

25 TEXAS ADMINISTRATIVE CODE

§289.258

Licensing and Radiation Safety Requirements for Irradiators

Texas Regulations for Control of Radiation

(revisions effective October 23, 2024, are shown as shaded text)

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TITLE 25 HEALTH SERVICES
PART 1 DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 289 RADIATION CONTROL
SUBCHAPTER F LICENSE REGULATIONS

§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 **used** in **irradiating** 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:

(A) §289.201 of this chapter (relating to General Provisions for Radioactive Material);

(B) §289.202 of this chapter (relating to Standards for Protection Against Radiation from Radioactive Materials);

(C) §289.203 of this chapter (relating to Notices, Instructions, and Reports to Workers; Inspections);

(D) §289.204 of this chapter (relating to Fees for Certificates of Registration, Radioactive Material Licenses, Emergency Planning and Implementation, and Other Regulatory Services);

(E) §289.205 of this chapter (relating to Hearing and Enforcement Procedures);

(F) §289.252 of this subchapter (relating to Licensing of Radioactive Material); and

(G) §289.257 of this subchapter (relating to Packaging and Transportation of Radioactive Material).

(2) 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.

(3) The requirements in this section apply to panoramic irradiators **having** either dry or wet storage of radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates **are greater than** 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.

(4) 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 non-destructive testing purposes), gauging, or open-field (agricultural) irradiations.

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

(1) Annually--At intervals not greater than 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 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 using radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates are greater than 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 not accessible to personnel.

(5) Irradiator operator--An individual who 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 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 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

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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 percent, 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 **must** be filed **as specified** in §289.252(d) of this **subchapter**.

(e) Specific licenses for irradiators.

(1) The **department approves** 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 **must** satisfy the general requirements specified in §289.252 of this **subchapter** and the requirements contained in this section.

(3) The application **must** 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 department's rules and licensing requirements and the irradiator operating, safety, and emergency procedures; and

(E) minimum training and experience of personnel providing training.

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

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

(6) The application must 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 showing 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 must establish procedures for leak testing and submit a description of these procedures to the department. The description must include at least:

(A) the instruments to be used;

(B) the methods of performing the analysis; and

(C) the pertinent experience of the individual analyzing the samples.

(8) If licensee personnel are to load or unload sources, the applicant must describe the qualifications and training of the personnel and the procedures used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by a person specifically authorized by the department, the United States Nuclear Regulatory Commission (NRC), or an agreement state to load or unload irradiator sources.

(9) The applicant must 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 must not begin construction of a new irradiator before the submission to the department of both an application for a

license for the irradiator and the fee required by §289.204 of this **chapter**. 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 **before** 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 **as specified** in the Act.

(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 **department approves** the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates they are likely to provide an adequate level of safety for workers and the public.

(h) Performance criteria for sealed sources.

(1) Cesium-137 **must** 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, **must**:

(A) be evaluated **as specified** in §289.252(v) of this **subchapter**;

(B) be doubly encapsulated;

(C) use radioactive material as **non-dispersible** as practical and 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) be 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 **must** be held at **negative 40** degrees Celsius for 20 minutes, 600 degrees Celsius for one hour, and then 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 **must** be subjected **twice**, for at least five minutes, to an external pressure (absolute) of 2 million newtons per square meter.

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

(6) Vibration. The test source **must** 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 **must** be vibrated for 30 minutes at each resonant frequency found.

(7) Puncture. A 50-gram weight and pin, 0.3-centimeter pin diameter, **must** 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 **must** 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 **chapter**.

(1) Each entrance to a radiation room at a panoramic irradiator **must** 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 if they reliably and consistently function as a barrier. It **must** 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 **must** cause the sources to return promptly to the shielded position. The personnel entrance door or barrier **must** have a lock operated by the same key used to move the sources. The doors and barriers **must** not prevent any individual in the radiation room from leaving.

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

(3) A radiation monitor **must** be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor **must** 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 **must** 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.

(4) Before the sources move from their shielded position in a panoramic

irradiator, the source control **must** 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 **must** 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 **must** have a clearly visible and readily accessible control **allowing** an individual in the room to return the sources to their fully shielded position.

(6) Each radiation room of a panoramic irradiator **must** contain a control **preventing** the sources from moving from the shielded position unless the control **is** 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 **must** have a sign bearing the radiation symbol and the words, "CAUTION (or DANGER), RADIOACTIVE MATERIAL." Panoramic irradiators **must** also have a sign stating "CAUTION (or DANGER), HIGH RADIATION AREA," as defined in §289.201(b) of this **chapter**, or "GRAVE DANGER, VERY HIGH RADIATION AREA," as defined in §289.201(b) of this **chapter**, 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 **must** not be possible to operate the irradiator unless the shielding is in its proper location. The requirement may be met by interlocks **preventing** operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

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

(j) Shielding.

(1) The radiation dose rate in areas normally occupied during operation of a panoramic irradiator **must not be greater than 2 millirem** (mrem) (0.02 millisievert (mSv)) per hour at any location 30 cm or more from the wall of the room when the sources are exposed. The dose rate **must** be averaged over an area not **greater than 100 square centimeters (cm²)** having no linear dimension greater than 20 cm. Areas where the radiation dose rate **is greater than 2 mrem** (0.02 mSv) per hour **must** be locked, roped off, or posted.

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(2) The radiation dose at 30 cm over the edge of the pool of a pool irradiator may not be greater than 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 must not be greater than 2 mrem (0.02 mSv) per hour and at 5 cm from the shield, not greater than 20 mrem (0.2 mSv) per hour.

(k) Fire protection.

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

(2) The radiation room at a panoramic irradiator must 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 must have a shut-off valve to control flooding into unrestricted areas.

(l) Radiation monitors.

(1) Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility 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 not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must 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 must be capable of alerting an individual prepared to respond promptly.

(m) Control of source movement.

(1) The mechanism moving the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate 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 must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

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(2) The console of a panoramic irradiator **must** have a source position indicator **indicating** 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 **must** have a control that, when activated, **must** return the source to its fully shielded position within its normal transit time.

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

(n) Irradiator pools.

(1) For licenses initially issued after August 1, 1996, irradiator pools **must** 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 there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee **must** have a method to safely store the sources during repairs of the pool.

(2) For licenses initially issued after August 1, 1996, irradiator pools **must** 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 **having** openings more than 0.5 m below the normal low water level and that could act as siphons **must** have siphon breakers to prevent the siphoning of pool water.

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

(4) A visible indicator **must** 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 **must** be equipped with a purification system designed to **maintain** the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so the sources can be seen clearly.

(6) A physical barrier, such as a railing or cover, **must** be used around or over irradiator pools during normal operation **preventing** 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 **be greater than** 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 **moving** the rack **must** 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 **must** automatically return to the shielded position.

(2) The lock on the door of the radiation room of a panoramic irradiator **must** 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 beginning **construction** after August 1, 1996.

(1) Shielding. For panoramic irradiators, the licensee **must** 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 **must** evaluate the effects of heating of the shielding walls by the irradiator sources.

(2) Foundations. For panoramic irradiators, the licensee **must** design the foundation, with consideration given to soil characteristics, **ensuring** it is adequate to support the weight of the facility shield walls.

(3) Pool integrity. For pool irradiators, the licensee **must** design the pool to assure it is leak resistant, strong enough to bear the weight of the pool water and shipping casks, a dropped cask would not fall on sealed sources, all outlets or pipes meet the requirements of subsection (n)(2) of this section, and metal components are metallurgically compatible with other components in the pool.

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

(5) Radiation monitors. For all irradiators, the licensee **must** 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 **must** verify 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 **as specified** in subsection (w)(2) of this section, the licensee **must** verify 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 **must** verify 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 **must** determine source rack drops due to loss of power will not damage the source rack and source rack drops due to failure of cables (or alternate means of support) **do** not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee **must** 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 **must** verify from the design and logic diagram the access control system **meets** the requirements of subsection (i) of this section.

(8) Fire protection. For panoramic irradiators, the licensee **must** verify the number, locations, and spacing of the smoke and heat detectors are appropriate to detect fires and the detectors are protected from mechanical and radiation damage. The licensee **must** verify the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and the system is protected from mechanical and radiation damage.

(9) Source return. For panoramic irradiators, the licensee **must** verify 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 **must** 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 **must** verify 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 **requirements for** construction monitoring and acceptance testing **must be met before** loading sources in irradiators that began construction after August 1, 1996.

(1) Shielding. For panoramic irradiators, the licensee **must** monitor the construction of the shielding to verify its construction meets design specifications

and generally accepted building code requirements for reinforced concrete.

(2) Foundations. For panoramic irradiators, the licensee **must** monitor the construction of the foundations to verify the foundation construction meets design specifications.

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

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

(5) Radiation monitors. For all irradiators, the licensee **must** 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 **must** 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 **must** 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 **must** test the movement of the source racks for proper operation **before** source loading. Testing **must** include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee **must** observe and test the operation of the conveyor system to assure the requirements in subsection (o) of this section are met for protection of the source rack and the mechanism **moving** the rack. Testing **must** include tests of any limit switches and interlocks **protecting** the source rack and mechanism moving that rack from **moving** product carriers.

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

(8) Fire protection. For panoramic irradiators, the licensee **must** test the ability of the heat and smoke detectors to detect a fire, activate alarms, and cause the source rack to automatically become fully shielded. The licensee **must** test the operability of the fire extinguishing system.

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

(10) Computer systems. For panoramic irradiators **using** a computer system to control the access control system, the licensee **must** verify the access control system **operates** properly if power is lost and **must** verify the computer has security

features preventing 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 must verify the electrical wiring and electrical equipment 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 must 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 must 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 chapter relevant to the irradiator;

(C) the operation of the irradiator;

(D) those operating, safety, and emergency procedures listed in subsection (t) of this section 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 must pass a written test on the instruction received consisting primarily of questions based on the licensee's operating, safety, and emergency procedures 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 must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual must also demonstrate the ability to perform those portions of the operating, safety, and emergency procedures he or she is to perform.

(4) The licensee must conduct safety reviews for irradiator operators at least

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annually. The licensee **must** give each operator a brief written test on the information. Each safety review **must** include, to the extent appropriate:

(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 **must** evaluate the safety performance of each irradiator operator at least annually **ensuring the department's** rules, license conditions, and operating, safety, and emergency procedures are followed. The licensee **must** discuss the results of the evaluation with the operator and **must** instruct the operator how to correct any mistakes or deficiencies observed.

(6) Individuals 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, **must** 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 they are expected to comply with **or perform**, and their proper response to alarms required in this section. Tests may be oral.

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

(t) Operating, safety, and emergency procedures.

(1) The licensee **must** 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;

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(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 are performed by the licensee; and

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

(2) The licensee **must** 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 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 approval **from the department** only if all **these** 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 are reviewed and approved by the radiation safety officer (RSO); 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 must be submitted to the department after the provisions of paragraph (3) of this subsection are completed.

(u) Personnel monitoring.

(1) Irradiator operators must wear an individual monitoring device while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The individual monitoring device must be capable of detecting high-energy photons in the normal and accident dose ranges. Each individual monitoring device must be assigned to and worn by only one individual. Film badges must be replaced at least monthly, and all other individual monitoring devices requiring replacement must be replaced at least quarterly. After replacement, individual monitoring devices requiring processing must be returned to the supplier for processing within 14 calendar days of the exchange date specified by the supplier, or as soon as practicable. All individual monitoring devices must be evaluated at least quarterly or promptly after replacement, whichever is more frequent. Circumstances preventing meeting these time limits must be documented, and those records must be available for review by the department.

(2) Other individuals entering the radiation room of a panoramic irradiator must wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people entering the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent 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 must be conducted with the sources in the exposed position before the facility starts operations. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts operations. Additional radiation surveys of the shielding must be performed at intervals not greater than three years and before resuming operations 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 **must** be modified to comply with the requirements in subsection (j) of this section.

(3) Portable radiation survey meters **must** be calibrated at least annually to an accuracy of plus or minus 20 percent for the gamma energy of the sources in use. The calibration **must** be done at two points on each scale or, for digital instruments, at one point per decade over the range used. Portable radiation survey meters **must** 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 **must** be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations **must not be greater than** those specified in Table 2, Column 2, or Table 3 of §289.202(ggg)(2) of this **chapter**.

(5) Before releasing resins for unrestricted use, **the resins must** be monitored in an area with a background level less than 0.05 mrem (0.5 **microsieverts (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 **must** 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 **must** be tested for leakage at intervals not **greater than** six months using a leak test kit or method approved by the **department, the NRC, or** an agreement state. In the absence of a certificate from a transferor that a test **was** made within the six months before the transfer, the sealed source **must** not be used until tested. The test **must** be capable of detecting the presence of 0.005 microcurie (200 becquerels) of radioactive material and **must** be performed by a person approved by the **department, the NRC, or** an agreement state.

(2) For pool irradiators, sources **must** 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 **was** done within the six months before the transfer. Water from the pool **must** 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 **must** 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 **must** activate an alarm. The alarm set-point **must** 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.

(3) If a leaking source is detected, the licensee **must** arrange to remove the leaking source from service and **decontaminate, repair, or dispose** of it by **a department, NRC, or** agreement state licensee authorized to perform these functions. The licensee **must** promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product **is** checked and found free of contamination. If a product **is** shipped **and** may have been inadvertently contaminated, the licensee **must** arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination **must** be performed promptly. If contaminated equipment, facilities, or products are found, the licensee **must** arrange to have them decontaminated or disposed of by **a department, NRC, or** agreement state licensee authorized to perform these functions. If a pool is contaminated, the licensee **must** arrange to clean the pool until the contamination levels **are not greater than** the appropriate concentration in Table 2, Column 2 of §289.202(ggg)(2) of this **chapter**. (See §289.202(xx) and (yy) of this **chapter** for reporting requirements.)

(x) Inspection and maintenance.

(1) The licensee **must** perform inspection and maintenance checks, **including, at** 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) **functionality** 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);

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(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) **functionality** 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 **must** be repaired without undue delay. If repairs are required, the irradiator **must** 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 **must** 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 **must** take prompt actions to lower the pool water conductivity and **must** take corrective actions to prevent future recurrences.

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

(z) Attendance during operation.

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

(2) At least one individual **trained** to respond to alarms described in subsection (s)(7) of this section **must** 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 **must** be met.

(A) Automatic means of communications **must** 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 **must** alert the individual to those emergency or abnormal events listed in subsection (t)(2) of this section.

(B) The irradiator control system **must** be secured from unauthorized access at any time an irradiator operator is not onsite. This security **must** 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 **must** 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 **must** 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 **must** use a survey meter to determine the source has returned to its fully shielded position. The operator **must** check the functioning of the survey meter with a radiation check source before entry.

(2) Before exiting from and locking the door to the radiation room of a panoramic irradiator **before** a planned irradiation, the irradiator operator **must**:

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

(B) activate a control in the radiation room **permitting** 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 **must** 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 **department**. Authorization is not granted unless the licensee can demonstrate 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 **receives** prior written authorization from the **department**. Authorization **is** not granted unless the licensee can demonstrate 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 **must** maintain records/documents at the irradiator for the time intervals indicated for inspection by the **department**, **including**:

(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 **department** terminates the license;

(2) records of each individual's training, tests, and safety reviews provided **meeting** 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 **department** 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) **individual monitoring device** results required by subsection (u) of this section until the **department** terminates the license;

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

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(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 involving 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 chapter;

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

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

(dd) Reports.

(1) In addition to the reporting requirements in other sections of this chapter, the licensee must report the following events if not reported as specified in other sections of this chapter:

(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;

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(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 **greater than** 100 microsiemens per centimeter during normal operations.

(2) The report **must** include a telephone report within 24 hours as described in §289.202(xx)(8)(A) of this **chapter**, and a written report within 30 days as described in §28