# TITLE 32: ENERGY CHAPTER II: ILLINOIS EMERGENCY MANAGEMENT AGENCY SUBCHAPTER b: RADIATION PROTECTION

# PART 346 LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

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AUTHORITY: Implementing and authorized by the Radiation Protection Act of 1990 [420 ILCS 40/10].

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SUBPART A: GENERAL PROVISIONS

# Section 346.10 Purpose

This Part contains requirements for the issuance of a license by the Illinois Emergency Management Agency (Agency), authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. Also included are radiation safety requirements for irradiators currently in operation.

# Section 346.20 Scope

- a) This Part is in addition to, and not in substitution for, other Parts in 32 Ill. Adm. Code: Chapter II, Subchapter b. The requirements of 32 Ill. Adm. Code: Chapter II, Subchapter b apply to applicants and licensees subject to this Part. Nothing in this Part 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.
- b) This Part also applies to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed

sources in air or in water, as applicable to the irradiator type, are covered by this Part.

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

#### **Section 346.30 Incorporations by Reference**

All rules, standards and guidelines of agencies of the United States or nationally recognized organizations or associations that are incorporated by reference in this Part are incorporated as of the date specified in the reference and do not include any later amendments or editions. Copies of rules, standards or guidelines that have been incorporated by reference are available for public inspection and copying at the Agency, 1035 Outer Park Drive, Springfield, Illinois.

AGENCY NOTE: In this Part, the Agency has incorporated by reference Title 10 of the Code of Federal Regulations (10 CFR 36; 2004).

#### **Section 346.40 Definitions**

"Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

"Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable to 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.

"Irradiator operator" means an individual who has successfully completed the training and testing described in Section 346.510 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

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

"Panoramic irradiator" means an irradiator in which the irradiations are done in air and in areas potentially accessible to personnel. The term includes beam-type irradiators.

"Panoramic wet-source-storage irradiator" means 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.

"Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water, including panoramic wet-source-storage irradiators and underwater irradiators.

"Product conveyor system" means a system for moving the product to be irradiated to, from and within the area where irradiation takes place.

"Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

"Sealed source" means any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the radioactive material.

"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.

"Underwater irradiator" means an irradiator in which the sources always remain shielded under water and personnel do not have access to the sealed sources or the space subject to irradiation without entering the pool.

(Source: Amended at 47 Ill. Reg. 9201, effective June 22, 2023)

#### SUBPART B: SPECIFIC LICENSING REQUIREMENTS

#### **Section 346.110 Application for Specific License**

A person, as defined in 32 Ill. Adm. Code 310.20, may file an application for a specific license authorizing the use of sealed sources in an irradiator on the Agency's application form entitled "Application Form for Non-Medical Radioactive Material License". Applications shall be filed in accordance with 32 Ill. Adm. Code 330.240.

# Section 346.130 Specific License for Irradiators

The Agency will approve an application for a specific license to operate an irradiator if the applicant meets the requirements contained in this Section.

- a) The applicant shall satisfy the general requirements specified in 32 Ill. Adm. Code 330.250 and the requirements contained in this Part.
- b) The application shall describe the training provided to irradiator operators including:
  - 1) Classroom training;
  - 2) On-the-job or simulator training;
  - 3) Safety reviews;
  - 4) Means employed by the applicant to test each operator's understanding of the Agency's regulations and licensing requirements and the irradiator operating and emergency procedures; and
  - 5) Minimum training and experience of personnel who may provide training.
- c) The application shall include an outline of the written operating and emergency procedures listed in Section 346.530 of this Part that describe the radiation safety aspects of the procedures.
- d) The application shall describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application shall specify who, within the management structure, has the authority to stop unsafe operations. The application shall also describe the training and experience required for the position of radiation safety officer.
- e) The application shall include a description of the access control systems required by Section 346.230 of this Part, the radiation monitors required by Section 346.290 of this Part, the method of detecting leaking sources required by Section 346.590 of this Part, including the sensitivity of the method, and a diagram of the facility that shows the location of all required interlocks and radiation monitors.
- f) An application for a panoramic irradiator shall include a description of the facility shielding and fire protection system.

- g) An application for a pool irradiator shall include a description of the irradiator pool construction, water level indicators, purification systems and source rack and protection system.
- h) If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Agency. The description shall include the:
  - 1) Instruments to be used;
  - 2) Methods of performing the analysis; and
  - 3) Pertinent experience of the personnel analyzing the samples.
- i) If the licensee's personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading shall be done by an organization specifically authorized by the Agency, U.S. Nuclear Regulatory Commission or an Agreement State to load or unload irradiator sources.
- j) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by Section 346.610 of this Part.
- k) A professional engineer licensed in Illinois shall seal all construction and design plans and specification documents submitted for review by the Agency.
- l) Appropriate Agency license fees, as specified in 32 Ill. Adm. Code 331: Appendix F, shall be paid prior to the approval of the specific license.

# **Section 346.150 Commencement of Construction**

Commencement of construction of a new irradiator may not occur prior to submission to the Agency of an application for a license for the irradiator. As used in this Section, the term "construction" is defined in 32 Ill. Adm. Code 310.20. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Radiation Protection Act of 1990 and regulations and orders issued under the Act. Commencement of construction as defined in 32 Ill. Adm. Code 310.20 may include non-construction activities if the activity has a reasonable nexus to radiological safety and security.

(Source: Amended at 47 Ill. Reg. 9201, effective June 22, 2023)

# SUBPART C: DESIGN AND PERFORMANCE REQUIREMENTS OF IRRADIATORS

#### Section 346.210 Performance Criteria for Sealed Sources

- a) Requirements. Sealed sources installed after December 1, 2005:
  - 1) Shall have an evaluation sheet issued by the Agency, an Agreement State, a Licensing State or the U.S. Nuclear Regulatory Commission;
  - 2) Shall be doubly encapsulated;
  - 3) Shall use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator. Cs-137 sources are prohibited from use in a wet-source-storage or wet-source-change irradiator;
  - 4) Shall 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;
  - 5) In prototype testing of the sealed source, shall have been leak tested and found leak-free after each of the tests described in subsections (b) through (g) of this Section.
- b) Temperature. The test source shall be held at -40°C for 20 minutes, 600°C for one hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.
- c) Pressure. The test source shall be twice subjected for at least 5 minutes to an external pressure (absolute) of 2 million newtons per square meter.
- d) Impact. A 2-kilogram steel weight, 2.5 centimeters in diameter, shall be dropped from a height of 1 meter onto the test source.
- e) Vibration. The test source shall be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source shall be vibrated for 30 minutes at each resonant frequency found.
- f) Puncture. A 50-gram weight and pin (0.3-centimeter pin diameter) shall be dropped from a height of 1 meter onto the test source.

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

#### Section 346.230 Access Control

- a) Each entrance to a radiation room at a panoramic irradiator shall have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyer systems may serve as barriers as long as they reliably and consistently function as a barrier. It shall not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed shall cause the sources to return promptly to their shielded position. The personnel entrance door or barrier shall have a lock that is operated by the same key used to move the sources. The doors and barriers shall not prevent any person in the radiation room from leaving.
- b) In addition, each entrance to a radiation room at a panoramic irradiator shall have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed shall cause the sources to return to their fully shielded position and shall also activate a visible and audible alarm to make the person entering the room aware of the hazard. The alarm shall also alert at least one other person who is onsite of the entry. That person shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.
- c) A radiation monitor shall be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor shall be integrated with a personnel access door to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels shall activate the alarm described in subsection (b). The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.
- d) Before the sources move from their shielded position in a panoramic irradiator, the source control shall automatically activate conspicuous visible and audible alarms to alert personnel in the radiation room that the sources will be moved from their shielded position. The alarms shall give personnel enough time to leave the room before the sources leave the shielded position.

- e) Each radiation room at a panoramic irradiator shall have a clearly visible and readily accessible control that would allow a person in the room to make the sources return to their fully shielded position.
- f) Each radiation room of a panoramic irradiator shall contain a control that prevents the sources from moving from the shielded positions unless the control has been activated and the door or barrier to the radiation room has been closed within a pre-set time after activation of the control.
- g) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator shall be posted as required by 32 Ill. Adm. Code 340.920. Radiation postings for panoramic irradiators shall comply with the posting requirements of 32 Ill. Adm. Code 340.920, except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.
- h) If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it shall not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.
- i) Underwater irradiators shall have a personnel access barrier around the pool that shall 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 shall be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm shall alert a person (not necessarily onsite) who is prepared to respond or summon assistance.

(Source: Amended at 47 Ill. Reg. 9201, effective June 22, 2023)

# Section 346.250 Shielding

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

- b) The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 millirems) per hour when the sources are in fully shielded position.
- c) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 millirems) per hour and at 5 centimeters from the shield may not exceed 0.2 millisievert (20 millirems) per hour.

(Source: Amended at 47 Ill. Reg. 9201, effective June 22, 2023)

#### **Section 346.270 Fire Protection**

- a) The radiation room at a panoramic irradiator shall have heat and smoke detectors. The detectors shall activate an audible alarm. The alarm shall be capable of alerting personnel prepared to summon assistance promptly. The sources shall automatically become fully shielded if a fire is detected.
- b) The radiation room at a panoramic irradiator shall be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room shall have a shut-off valve to control flooding into unrestricted areas.
- c) For fire suppression systems using an extinguishing gas, the radiation room ventilation system shall automatically shut down when the suppression system is activated.

#### **Section 346.290 Radiation Monitors**

- a) Irradiators with automatic product conveyor systems shall have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm shall sound and product conveyors shall stop automatically and the sources shall become fully shielded. The alarm shall be capable of alerting personnel in the facility who are prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this subsection.
- b) Underwater irradiators that are not in a shielded radiation room shall have a radiation monitor over the pool to detect abnormal radiation levels. The monitor shall have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off.

The alarm shall be capable of alerting personnel who are prepared to respond promptly.

#### **Section 346.310 Control of Source Movement**

- a) The mechanism that moves the source of a panoramic irradiator shall require a key to actuate. Actuation of the mechanism shall cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key shall be attached to a portable radiation survey meter by a chain or cable. The lock for source control shall be designed so that the key may not be removed if the sources are in an unshielded position. The personnel entrance door or barrier to the radiation room shall require the same key.
- b) The console of a panoramic irradiator shall have a source position indicator that indicates when the sources are in the fully shielded position, when the sources are in transit and when the sources are exposed.
- c) The control console of a panoramic irradiator shall have a control that promptly returns the sources to the shielded position.
- d) Each control for a panoramic irradiator shall be clearly marked as to its function.

#### Section 346.330 Irradiator Pools

- a) For licenses initially issued after December 1, 2005, irradiator pools shall either:
  - 1) Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or
  - 2) Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination.

In either case, the licensee shall have a method to safely store the sources during repair of the pool.

- b) For licenses initially issued after December 1, 2005, irradiator pools shall have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons shall have siphon breakers to prevent the siphoning of pool water.
- c) A means shall be provided to replenish water losses from the pool.

- d) A visible indicator shall be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.
- e) Irradiator pools shall be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.
- f) A physical barrier, such as a railing or cover, shall be used around or over radiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection and service operations.
- g) If long handled tools or poles are used in irradiator pools, the radiation dose rate in the handling areas of the tools may not exceed 0.02 millisievert (2 millirems) per hour.

(Source: Amended at 47 Ill. Reg. 9201, effective June 22, 2023)

#### **Section 346.350 Source Rack Protection**

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

(Source: Amended at 47 Ill. Reg. 9201, effective June 22, 2023)

#### **Section 346.370 Power Failures**

- a) If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources shall automatically return to the shielded position.
- b) The lock on the door of the radiation room of a panoramic irradiator shall not be deactivated by a power failure.
- c) During a power failure, the area of any irradiator where the sources are located may be entered only when using an operable and calibrated radiation survey meter.

d) If non-electrical power is used to control or operate any irradiator safety feature, failure of that power source shall automatically return the radiation sources to their fully shielded position.

# Section 346.390 Design Requirements

Irradiators whose construction begins after December 1, 2005, shall meet the design requirements of this Section.

- a) Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of Section 346.250. If the irradiator will use more than 2 x 10<sup>17</sup> becquerels (5 million curies) of activity, the licensee shall evaluate the effects of heating of the shielding by the irradiator sources.
- b) Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.
- c) Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of Section 346.330(b) and that metal components are metallurgically compatible with other components in the pool.
- d) Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of Section 346.330(e). The system shall be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.
- e) Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by Section 346.290(a). The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under Section 346.590(b), the licensee shall verify that the design of radiation monitoring systems to detect pool contamination included sensitive detectors located close to where contamination is likely to concentrate.
- f) Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would

promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternative means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

- g) Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of Section 346.230.
- h) Fire protection. For panoramic irradiators, the licensee shall verify that the number, location and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.
- i) Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.
- j) Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source, such as Chapter 21, "Special Provisions for Seismic Design", of the American Concrete Institute Standard "Building Code Requirements for Reinforced Concrete" (ACI 318-89) or local building codes, whichever is most current.
- k) Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

(Source: Amended at 47 Ill. Reg. 9201, effective June 22, 2023)

# Section 346.410 Construction Monitoring and Acceptance Testing

The requirements of this Section shall be met by irradiators whose construction begins after December 1, 2005. The requirements shall be met prior to loading sources.

- a) Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.
- b) Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.
- c) Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of Section 346.330(b) of this Part.
- d) Water handling systems. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter and the water level indicators operate properly.
- e) Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by Section 346.290(a) of this Part. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet Section 346.590(b) of this Part. For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by Section 346.290(b) of this Part.
- f) Source rack. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading. Testing shall include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in Section 346.350 of this Part are met for protection of the source rack and the mechanism that moves the rack. Testing shall include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.
- g) Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls and interlocks work properly.
- h) Fire protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the

- source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.
- i) Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.
- j) Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.
- k) Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

#### SUBPART D: OPERATION OF IRRADIATORS

# **Section 346.510 Training**

- a) Before personnel are permitted to operate an irradiator without a supervisor present, they shall be instructed in:
  - The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination; units of radiation dose; IEMA, Division of Nuclear Safety, dose limits; why large radiation doses shall be avoided; how shielding and access controls prevent large doses; how an irradiator is designed to prevent contamination; the proper use of survey meters and personnel dosimeters; other radiation safety features of an irradiator; and the basic function of the irradiator);
  - 2) The requirements of this Part and 32 Ill. Adm. Code 340 and 400 that are relevant to the irradiator;
  - 3) The operation of the irradiator;
  - 4) Those operating and emergency procedures listed in Section 346.530 that the person is responsible for performing;
  - 5) Case histories of accidents or problems involving irradiators.

- b) Before personnel are permitted to operate an irradiator without a supervisor present, they shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the person is responsible for performing and other operations necessary to safely operate the irradiator without supervision.
- c) Before personnel are permitted to operate an irradiator without a supervisor present, they shall have received on-the-job training or simulator training in the use of the irradiator as described in the license application, and shall also demonstrate the ability to perform those portions of the operating and emergency procedures that they are to perform.
- d) The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review shall include, to the extent appropriate, each of the following:
  - 1) Changes in operating and emergency procedures since the last review, if any;
  - 2) Changes in regulations and license conditions since the last review, if any;
  - Reports on recent accidents, mistakes or problems that have occurred at irradiators, if any;
  - 4) Relevant results of inspections of operator safety performance;
  - 5) Relevant results of the facility's inspection and maintenance checks; and
  - 6) A drill to practice an emergency or abnormal event procedure.
- e) The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions and operating and emergency procedures are followed. 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.
- f) Personnel who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for the operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in Section 346.530 that they are expected to perform or comply with, and their proper response to alarms required in this Part. Tests may be oral.

g) Personnel who shall be prepared to respond to alarms required by Sections 346.230(b), 346.230(i), 346.270(a), 346.290(a), 346.290(b), and 346.590(b) shall be trained and tested on how to respond. Each person shall be retested at least once a year. Tests may be oral.

(Source: Amended at 47 Ill. Reg. 9201, effective June 22, 2023)

# **Section 346.530 Operating and Emergency Procedures**

- a) The licensee shall have and follow written operating procedures for:
  - 1) Operation of the irradiator, including entering and leaving the radiation room;
  - 2) Use of personnel dosimeters;
  - 3) Surveying the shielding of panoramic irradiators;
  - 4) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
  - 5) Leak testing of sources;
  - 6) Inspection and maintenance checks required by Section 346.610 of this Part;
  - 7) Loading, unloading and repositioning sources, if the operations will be performed by the licensee; and
  - 8) Inspection of movable shielding required by Section 346.230(h) of this Part, if applicable.
- b) The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:
  - 1) Sources stuck in the unshielded position;
  - 2) Failure of hoists or cables involving the source racks;
  - 3) Personnel overexposures;
  - 4) A radiation alarm from the product exit portal monitor or pool monitor;

- 5) Detection of leaking sources, pool contamination or alarm caused by contamination of pool water;
- A low or high water level indicator or an abnormal water loss or leakage from the source storage pool;
- 7) A prolonged loss of electrical power;
- 8) A fire alarm or explosion in the radiation room;
- 9) An alarm indicating unauthorized entry into the radiation room, area around the pool or another alarmed area;
- 10) Natural phenomena, including an earthquake, tornado, flooding or other phenomena as appropriate for the geological location of the facility; and
- 11) The jamming of automatic conveyor systems.

## **Section 346.550 Personnel Monitoring**

- a) Irradiator operators shall wear a personnel dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter must be capable of detecting high energy photons in the normal and accident dose ranges. Personnel monitoring shall be provided in accordance with the requirements of 32 Ill. Adm. Code 340.510(d), (e) and (f).
- b) Each dosimeter shall be assigned to and worn by only one person. Film badges shall be processed at least monthly and all other personnel dosimeters that require replacement shall be replaced at least quarterly. All personnel dosimeters shall be evaluated at least quarterly or promptly after replacement, whichever is more frequent.
- c) Other personnel who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only 2 people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this subsection, a check of their response to radiation shall be done at intervals not to exceed 12 months. Acceptable dosimeters shall read within ±30 percent of the true radiation dose.

(Source: Amended at 47 Ill. Reg. 9201, effective June 22, 2023)

# Section 346.570 Radiation Surveys

- a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator shall be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area about the pool of pool irradiators shall be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding shall be performed at intervals not to exceed 3 years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.
- b) If the radiation levels specified in Section 346.250 are exceeded, the facility shall be modified to comply with the requirements in Section 346.250.
- c) Portable radiation survey meters used for required surveys shall be calibrated at intervals not to exceed 12 months to an accuracy of ±20% for the gamma energy of the sources in use. The calibration shall be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters shall be a type that does not saturate and read zero at high radiation dose rate.
- d) Water from the irradiator pool, other potentially contaminated liquids and sediments from pool vacuuming shall be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations shall not exceed those specified in table 2, column 2, or table 3 of Appendix B to 10 CFR 20, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage.", published at 72 Fed. Reg. 55922, October 1, 2007.
- e) Before releasing resins for unrestricted use, the resins shall be monitored in an area with a background level less than 0.5 microsievert (0.05 millirem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used shall be capable of detecting radiation levels of 0.5 microsievert (0.05 millirem) per hour.
- f) For pool irradiators, all empty or loaded source transport containers shall be surveyed for removable contamination prior to insertion into the pool.

(Source: Amended at 47 Ill. Reg. 9201, effective June 22, 2023)

**Section 346.590 Detection of Leaking Sources** 

- a) Each dry-source-storage sealed source shall be tested for leakage in accordance with the requirements of 32 Ill. Adm. Code 340.410.
- b) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within the 6 months before the transfer. Water from the pool shall be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis shall be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels shall activate an alarm. The alarm set-point shall be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.
- If a leaking source is detected, the licensee shall arrange to remove the leaking c) source from service and have it decontaminated, repaired or disposed of by an Agency, U.S. Nuclear Regulatory Commission, or Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination shall be performed promptly. If contaminated equipment, facilities or products are found, the licensee shall have them decontaminated or disposed of by an Agency, U.S. Nuclear Regulatory Commission, or Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in table 2, column 2, of Appendix B to 10 CFR 20, published at 72 Fed. Reg. 55922, October 1, 2007. (See 32 Ill. Adm. Code 340.1220 for reporting requirements.)

(Source: Amended at 47 Ill. Reg. 9201, effective June 22, 2023)

#### **Section 346.610 Inspection and Maintenance**

a) The licensee shall perform inspection and maintenance checks that include, at a minimum, each of the following at the frequency specified in the license or license application:

- 1) Operability of each aspect of the access control system required by Section 346.230 of this Part.
- 2) Functioning of the source position indicator required by Section 346.310(b) of this Part.
- 3) Operability of the radiation monitor for radioactive contamination in pool water required by Section 346.590(b) of this Part using a radiation check source, if applicable.
- 4) Operability of the over-pool radiation monitor at underwater irradiators as required by Section 346.290(b) of this Part.
- 5) Operability of the product exit monitor required by Section 346.290(a) of this Part.
- 6) Operability of the emergency source return control required by Section 346.310(c) of this Part.
- 7) Leak-tightness of systems through which pool water circulates (visual inspection).
- 8) Operability of heat and smoke detectors and extinguisher systems required by Section 346.270 of this Part (but without turning extinguishers on).
- 9) Operability of the mean of pool water replenishment required by Section 346.330(c) of this Part.
- Operability of the indicators of high and low pool water levels required by Section 346.330(d) of this Part.
- Operability of the intrusion alarm required by Section 346.230(i) of this Part, if applicable.
- 12) Functioning and wear of the system, mechanisms and cables used to raise and lower sources.
- Condition of the barrier to prevent products from hitting the sources or source mechanism as required by Section 346.350 of this Part.
- 14) Amount of water added to the pool to determine if the pool is leaking.
- 15) Electrical wiring on required safety systems for radiation damage.

- Pool water conductivity measurements and analysis as required by Section 346.630(b) of this Part.
- b) Malfunctions and defects found during inspection and maintenance checks shall be repaired without undue delay.

# Section 346.630 Pool Water Purity

- a) Pool water purification system shall be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.
- b) 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 shall be calibrated at least annually.

## **Section 346.650 Attendance During Operation**

- a) Both an irradiator operator and at least one other person, trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite:
  - 1) Whenever the irradiator is operated using an automatic product conveyor system; and
  - 2) Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.
- b) At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, personnel who have received the training on how to respond to alarms described in Section 346.510(g) of this Part shall be onsite.
- c) At an underwater irradiator, an irradiator operator shall be present at the facility whenever the product is moved into or out of the pool. Personnel who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they shall have received the training described in Section 346.510(f) and (g) of this Part. Static irradiations may be performed without personnel present at the facility.

# Section 346.670 Entering and Leaving the Radiation Room

- a) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.
- b) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:
  - 1) Visually inspect the entire radiation room to verify that no one else is in it; and
  - 2) Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a pre-set time after setting the control.
- c) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter, unless the over-the-pool monitor required by Section 346.290(b) is operating with backup power.

(Source: Amended at 47 Ill. Reg. 9201, effective June 22, 2023)

#### Section 346.690 Irradiation of Explosive or Flammable Materials

- a) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Agency. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems or cause radiation overexposure of personnel.
- b) Irradiation of more than small quantities of flammable material (flashpoint below 140°F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Agency. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposure of licensee or offsite responding personnel.

SUBPART E: RECORDS

#### Section 346.810 Records and Retention Periods

The licensee shall maintain the following records at the irradiator for the periods specified.

- a) A copy of the license, license conditions, documents incorporated into a license by reference and amendments to these materials, until superseded by new documents or until the Agency terminates the license for documents not superseded.
- b) Records of each individual's training, tests and safety reviews provided to meet the requirements of Section 346.510(a), (b), (c), (d), (f), and (g), until 5 years after the individual terminates work.
- c) Records of the annual evaluations of the safety performance of irradiator operators required by Section 346.510(e), for 5 years after the evaluation.
- d) A copy of the current operating and emergency procedures required by Section 346.530, until superseded or the Agency terminates the license.
- e) Evaluations of personnel dosimeters required by Section 346.550, until the Agency terminates the license.
- f) Records of radiation surveys required by Section 346.570, for 5 years from the date of the survey.
- g) Records of radiation survey meter calibrations required by Section 346.570 and pool water conductivity meter calibrations required by Section 346.630(b), until 5 years from the date of each test.
- h) Records of the results of leak tests required by Section 346.590(a) and the results of contamination checks required by Section 346.590(b), for 5 years from the date of each test.
- i) Records of inspection and maintenance checks required by Section 346.610, for 5 years.
- j) Records of major malfunctions, significant defects, operating difficulties or irregularities and major operating problems that involve required radiation safety equipment, for 5 years after repairs are completed.
- k) Records of the receipt, transfer and disposal of all licensed sealed sources as required by 32 Ill. Adm. Code 310.40. The licensee shall retain each record of receipt of byproduct material as long as the material is possessed and for 5 years following transfer or disposal of the material. The licensee who disposed of the material shall retain each record of disposal of byproduct material until the Agency terminates each license that authorizes disposal of the material.

- Records on the design checks required by Section 346.390 and the construction control checks as required by Section 346.410, until the license is terminated. The records shall be signed and dated. The title or qualifications of the personnel signing the record shall be included.
- m) Records related to decommissioning of the irradiator as required by 32 Ill. Adm. Code 330.310 and 330.320.

(Source: Amended at 47 III. Reg. 9201, effective June 22, 2023)

#### Section 346.830 Reports

- a) In addition to the reporting requirements in other Parts of Agency regulations, the licensee shall report the following events if not reported under other Parts of Agency regulations:
  - 1) Source stuck in an unshielded position.
  - 2) Any fire or explosion in a radiation room.
  - 3) Damage to the source racks.
  - 4) Failure of cable or drive mechanism used to move the source racks.
  - 5) Inoperability of the access control system.
  - 6) Detection of radiation source by the product exit monitor.
  - 7) Detection of radioactive contamination attributable to licensed radioactive material.
  - 8) Structural damage to the pool liner or walls.
  - 9) Abnormal water loss or leakage from the source storage pool.
  - 10) Pool water conductivity exceeding 100 microsiemens per centimeter.
- b) The report shall include a telephone report within 24 hours as described in 32 Ill. Adm. Code 340.1220 and a written report within 30 days as described in 32 Ill. Adm. Code 340.1230.

(Source: Amended at 47 Ill. Reg. 9201, effective June 22, 2023)