monitoring and acceptance testing requirements to be met prior to loading sources in irradiators that have begun construction after August 1, 1996.

(1) Shielding. For panoramic irradiators, the licensee 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) Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that the foundation construction meets design specifications.

(3) Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of subsection (n)(2) of this section.

(4) Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

(5) Radiation monitors. For all irradiators, the licensee 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 subsection (l)(1) of this section. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet subsection (w)(2) of this section. For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by subsection (l)(2) of this section.

(6) Source rack. For panoramic irradiators, the licensee 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. 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 subsection (o) of this section 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 that rack from moving product carriers.

(7) Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

(8) Fire protection. For panoramic irradiators, the licensee 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. The licensee shall test the operability of the fire extinguishing system.

(9) Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without power.

(10) Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if 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.

(11) Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

(s) Training.

(1) Before an individual is permitted to operate an irradiator without a supervisor present, who has completed the requirements of this paragraph and paragraphs (2) and (3) of this subsection, the individual shall be instructed in:

(A) the fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, 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 individual monitoring devices, other radiation safety features of an irradiator, and the basic function of the irradiator);

(B) the requirements of this section and §289.203 of this title that are relevant to the irradiator;

(C) the operation of the irradiator;

(D) those operating, safety, and emergency procedures listed in subsection (t) of this section that the individual is responsible for performing; and

(E) case histories of accidents or problems involving irradiators.

(2) Before an individual is permitted to operate an irradiator without a supervisor present, who has completed the requirements of this paragraph and paragraphs (1) and (3) of this subsection, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating, safety, and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(3) Before an individual is permitted to operate an irradiator without a supervisor present, who has completed the requirements of this paragraph and paragraphs (1) and (2) of this subsection, 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, safety, and emergency procedures that he or she is to perform.

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

(A) changes in operating, safety, and emergency procedures since the last review, if any;

(B) changes in rules and license conditions since the last review, if any;

(C) reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

(D) relevant results of inspections of operator safety performance;

(E) relevant results of the facility's inspection and maintenance checks; and

(F) a drill to practice an emergency or abnormal event procedure.

(5) The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that agency rules, license conditions, and operating, safety, and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

(6) 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 and the RSO, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in subsection (t) of this section that they are expected to perform or comply with, and their proper response to alarms required in this section. Tests may be oral.

(7) Individuals who shall be prepared to respond to alarms required by subsections (i)(2) and (9), (k), (l), and (w)(2) of this section shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

(t) Operating, safety, and emergency procedures.

(1) The licensee shall have and follow written operating, safety, and emergency procedures for:

(A) operation of the irradiator, including entering and leaving the radiation room;

(B) use of individual monitoring devices;

(C) surveying the shielding of panoramic irradiators;

(D) monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

(E) leak testing of sources;

(F) inspection and maintenance checks required by subsection (x) of this section;

(G) loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

(H) inspection of movable shielding required by subsection (i)(8) of this section, if applicable.

(2) The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

(A) sources stuck in the unshielded position;

(B) personnel overexposures;

(C) a radiation alarm from the product exit portal monitor or pool monitor;

(D) detection of leaking source, pool contamination, or alarm caused by contamination of pool water;

(E) a low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

(F) a prolonged loss of electrical power;

(G) a fire alarm or explosion in the radiation room;

(H) an alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

(I) natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

(J) the jamming of automatic conveyor systems.

(3) The licensee may revise operating, safety, and emergency procedures without agency approval only if all of the following conditions are met:

(A) the revisions do not reduce the safety of the facility;

(B) the revisions are consistent with the outline or summary of procedures including procedures for changes to operating, safety, and emergency procedures submitted with the license application;

(C) the revisions have been reviewed and approved by the radiation safety officer; and

(D) the users or operators are instructed and tested on the revised procedures before they are put into use.

(4) Changes to operating, safety, and emergency procedures shall be submitted to the agency after the provisions of paragraph (3) of this subsection are completed.

(u) Personnel monitoring.

(1) Irradiator operators shall wear an individual monitoring device that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter processor must be accredited for high-energy photons in the normal and accident dose ranges (see §289.202(p)(3) of this title). Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and other personnel dosimeters must be processed at least quarterly. After replacement, each film badge, a thermoluminescent dosimeter (TLD), or optically stimulated luminescence device (OSL) shall be returned to the supplier for processing within 14 calendar days of the exchange date specified by the personnel monitoring supplier or as soon as practicable. In circumstances that make it impossible to return each film badge, TLD, or OSL within 14 calendar days, such circumstances shall be documented and available for review by the agency.

(2) 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 the paragraph, 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.

(v) Radiation surveys.

(1) 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.

(2) If the radiation levels specified in subsection (j) of this section are exceeded, the facility shall be modified to comply with the requirements in subsection (j) of this section.

(3) 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.

(4) 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 §289.202(ggg)(2) of this title.

(5) 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.

(w) Detection of leaking sources.

(1) 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, the commission, an agreement state, or a licensing 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 microcurie (200 becquerels) of radioactive material and shall be performed by a person approved by the agency, the NRC, an agreement state, or a licensing state to perform the test.

(2) 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 clear up contamination in the pool if specifically provided for in written emergency procedures.

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(3) 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, NRC, agreement state, or licensing state licensee who 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, NRC, agreement state, or licensing state licensee who 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 §289.202(ggg)(2) of this title. (See §289.202(xx) and (yy) of this title for reporting requirements.)

(x) Inspection and maintenance.

(1) The licensee 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:

(A) operability of each aspect of the access control system required by subsection (i) of this section;

(B) functioning of the source position indicator required by subsection (m)(2) of this section;

(C) operability of the radiation monitor for radioactive contamination in pool water required by subsection (w)(2) of this section using a radiation check source, if applicable;

(D) operability of the over-pool radiation monitor at underwater irradiators as required by subsection (l)(2) of this section;

(E) operability of the product exit monitor required by subsection (l)(1) of this section;

(F) operability of the emergency source return control required by subsection (m)(3) of this section;

(G) leak-tightness of systems through which pool water circulates (visual inspection);

(H) operability of the heat and smoke detectors and extinguisher system required by subsection (k) of this section (but without turning extinguishers on);

(I) operability of the means of pool water replenishment required by subsection (n)(3) of this section;

(J) operability of the indicators of high and low pool water levels required by subsection (n)(4) of this section;

(K) operability of the intrusion alarm required by subsection (i)(8) of this section, if applicable;

(L) functioning and wear of the system, mechanisms, and cables used to raise and lower sources;

(M) condition of the barrier to prevent products from hitting the sources or source mechanism as required by subsection (o) of this section;

(N) amount of water added to the pool to determine if the pool is leaking;

(O) electrical wiring on required safety systems for radiation damage;

(P) pool water conductivity measurements and analysis as required by subsection (y)(2) of this section; and

(Q) operability of automatic communications systems used to alert individuals to alarms, emergencies, or abnormal event conditions if required by subsection (z)(2)(A) of this section.

(2) Malfunctions and defects found during inspection and maintenance checks shall be repaired without undue delay. If repairs are required, the irradiator shall not be operated unless alternative methods are utilized to provide an equivalent level of safety until repairs are completed.

(y) Pool water purity.

(1) 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, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

(2) The licensee shall measure the pool water conductivity no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters shall be calibrated at least annually.

(z) Attendance during operation.

(1) Both an irradiator operator and at least one other individual, who is trained on how to respond to alarms in accordance with subsection (s)(7) of this section and is prepared to promptly render or summon assistance, shall be present onsite whenever it is necessary to enter the radiation room.

(2) At least one individual who has received the training on how to respond to alarms described in subsection (s)(7) of this section shall be available and prepared to promptly respond to alarms, emergencies, or abnormal event conditions at any time a panoramic irradiator is operating. If the individual is not onsite, the following requirements shall be met.

(A) Automatic means of communications shall be provided from the irradiator control system to alert the individual to alarms, emergencies, or abnormal event conditions. As a minimum, the automatic communication system shall alert the individual to those emergency or abnormal events listed in subsection (t)(2) of this section.

(B) The irradiator control system shall be secured from unauthorized access at any time an irradiator operator is not onsite. This security shall include physically securing the key described in subsection (m)(1) of this section to ensure the key is not removed from the control console.

(3) 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 subsection (s)(6) and (7) of this section. Static irradiations may be performed without a person present at the facility.

(aa) Entering and leaving the radiation room.

(1) 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 its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

(2) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall do the following:

(A) visually inspect the entire radiation room to verify that no one else is in it; and

(B) 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.

(3) 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 subsection (l)(2) of this section is operating with backup power.

(bb) Irradiation of explosive or flammable materials.

(1) 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 detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

(2) Irradiation of more than small quantities of flammable material (flash point below 140 degrees Fahrenheit) 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 of personnel.

(cc) Records/documents. The licensee shall maintain the following records/documents at the irradiator for the time intervals indicated for inspection by the agency:

(1) a copy of the license, license conditions, documents incorporated into a license by reference, and amendments to the license until superseded by new documents or until the agency terminates the license;

(2) records of each individual's training, tests, and safety reviews provided to meet the requirements of subsection (s)(1)-(4), (6), and (7) of this section until three years after the individual terminates work;

(3) records of the annual evaluations of the safety performance of irradiator operators required by subsection (s)(5) of this section for three years after the evaluation;

(4) a copy of the current operating, safety, and emergency procedures required by subsection (t) of this section until superseded or the agency terminates the license. Records of the RSO review and approval of changes in procedures as required by subsection (t)(3)(C) of this section, retained for three years from the date of the change;

(5) film badge, TLD, or OSL results required by subsection (u) of this section until the agency terminates the license;

(6) records of radiation surveys required by subsection (v) of this section for three years from the date of the survey;

(7) records of radiation survey meter calibrations required by subsection (v) of this section and pool water conductivity meter calibrations required by subsection (y)(2) of this section until three years from the date of calibration;

(8) records of the results of leak tests required by subsection (w)(1) of this section and the results of contamination checks required by subsection (w)(2) of this section for three years from the date of each test;

(9) records of inspection and maintenance checks required by subsection (x) of this section 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 the receipt, transfer and disposal, of all licensed sealed sources as required by §289.201(d) and §289.252(x) and (cc) of this title;

(12) records on the design checks required by subsection (q) of this section and the construction control checks as required by subsection (r) of this section until the license is terminated. The records shall be signed and dated. The title or qualification of the person signing shall be included; and

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(13) records related to decommissioning of the irradiator as required by §289.252(gg)(7) of this title.

(dd) Reports.

(1) In addition to the reporting requirements in other sections of this title, the licensee shall report the following events if not reported in accordance with other sections of this title:

(A) source stuck in an unshielded position;

(B) any fire or explosion in a radiation room;

(C) damage to the source racks;

(D) failure of the cable or drive mechanism used to move the source racks;

(E) inoperability of the access control system;

(F) detection of radiation source by the product exit monitor;

(G) detection of radioactive contamination attributable to licensed radioactive material;

(H) structural damage to the pool liner or walls;

(I) abnormal water loss or leakage from the source storage pool; and

(J) pool water conductivity exceeding 100 microsiemens per centimeter during normal operations.

(2) The report shall include a telephone report within 24 hours as described in §289.202(xx)(8)(A) of this title, and a written report within 30 days as described in §289.202(xx)(8)(B) of this title.