

PART XIV

LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

SUBPART A GENERAL PROVISIONS

64E-5.1401 Irradiators.

- (1) This part contains requirements for licenses authorizing the use of sealed sources containing radioactive materials in irradiators to irradiate objects or material. This part also contains radiation safety requirements for operating irradiators.
- (2) The rules in this part apply to panoramic irradiators which have 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 covered by the rules in this part are those whose radiation dose rates exceed 500 rads (5 grays) per hour at 1 meter from the radioactive sealed sources in air or in water.
- (3) The rules in this part do not apply to self-contained dry-source-storage irradiators in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel. This part also does not apply to radioactive material used for medical radiology, teletherapy, industrial radiography, gauging, calibration of radiation instruments, or open-field agricultural irradiations.
- (4) The requirements of this part are in addition to other applicable requirements of these rules.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1501.

64E-5.1402 Definitions.

- (1) "Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within a capsule which is sealed within another capsule.
- (2) "Irradiator" means a facility which uses radioactive sealed sources to irradiate objects or materials and in which radiation dose rates exceeding 500 rads (5 grays) per hour exist at 1 meter 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.

- (3) "Irradiator operator" means an individual who successfully completed the training and testing specified in 64E-5.1416 and who is authorized by the licensee and approved by the department to operate the irradiator without a supervisor present.
- (4) "Panoramic dry-source-storage irradiator" means an irradiator in which the irradiation occurs 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 to perform irradiations.
- (5) "Panoramic irradiator" means an irradiator in which the irradiation occurs in air in areas potentially accessible to personnel. The term includes beam-type irradiators.
- (6) "Panoramic wet-source-storage irradiator" means an irradiator in which the irradiation occurs in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.
- (7) "Pool irradiator" means an irradiator in which the sources are stored or used in a pool of water, including panoramic wet-source-storage irradiators and underwater irradiators.
- (8) "Product conveyor system" means a system to move the product to be irradiated to, from, and within the area where irradiation occurs.
- (9) "Radiation room" means a shielded room in which irradiation occurs. Underwater irradiators do not have radiation rooms.
- (10) "Seismic area" means any area where the probability of a 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 U.S. Geological Survey.
- (11) "Underwater irradiator" means an irradiator in which the sources always remain shielded under water and personnel cannot access the sealed source or the space subject to irradiation without entering the pool.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1502.

SUBPART B
SPECIFIC LICENSING REQUIREMENTS

64E-5.1403 Specific License for Large Irradiators. An application for a specific license to use sealed sources in a large irradiator shall be made as specified in 64E-5.207. A separate license is required for each large irradiator, radiation room or underwater irradiator. The department 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.

- (1) The applicant must satisfy the general requirements specified in 64E-5.208 and the requirements contained in this part.
- (2) The applicant must describe training for irradiator operators which includes the following:
 - (a) At least 40 hours of classroom training;
 - (b) At least 160 hours of on-the-job or simulator training;
 - (c) Safety reviews;
 - (d) The means the applicant will use to evaluate the operator's knowledge and understanding of and ability to comply with the department's rules and licensing requirements and the applicant's operating and emergency procedures; and
 - (e) The minimum qualifications of personnel who provide training.
- (3) The applicant shall submit an outline or summary of the written operating and emergency procedures specified in 64E-5.1417. The outline or summary must include important radiation safety aspects of the procedures.
- (4) The applicant shall describe the radiation safety responsibilities and authority of the radiation safety officer and other management personnel and specify who has the authority to stop unsafe operations. The applicant also shall describe the qualifications required of the radiation safety officer.
- (5) The applicant shall submit a description of the access control systems required by 64E-5.1406, the radiation monitors required by 64E-5.1409, the method to detect leaking sources required by 64E-5.1420, including the sensitivity of the method, and a diagram of the facility which shows the position of all required interlocks and radiation monitors.
- (6) The applicant shall assure that any radioactive source not used in the irradiation process shall be removed from the irradiator pool and disposed of or returned to the manufacturer unless otherwise approved by the department.

- (7) If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the department for approval. The procedures must include the following:
 - (a) Instruments to be used;
 - (b) Methods of performing the analysis; and
 - (c) Pertinent experience of individuals who analyze the samples.
- (8) If licensee personnel load or unload sources, the applicant shall describe the qualifications of the personnel and the procedures to be used. If the applicant contracts for source loading or unloading, the loading or unloading must be done by an organization licensed by the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state to load or unload irradiator sources.
- (9) The applicant shall perform operational tests on the following to ensure proper functioning of all equipment and safety devices before the irradiator is loaded with sources:
 - (a) Interlock and radiation safety systems;
 - (b) Pool integrity and plumbing;
 - (c) Source rack mechanical positioning system;
 - (d) Source rack movement and position sensing systems;
 - (e) Source rack electrical control system;
 - (f) Uninterruptable electrical power supply for radiation monitoring warning systems;
 - (g) Fire protection system;
 - (h) Emergency systems for returning a stuck source rack into the pool;
 - (i) Systems used for transferring sources to and from transport vehicles; and
 - (j) Product conveyor system.
- (10) The applicant shall describe the operational inspection and maintenance program, including the frequency of operational checks required by 64E-5.1421.
- (11) The roof plug opening or removable shielding providing access for the loading and removal of sources shall be large enough to accommodate the largest applicable transportation cask.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1503.

64E-5.1404 Start of Construction.

- (1) The applicant shall not begin construction of a new irradiator before sending a license application to the department for the irradiator. As used in this paragraph, the term "construction" includes the construction of any portion of the permanent facility on the site but does not include:
 - (a) Engineering and design work;
 - (b) Purchase of the site;
 - (c) Site surveys or soil testing;
 - (d) Site preparation;
 - (e) Site excavation;
 - (f) Construction of warehouse structures; and
 - (g) Other similar tasks.
- (2) Site requirements for an irradiator include geological, radiological and hydrological testing to ensure a stable environment before construction begins. Records of the results of the siting requirements shall be maintained for the life of the facility.
- (3) Any activities undertaken before the issuance of a license will be entirely at the risk of the applicant and will have no bearing on the issuance of a license.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1504.

SUBPART C**DESIGN AND PERFORMANCE REQUIREMENTS FOR LARGE IRRADIATORS****64E-5.1405 Performance Criteria for Sealed Sources.**

- (1) The licensee shall assure that sealed sources installed after August 14, 1996 meet the requirements of this section. A prototype of the sealed source must be leak tested and found leak-free after each of the following tests:
 - (a) Temperature. The test source must be held at minus 40 degrees Celsius for 20 minutes, 600 degrees Celsius for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600 degrees Celsius to 20 degrees Celsius within 15 seconds.
 - (b) Pressure. The test source must be subjected twice to an external pressure of 290 pounds per square inch absolute for at least 5 minutes.
 - (c) Impact. A 2 kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

- (d) Vibration. The test source must be subjected three times for 10 minutes each time to a range of vibration from 25 Hertz to 500 Hertz at 5 times the acceleration of gravity for 30 minutes. Each test source must be vibrated for 30 minutes at each resonant frequency found.
 - (e) Puncture. A 50 gram weight and pin, 0.3 centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.
 - (f) 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 the support cylinders is 10 times the minimum cross-sectional dimension of the source.
- (2) Sealed sources installed after August 14, 1996 must be doubly encapsulated, the isotope or isotope and matrix contained within the sealed sources must be as nondispersible and insoluble as practical or rendered insoluble in water if the source is used in a wet-source-storage or wet-source-change irradiator and must satisfy the requirements specified in 64E-5.210(14).

Specific Authority: 404.051(4), F.S.
Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
History: New August 14, 1996, Formerly 10D-91.1505.

64E-5.1406 Access Control.

- (1) Panoramic irradiators shall not be operated unless the following are met:
 - (a) Each entrance to a radiation room must have a door or other physical barrier to prevent inadvertent entry of personnel while the sources are exposed. Product conveyor systems can serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if any door or barrier to the radiation room is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The primary entry door must have a lock which is operated by the same key used to control source movement. The doors and barriers must not prevent any individual in the radiation room from leaving.
 - (b) Each entrance to a radiation room must have an independent backup access control to detect personnel entry while the sources are exposed if the primary access control fails. Entry while the sources are exposed must cause the sources to return to their fully shielded position and also must activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm also must alert at least one other individual of the entry who is on site and who is trained to render or summon assistance promptly.

- (c) A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when the monitor detects high radiation levels. The monitor must generate audible and visible alarms if high radiation levels are detected when personnel entry is attempted. The monitor can be located in the entrance or maze but not in the direct radiation beam.
- (d) Before sources move from their shielded position, the source control automatically must 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 before the sources leave the shielded position.
- (e) Each radiation room must have a clearly visible and readily accessible control which will allow an individual in the room to return the sources to their fully shielded position.
- (f) Each radiation room must contain a control which allows the sources to move from the shielded position only if the control has been activated and the door or barrier to the radiation room subsequently has been closed within a preset time.
- (g) Each entrance to the radiation room and each entrance to the area within the personnel access barrier of an underwater irradiator must be posted as required by Rule 64E-5.323, F.A.C. Panoramic irradiators also must be posted as required by Rule 64E-5.323, F.A.C. The sign can be removed, covered, or otherwise made inoperative when the sources are shielded fully.
- (h) If the radiation room has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement can be met by interlocks which prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

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- (2) Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management shall have access to 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 on site, who is prepared to respond or summon assistance.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

R2 History: New August 14, 1996, Formerly 10D-91.1506, **Amended October 8, 2000.**

64E-5.1407 Shielding.

- (1) The radiation dose rate in areas which normally are occupied during operation of a panoramic irradiator must not exceed 2 millirem (0.02 millisievert) per hour at 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Areas where the radiation dose rates exceed 2 millirem (0.02 millisievert) per hour must be locked, roped off, or posted to prevent access and not entered without written approval or in the physical presence of the radiation safety officer or his designee.
- (2) The radiation dose at 30 centimeters over the pool of a pool irradiator when the source is in the fully shielded position must not exceed 2 millirem (0.02 millisievert) per hour.
- (3) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator must not exceed 2 millirem (0.02 millisievert) per hour and at 5 centimeters from the shield must not exceed 20 millirem (0.02 millisievert) per hour.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1507.

64E-5.1408 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 who is prepared to summon assistance promptly. The sources must become fully shielded automatically and the air handling systems within the radiation room must be disabled automatically if a fire is detected.
- (2) The radiation room at a panoramic irradiator must be equipped with a fire suppression or extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1508.

64E-5.1409 Radiation Monitors.

- (1) Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radiation sources which are 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 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) For pool irradiators, the licensee shall provide a means to detect radioactive contamination in pool water each day the irradiator operates. The means can be either an on-line radiation monitor on the pool water purification system or an analysis of pool water. If the licensee uses an on-line radiation monitor, the detection of above normal background radiation levels must activate the alarm. The alarm set-point must be set as low as practical but high enough to avoid false alarms. If a false alarm due to background radiation occurs, the alarm set-point must be increased. Activation of the alarm must cause the water purification system to shut off automatically. However, the licensee can reset the alarm set-point to a higher level if necessary to operate the pool purification system to clean up contamination in the pool as provided specifically in written emergency procedures.
- (3) Underwater irradiators which are 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 can have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1509.

64E-5.1410 Control of Source Movement.

- (1) The mechanism which moves the sources of a panoramic irradiator must require a key to operate. Operation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key shall be available for use at any time and only operators or facility management can possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock must be designed so that the key cannot be removed if the source is in an unshielded position. The door to the radiation room must require the same key. The key must be in the possession of a person entering the radiation room.
- (2) The console of a panoramic irradiator must have a source position indicator which indicates when the sources are in the fully shielded position, when they are in transit, and when they are exposed.

- (3) The control console of a panoramic irradiator must have a control which promptly returns the sources to the shielded position.
- (4) Each control for a panoramic irradiator must be labeled clearly as to its function.
- (5) Controls for a panoramic irradiator must be color-coded or illuminated as follows:
 - (a) Red represents emergency or critical information;
 - (b) Yellow or orange represents caution, no emergency but some function taking place to be aware of; and
 - (c) Green or blue represents normal or safe functioning or information.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1510.

64E-5.1411 Irradiator Pools.

- (1) For licenses initially issued after August 14, 1996, irradiator pools must possess a watertight stainless steel liner or a liner metallurgically compatible with other components in the pool or be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination and must include a means of safely storing sources during repairs of the pool.
- (2) For licenses initially issued after August 14, 1996, irradiator pools must have no penetration more than 0.5 meter below the normal low water level which could allow water to drain out of the pool. Pipes which have intakes more than 0.5 meter below the normal low water level must have siphon breakers to prevent the siphoning of the pool.
- (3) A means must be provided to replenish water losses from the pool.
- (4) An audible and visible indicator must be provided 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 level of conductance not exceeding 20 microsiemens per centimeter 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 irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier can 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 must not exceed 2 millirem (0.02 millisievert) per hour.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1511.

64E-5.1412 Source Rack Protection. If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism which moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism. A collision alarm system on the protective barrier must cause an alarm at the control console notifying the operator that a collision between the barrier and product conveyor has occurred.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1512.

64E-5.1413 Power Failures.

- (1) If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must return automatically 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 around the pool of an irradiator shall not be entered without using an operable and calibrated radiation survey meter.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1513.

64E-5.1414 Design Requirements. Irradiators whose construction begins after August 14, 1996 must meet the design requirements of this section. The requirements must be met before the start of the construction of the specific component, but do not have to be met before submitting a license application. After construction of the irradiator is completed, the licensee must submit to the department copies of as-built construction drawings signed by the architect and the licensee.

- (1) Panoramic irradiators shall meet the following design requirements:
 - (a) Shielding. The licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and shall design the walls, wall penetrations, and entrance ways to meet the radiation shielding requirements of 64E-5.1407. If the irradiator will use more than 2×10^{17} becquerels (5 million curies) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.
 - (b) Foundations. The licensee shall design the foundation with consideration given to soil characteristics to ensure it is adequate to support the weight of the facility.

- (c) Source Rack. 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. The licensee shall review the design of the mechanism which moves the sources to assure that the likelihood of a stuck source is low and that if the rack sticks it can be freed without causing radiation overexposure of personnel.
 - (d) Access Control. The licensee shall verify from the design and logic diagram that the access control system will meet the requirements of 64E-5.1406.
 - (e) Fire Protection. The licensee shall verify that the number, design, locations and spacing of the smoke and heat detectors and extinguishing system 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.
 - (f) Source Return. The licensee shall verify that the source rack will be returned automatically to the fully shielded position if off-site power is lost for more than 10 seconds. If a component of the return mechanism fails, the design must allow for accomplishing the return without causing radiation overexposures of personnel.
 - (g) Seismicity. 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 seismic requirements of an appropriate source such as American Concrete Institute Standard 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes.
 - (h) Wiring. 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.
- (2) Pool irradiators shall meet the following design requirements:
- (a) Pool Integrity. 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 penetrations meet the requirements of 64E-5.1411(2), and that metal components are metallurgically compatible with other components in the pool.

- (b) Water Handling System. The licensee shall design the water purification system to meet the requirements of 64E-5.1411(5). The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored. The licensee shall design the water chiller system so that it shall compensate adequately for the amount of heat generated by the sealed sources. The water handling system must have remote controls capable of safely operating a contaminated system.
 - (c) Source rack. 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. The lift mechanisms for the source rack and source transport cask must be of designed working and breaking strength to lift safely a source transport cask and sources into and out of the irradiator pool.
- (3) All irradiators shall meet the following design requirements:
- (a) Radiation Monitors. The licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by 64E-5.1409(1). The licensee shall verify that the product conveyor will stop before a source on the product conveyor causes a radiation overexposure. For pool irradiators, the licensee shall verify that the radiation monitor on the water purification system is located near the area in which elevated radiation levels will be expected.
 - (b) Product carriers. For irradiators using product carriers, the design of the carrier shall prevent the carrier from opening or coming into contact with the source rack or protective barrier. The design shall be submitted to the department for approval.
 - (c) Floor penetrations. No floor penetrations, including expansion joints, floor joints and drains, shall allow the uncontrolled release of water from the radiation room that has not been analyzed for its radioactive content.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1514.

64E-5.1415 Construction Control. The requirements of this section must be met before loading sources.

- (1) Panoramic irradiators shall meet the following construction requirements:
 - (a) **Shielding.** The licensee shall monitor the construction of the shielding to verify that it meets design specifications and generally accepted building code requirements for reinforced concrete.
 - (b) **Foundations.** The licensee shall monitor the construction of the foundations to verify that they meet design specifications.
 - (c) **Source Rack.** The licensee shall 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 shall observe and test the operation of the conveyor system to assure that the requirements in 64E-5.1412 and 64E-5.1414(3)(b) are met for protection of the source racks and the mechanism which moves the rack. Testing must include any limit switches and interlocks used to protect the source rack and the mechanism which moves the rack from moving product carriers.
 - (d) **Access Control.** The licensee shall test the access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.
 - (e) **Fire Protection.** The licensee shall verify the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to become fully shielded automatically. The licensee also shall verify the operability of the fire suppression or extinguishing system.
 - (f) **Source Return.** The licensee shall demonstrate that the source racks can be returned to their fully shielded position without off-site power.
 - (g) **Computer Systems.** If a computer is used to control the access control system, the licensee shall demonstrate that the computer and the access control system will operate as planned if off-site power is lost by attempting to defeat the access control system in as many ways as possible. The computer must have suitable security features which prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.
 - (h) **Wiring.** The licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

- (2) Pool irradiators shall meet the following construction requirements:
- (a) Pool Integrity. The licensee shall test the integrity of the pool and verify that the pool meets the design specifications. The licensee shall verify that penetrations and water intakes meet the requirements of 64E-5.1411(2).
 - (b) Water Handling System. The licensee shall verify that the water purification system, the conductivity meter and the water level alarms operate properly.
- (3) 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 related alarms and interlocks required by 64E-5.1409(1). For pool irradiators, the licensee shall verify the proper operation of the radiation monitor on the water purification system and the related alarms and interlocks required by 64E-5.1409(2). For underwater irradiators, the licensee shall verify the proper operation of the pool monitor, alarms, and interlocks required by 64E-5.1409(3).

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1515.

SUBPART D OPERATION OF IRRADIATORS

64E-5.1416 Training.

- (1) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in the following:
- (a) The fundamentals of radiation protection applied to irradiators, including:
 - 1. The difference between external radiation and radioactive contamination;
 - 2. Units of radiation dose;
 - 3. The department's dose limits;
 - 4. Why large radiation doses must be avoided;
 - 5. How shielding and access controls prevent large doses;
 - 6. How an irradiator is designed to avoid contamination;
 - 7. The use of survey meters and personnel dosimeters;
 - 8. Other radiation safety features of an irradiator; and
 - 9. The basic function of the irradiator.

- (b) The requirements of this part and Part IX of these rules;
 - (c) The operation of the irradiator;
 - (d) Licensee operating and emergency procedures which the individual is responsible for performing; and
 - (e) Case histories of accidents or problems involving irradiators similar to those to be used by the individual.
- (2) Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received, consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to operate the irradiator safely without supervision.
- (3) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job or simulator training in the use of the irradiator as described in the license application. The individual also shall demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.
- (4) The licensee shall conduct safety reviews and emergency drills as described below for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:
- (a) Changes in operating and emergency procedures since the last review;
 - (b) Changes in rules and license conditions since the last review;
 - (c) Reports on recent accidents, mistakes, or problems which have occurred at irradiators;
 - (d) Relevant results of inspection 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 rules, license conditions, and operating 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 irradiators but who have not received the training required for operators and the radiation safety officer shall be trained and tested in precautions they should take to avoid radiation exposure, procedures or parts of procedures in 64E-5.1418 which they are expected to perform or comply with, and the proper response to alarms required in this part. Tests can be oral.
- (7) Individuals who must be prepared to respond to alarms required by 64E-5.1406, 64E-5.1408, 64E-5.1409, 64E-5.1411, and 64E-5.1412 shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests can be oral.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1516.

64E-5.1417 Operating and Emergency Procedures.

- (1) The licensee shall have and follow written operating procedures for the following:
 - (a) Operation of the irradiator, including entering and leaving the radiation room;
 - (b) Use of personnel dosimeters;
 - (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 64E-5.1422;
 - (g) Loading, unloading, and repositioning sources, if to be performed by the licensee;
 - (h) Inspection of movable shielding required by 64E-5.1406(1)(h), if applicable; and
 - (i) Security precautions while sources are stored outside the radiation room. Sealed sources must be moved into the radiation room within 48 hours of receipt unless the department is notified in writing that extenuating circumstances do not allow for source loading within the prescribed 48 hour period.
- (2) The licensee shall have and follow emergency or abnormal event procedures for the following:
 - (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 sources, pool contamination, or alarm caused by contamination of pool water;
 - (e) A low water level alarm, a high water level alarm, 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, the area around the pool, or another alarmed area;
 - (i) Natural phenomena, including an earthquake, a hurricane, a tornado, flooding, sinkhole formation, or other phenomena; and
 - (j) The jamming of automatic conveyor systems or an alarm indicating a collision between the barrier and product conveyor.
- (3) The licensee can revise operating and emergency procedures only with departmental approval.
- (4) The licensee shall provide and coordinate current emergency procedures annually with the local police, fire department, and civil authorities, including notification of responsible individuals and places of emergency treatment.

Specific Authority: 404.051(4), F.S.
Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
History: New August 14, 1996, Formerly 10D-91.1517.

64E-5.1418 Personnel Monitoring.

- R2 (1) Irradiator operators shall wear either a film badge, OSLD or a TLD while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge, OSLD, and TLD processor must be accredited by NVLAP for high energy photons in the normal and accident dose ranges. Each film badge, OSLD, and TLD must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and OSLDs and TLDs must be replaced at least quarterly. After replacement, each film badge OSLD, and TLD must be processed promptly.
- R2
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- (2) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which can be a pocket dosimeter. For groups of visitors, only two people are required to wear dosimeters. Date of entry, all names and total dose must be recorded. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response must be done at least annually. Acceptable dosimeters must read within 30 percent of the true radiation dose.

Specific Authority: 404.051(4), F.S.
Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
R2 History: New August 14, 1996, Formerly 10D-91.1518, Amended October 8, 2000.

64E-5.1419 Radiation Surveys.

- (1) Before the facility starts operation, the following radiation surveys must be performed:
 - (a) A radiation survey of the area above the pool after the sources are loaded and in the shielded position; and
 - (b) A survey of the area outside the shielding of the radiation room of a panoramic irradiator with the sources in the exposed position.
- (2) If the surveys indicate that radiation levels specified in 64E-5.1407 are exceeded, the shielding must be repaired to comply with the dose rate requirement in 64E-5.1407 before operation of the facility can start.
- (3) Radiation surveys described in (1) above must be performed after new sources are loaded and after any modifications which might increase dose rates are made to the radiation room, shielding or structure and at intervals not to exceed 3 years.
- (4) Portable radiation survey meters used to meet the requirements of paragraphs (1) and (3) of this section and the requirements of 64E-5.1413(3) and 64E-5.1424(1) must be calibrated at least annually to an accuracy of 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 that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.
- (5) Water from the irradiator pool or other potentially contaminated liquids and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table II, Column 2, or Table III, as applicable. The lower limit of detection for the measurements must be below those concentrations.
- (6) Resins to be released for unrestricted use must be monitored before release in an area with a background level less than 0.05 millirem (0.0005 millisievert) per hour. The resins can be released only if the survey does not detect radiation levels above background radiation levels. The survey meter must be capable of detecting radiation levels of 0.05 millirem (0.0005 millisievert) per hour.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1519.

64E-5.1420 Detection of Leaking or Contaminated Sources.

- (1) Each dry-source-storage sealed source must be tested for leakage at least every 6 months using a leak test kit or a method approved by the department, U.S. Nuclear Regulatory Commission, agreement state or licensing state. The analysis must be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material and must be performed by a person approved by the department, U.S. Nuclear Regulatory Commission, agreement state or licensing state to perform the analysis.
- (2) For pool irradiators, the pool water must be checked for contamination each day the irradiator operates. The check must be done by using an on-line radiation monitor on a pool water circulating system as described in 64E-5.1410(2) or by analysis of pool water. If a check for contamination is done by analysis 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 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 can reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.
- (3) The licensee shall have written procedures and equipment available for the detection, isolation and removal of leaking sources.
- (4) If a leaking source is detected, the licensee shall remove the leaking source from service and have it decontaminated, repaired, or disposed of by a licensee of the department, U.S. Nuclear Regulatory Commission, agreement state or licensing state authorized to perform these functions. The licensee shall check its personnel, equipment, facilities, and irradiated product promptly for radioactive contamination. No product shall be shipped until the product has been checked and found free of contamination. If a product has been shipped that could have been contaminated inadvertently, the licensee shall arrange to locate and survey that product for contamination. If any personnel are contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall have them decontaminated or disposed of by a licensee of the department, U.S. Nuclear Regulatory Commission, agreement state or licensing state authorized to perform these functions. If the pool water is contaminated, the licensee shall clean the pool water until the contamination levels do not exceed the appropriate concentration in State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations, July 1993, Table II, Column 2.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1520.

64E-5.1421 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) Operation of each aspect of the access control system required by 64E-5.1406;
 - (b) Functioning of the source position indicator required by 64E-5.1410(2);
 - (c) Operation of the radiation monitor on the pool water purification system using a radioactive check source to detect radioactive contamination in pool water as required by 64E-5.1409(2);
 - (d) Operation of the over-pool radiation monitor at underwater irradiators as required by 64E-5.1409(3).
 - (e) Operation of the product exit monitor required by 64E-5.1409(1);
 - (f) Operation of the emergency source return control required by 64E-5.1410(3);
 - (g) Leak-tightness of systems through which pool water circulates (visual inspection);
 - (h) Operation of the heat and smoke detectors and extinguisher system required by 64E-5.1408 but without turning on extinguishers;
 - (i) Operation of the means of pool water replenishment required by 64E-5.1411(3);
 - (j) Operation of the visible indicator of low and high pool water level required by 64E-5.1411(4);
 - (k) Operation of the intrusion alarm required by 64E-5.1406(2);
 - (l) Functioning and wear on 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 and the operation of the collision alarm system, as required by 64E-5.1412;
 - (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 64E-5.1422;
 - (q) Condition of the product carriers; and

- (r) Operation of the siphon breakers in the pool plumbing.
- (2) Malfunction and defects found during inspection and maintenance checks must be repaired without undue delay.

Specific Authority: 404.051(4), F.S.
Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
History: New August 14, 1996, Formerly 10D-91.1521.

64E-5.1422 Pool Water Purity.

- (1) Pool water purification systems 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 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 frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

Specific Authority: 404.051(4), F.S.
Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
History: New August 14, 1996, Formerly 10D-91.1522.

64E-5.1423 Attendance During Operation.

- (1) An operator and at least one other individual trained and prepared to render or summon assistance promptly if the access control alarm sounds shall be present on site whenever a panoramic irradiator is operated using an automatic product conveyor system and whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.
- (2) At an underwater irradiator, an operator must be present 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 64E-5.1416(6) and (7). Static irradiation can be performed without a person present at the facility only if the personnel access barrier around the pool is locked to prevent unauthorized entry and all required alarms are operable.

Specific Authority: 404.051(4), F.S.
Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.
History: New August 14, 1996, Formerly 10D-91.1523.

64E-5.1424 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 before entry. The response of the survey meter to the radiation check source must be consistent and reproducible.
- (2) Before exiting from and locking the door to the radiation room of a panoramic irradiator before a planned irradiation, the irradiator operator shall perform the following:
 - (a) Inspect visually the entire radiation room to verify that no one else is in it; and
 - (b) Activate a control in the radiation room which permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.
 - (c) During a power failure, the area around the pool of an underwater irradiator cannot be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by 64E-5.1409(3) is operating with backup power.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1524.

64E-5.1425 Irradiation of Explosive or Highly Flammable Materials.

- (1) Irradiation of explosive materials is prohibited unless the licensee has received prior written authorization from the department. 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 highly flammable material with a flash point below 140 degrees Fahrenheit is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the department. 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.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1525.

**SUBPART E
RECORDS AND REPORTS**

64E-5.1426 Records and Retention Periods.

- (1) The licensee shall maintain the following records at the irradiator for the periods specified:
 - (a) A copy of the license application and the license authorizing the licensee to operate the facility until a new license is issued;
 - (b) Records of each individual's training, tests, and safety reviews provided to meet the requirements of 64E-5.1416 until 3 years after the individual terminates work;
 - (c) Records of the annual evaluation of the safety performance of irradiator operators required by 64E-5.1416(5) for 3 years after the evaluation;
 - (d) An up-to-date copy of the operating and emergency procedures required by 64E-5.1417 until superseded or the department terminates the license;
 - (e) Personnel monitoring results required by 64E-5.1418 until the department terminates the license;
 - (f) Records of radiation surveys required by 64E-5.1420 for 3 years from the date of the survey;
 - (g) Records of radiation survey meter calibrations required by 64E-5.1419 and pool water conductivity meter calibrations required by 64E-5.1422(2) until 3 years from the date of the calibration;
 - (h) Records of the results of leak tests required by 64E-5.1420 and the results of contamination checks required by 64E-5.1420(2) for 3 years from the date of the leak tests;
 - (i) Records of inspection and maintenance checks required by 64E-5.1421 for 3 years;
 - (j) Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for 3 years after repairs are completed;
 - (k) Records of the receipt, transfer and disposal of all licensed sealed sources as required by 64E-5.103.
 - (l) An inventory of all licensed sealed sources until the irradiator is decommissioned. The inventory must include for each sealed source the following:
 1. The date received;

2. The person from whom it was received;
 3. The model of the source;
 4. The serial number of the source;
 5. The radionuclide in the source;
 6. The activity of the source as supplied from the manufacturer and the date of the assigned activity;
 7. An up-to-date location of the source;
 8. Information on leaking or damaged sources and any actions taken to decontaminate or repair those sources;
 9. The date disposed of; and
 10. The person to whom the source was transferred.
- (m) Records on the design checks required by 64E-5.1414 and the construction control checks required by 64E-5.1415 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included;
- (n) Records of water added to the pool as required by 64E-5.1421(1)(n) for 3 years;
- (o) Records related to decommissioning the irradiator as required by 64E-5.214(4)(c)2.
- (p) Records of annual notification to local police, fire department and civil authorities of the current emergency procedures, responsible individuals and places of emergency treatment for 3 years;
- (q) Records of conductivity meter calibration as required by 64E-5.1422(2) for 3 years; and
- (r) Records of written approval of access to restricted areas as required by 64E-5.1407(1) for 3 years.
- (2) Records required by this section shall be available for inspection by the department.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1526.

64E-5.1427 Reports and Notifications.

- (1) In addition to the other reporting requirements in these rules, each licensee shall notify the department as soon as possible but not later than 4 hours after the discovery of the following events:
 - (a) Threats of violence or acts of terrorism against the operation of this facility;
 - (b) Fire or explosion in the radiation room;
 - (c) Detection of radiation by the product portal monitors;
 - (d) Detection of any radioactive contamination.
 - (e) Sources stuck in an unshielded position;
 - (f) Damage to source racks;
 - (g) Failure of the cable or drive mechanism used to move the source racks;
 - (h) Inoperability of the access control system;
 - (i) Structural damage to the pool liner or walls;
 - (j) Abnormal water loss or leakage from the source storage pool; or
 - (k) Pool water conductivity exceeding 100 microsiemens per centimeter.
- (2) The licensee must submit a written report within 30 days for any reports required by paragraph (1) above. The report must describe the event, what caused the event to the extent known, and corrective actions to prevent recurrence taken up to the time the report is made.
- (3) The licensee shall notify individuals of their exposure to radiation or radioactive materials as required by 64E-5.903.
- (4) The licensee shall notify the department at least 14 days before a source loading or unloading.

Specific Authority: 404.051(4), F.S.

Law Implemented: 404.051(1)(5)(6), 404.061, 404.081, 404.141, F.S.

History: New August 14, 1996, Formerly 10D-91.1527.