

CHAPTER 33.1-10-14.1
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

Section

33.1-10-14.1-01 Adoption by Reference of Several Sections in 10 Code of Federal Regulations
Part 36

33.1-10-14.1-01. Adoption by reference of several sections in 10 Code of Federal Regulations part 36.

10 Code of Federal Regulations 36.1, 36.2, 36.11, 36.13, 36.15, 36.17, 36.19, 36.21, 36.23, 36.25, 36.27, 36.29, 36.31, 36.33, 36.35, 36.37, 36.39, 36.41, 36.51, 36.53, 36.55, 36.57, 36.59, 36.61, 36.63, 36.65, 36.67, 36.69, 36.81, and 36.83 are adopted by reference as they exist on June 16, 2020, with the following exceptions:

1. Not adopted by reference is paragraph (2) of the definition of "commencement of construction", and paragraph (9)(ii) of the definition "construction".
2. Requirements in 10 Code of Federal Regulations part 36 that apply to "byproduct material" also apply to naturally occurring or accelerator-produced radioactive material.
3. Where the words "NRC", "commission", or "NRC regional office" appear in 10 Code of Federal Regulations part 36, substitute the words "department of environmental quality".
4. "Act" includes North Dakota Century Code chapters 23.1-02 and 23.1-03.
5. North Dakota state form number 8418, "application for radioactive material license", must be used instead of NRC form 313 as specified in 10 Code of Federal Regulations part 36.
6. For references to 10 Code of Federal Regulations parts 170 and 171, see chapter 33.1-10-11 for applicable fee schedules.

History: Effective January 1, 2019; amended effective January 1, 2023.

General Authority: NDCC 23.1-03-04; S.L. 2017, ch. 199, § 1

Law Implemented: NDCC 23.1-03-03; S.L. 2017, ch. 199, § 18

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Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Source: 58 FR 7728, Feb. 9, 1993, unless otherwise noted.

Subpart A--General Provisions

§ 36.1 Purpose and scope.

(a) This part contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This part also contains radiation safety requirements for operating irradiators. The requirements of this part are in addition to other requirements of this chapter. In particular, the provisions of parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applications and licenses 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) The regulations in this part apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this part.

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

§ 36.2 Definitions.

Annually means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time each year (plus or minus 1 month).

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 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.

Irradiator operator means an individual who has successfully completed the training and testing described in § 36.51 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 the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

Panoramic irradiator means an irradiator in which the irradiations are done in air 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.

Radiation safety officer means an individual with responsibility for the overall radiation safety program at the facility.

Sealed source means any byproduct material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct 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 humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

§ 36.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission, other than a written interpretation by the General Counsel, will be recognized to be binding upon the Commission.

§ 36.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0158.

(b) The approved information collection requirements contained in this part appear in §§ 36.11, 36.13, 36.17, 36.19, 36.21, 36.53, 36.69, 36.81, and 36.83.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 36.11, NRC Form 313 is approved under control number 3150-0120.

(2) [Reserved]

[58 FR 7728, Feb. 9, 1993, as amended at 62 FR 52187, Oct. 6, 1997]

Subpart B--Specific Licensing Requirements

§ 36.11 Application for a specific license.

A person, as defined in § 30.4 of this chapter, may file an application for a specific license authorizing the use of sealed sources in an irradiator on Form NRC 313, "Application for Material License." Each application for a license, other than a license exempted from part 170 of this chapter, must be accompanied by the fee prescribed in § 170.31 of this chapter. The application and one copy must be sent to the appropriate NRC Regional Office listed in appendix D to part 20 of this chapter.

§ 36.13 Specific licenses for irradiators.

The Commission 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.

(a) The applicant shall satisfy the general requirements specified in §§ 30.33(a)(1)–(4) and 30.33(b) of this chapter and the requirements contained in this part.

(b) The application must 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 Commission'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 must include an outline of the written operating and emergency procedures listed in § 36.53 that describes the radiation safety aspects of the procedures.

(d) The application must 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 must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

(e) The application must include a description of the access control systems required by § 36.23, the radiation monitors required by § 36.29, the method of detecting leaking sources required by § 36.59 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(f) 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 Commission. The description must include the--

(1) Instruments to be used;

(2) Methods of performing the analysis; and

(3) Pertinent experience of the individual who analyzes the samples.

(g) If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the Commission or an Agreement State to load or unload irradiator sources.

(h) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by § 36.61.

§ 36.15 Start of construction.

The applicant may not begin construction of a new irradiator prior to the submission to NRC of both an application for a license for the irradiator and the fee required by § 170.31. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: Engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any 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 Atomic Energy Act of 1954, as amended, and rules, regulations, and orders issued under the Act.

§ 36.17 Applications for exemptions.

(a) The Commission may, upon application of any interested person or upon its own initiative,

grant any exemptions from the requirements in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(b) Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this part. The Commission will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

§ 36.19 Request for written statements.

(a) After the filing of the original application, the Commission may request further information necessary to enable the Commission to determine whether the application should be granted or denied.

(b) Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Commission's request, submit written statements to enable the Commission to determine whether the license should be modified, suspended, or revoked.

Subpart C--Design and Performance Requirements for Irradiators

§ 36.21 Performance criteria for sealed sources.

(a) *Requirements.* Sealed sources installed after July 1, 1993:

(1) Must have a certificate of registration issued under 10 CFR 32.210;

(2) Must be doubly encapsulated;

(3) Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

(4) Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

(5) In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in paragraphs (b) through (g) of this section.

(b) *Temperature.* The test source must be held at -40°C for 20 minutes, 600°C for 1 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 must 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, must be dropped from a height of 1 meter onto the test source.

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

(f) *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.

(g) *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 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

§ 36.23 Access control.

(a) Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers 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 the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

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

(c) A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in paragraph (b) of this section. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

(d) Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

(e) Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

(f) Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

(g) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must be posted as required by 10 CFR 20.1902. Radiation postings for panoramic irradiators must comply with the posting requirements of 10 CFR 20.1902, 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 must 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 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 may 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 onsite) who is prepared to respond or summon assistance.

§ 36.25 Shielding.

(a) The radiation dose rate in areas that are normally occupied during operation 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 must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 0.02 millisievert (2 millirems) per hour must 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 the 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.

§ 36.27 Fire protection.

(a) 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 automatically become fully shielded if a fire is detected.

(b) The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

§ 36.29 Radiation monitors.

(a) Irradiators with automatic product conveyor systems must 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 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.

(b) Underwater irradiators that 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 may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

§ 36.31 Control of source movement.

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

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

(c) The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

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

§ 36.33 Irradiator pools.

(a) For licenses initially issued after July 1, 1993, irradiator pools must 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 repairs of the pool.

(b) For licenses initially issued after July 1, 1993, irradiator pools must 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 must have siphon breakers to prevent the siphoning of pool water.

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

(d) A visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

(e) Irradiator pools must 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, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

(g) If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 0.02 millisievert (2 millirems) per hour.

§ 36.35 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 must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

§ 36.37 Power failures.

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

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

(c) During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

§ 36.39 Design requirements.

Irradiators whose construction begins after July 1, 1993, must 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 § 36.25. 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*. 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 § 36.33(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 § 36.33(e). The system must 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 § 36.29(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 § 36.59(b), the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(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 alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

(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 § 36.23.

(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 American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

(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.

§ 36.41 Construction monitoring and acceptance testing.

The requirements of this section must be met for irradiators whose construction begins after July 1, 1993. The requirements must 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 § 36.33(b).

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

(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 § 36.29(a). For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet § 36.59(b). For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by § 36.29(b).

(f) *Source rack.* For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to 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 § 36.35 are met for protection of the source rack and the mechanism that moves the rack; testing must 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

§ 36.51 Training.

(a) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

(1) The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, NRC dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);

(2) The requirements of parts 19 and 36 of NRC regulations that are relevant to the irradiator;

(3) The operation of the irradiator;

(4) Those operating and emergency procedures listed in § 36.53 that the individual is responsible for performing; and

(5) Case histories of accidents or problems involving irradiators.

(b) Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(c) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is 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 must 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;

(3) 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) Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the 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 § 36.53 that they are expected to perform or comply with, and their proper response to alarms required in this part. Tests may be oral.

(g) Individuals who must be prepared to respond to alarms required by §§ 36.23(b), 36.23(i), 36.27(a), 36.29(a), 36.29(b), and 36.59(b) shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

§ 36.53 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 § 36.61;
 - (7) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and
 - (8) Inspection of movable shielding required by § 36.23(h), 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) Personnel overexposures;
 - (3) A radiation alarm from the product exit portal monitor or pool monitor;
 - (4) Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;
 - (5) A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;
 - (6) A prolonged loss of electrical power;
 - (7) A fire alarm or explosion in the radiation room;
 - (8) An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;
 - (9) Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and
 - (10) The jamming of automatic conveyor systems.

(c) The licensee may revise operating and emergency procedures without Commission approval only if all of the following conditions are met:

(1) The revisions do not reduce the safety of the facility,

(2) The revisions are consistent with the outline or summary of procedures submitted with the license application,

(3) The revisions have been reviewed and approved by the radiation safety officer, and

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

§ 36.55 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. Each personnel dosimeter must be assigned to and worn by only one individual. Film badges must be replaced at least monthly and all other personnel dosimeters that require replacement must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

(b) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

[85 FR 15347, Mar. 18, 2020]

§ 36.57 Radiation surveys.

(a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must 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 § 36.25 are exceeded, the facility must be modified to comply with the requirements in § 36.25.

(c) Portable radiation survey meters 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.

(d) Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in 10 CFR part 20, Table 2, Column 2 or Table 3 of appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

(e) Before releasing resins for unrestricted use, they must be monitored before release 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 must be capable of detecting radiation levels of 0.5 microsievert (0.05 millirem) per hour.

§ 36.59 Detection of leaking sources.

(a) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the Commission or an Agreement State. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the Commission or an Agreement State to perform the test.

(b) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the 6 months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

(c) If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an NRC 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 must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an NRC 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, appendix B to part 20. (See 10 CFR 30.50 for reporting requirements.)

[58 FR 7728, Feb. 9, 1993, as amended at 58 FR 67660, Dec. 22, 1993]

§ 36.61 Inspection and maintenance.

(a) 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:

- (1) Operability of each aspect of the access control system required by § 36.23.
- (2) Functioning of the source position indicator required by § 36.31(b).
- (3) Operability of the radiation monitor for radioactive contamination in pool water required by § 36.59(b) using a radiation check source, if applicable.
- (4) Operability of the over-pool radiation monitor at underwater irradiators as required by § 36.29(b).
- (5) Operability of the product exit monitor required by § 36.29(a).
- (6) Operability of the emergency source return control required by § 36.31(c).
- (7) Leak-tightness of systems through which pool water circulates (visual inspection).
- (8) Operability of the heat and smoke detectors and extinguisher system required by § 36.27 (but without turning extinguishers on).
- (9) Operability of the means of pool water replenishment required by § 36.33(c).
- (10) Operability of the indicators of high and low pool water levels required by § 36.33(d).
- (11) Operability of the intrusion alarm required by § 36.23(i), if applicable.
- (12) Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.
- (13) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by § 36.35.
- (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.

(16) Pool water conductivity measurements and analysis as required by § 36.63(b).

(b) Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

§ 36.63 Pool water purity.

(a) Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee 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 must be calibrated at least annually.

§ 36.65 Attendance during operation.

(a) Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present 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, a person who has received the training on how to respond to alarms described in § 36.51(g) must be onsite.

(c) At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in § 36.51 (f) and (g). Static irradiations may be performed without a person present at the facility.

§ 36.67 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 preset time after setting the control.

(c) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by § 36.29(b) is operating with backup power.

§ 36.69 Irradiation of explosive or flammable materials.

(a) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Commission. 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.

(b) Irradiation of more than small quantities of flammable material (flash point below 140 F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Commission. 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.

Subpart E--Records

§ 36.81 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 thereto until superseded by new documents or until the Commission terminates the license for documents not superseded.

(b) Records of each individual's training, tests, and safety reviews provided to meet the requirements of § 36.51(a), (b), (c), (d), (f), and (g) until 3 years after the individual terminates work.

(c) Records of the annual evaluations of the safety performance of irradiator operators required by § 36.51(e) for 3 years after the evaluation.

(d) A copy of the current operating and emergency procedures required by § 36.53 until superseded or the Commission terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by § 36.53(c)(3) retained for 3 years

from the date of the change.

(e) Evaluations of personnel dosimeters required by § 36.55 until the Commission terminates the license.

(f) Records of radiation surveys required by § 36.57 for 3 years from the date of the survey.

(g) Records of radiation survey meter calibrations required by § 36.57 and pool water conductivity meter calibrations required by § 36.63(b) until 3 years from the date of calibration.

(h) Records of the results of leak tests required by § 36.59(a) and the results of contamination checks required by § 36.59(b) for 3 years from the date of each test.

(i) Records of inspection and maintenance checks required by § 36.61 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 §§ 30.51 and 30.41.

(l) Records on the design checks required by § 36.39 and the construction control checks as required by § 36.41 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

(m) Records related to decommissioning of the irradiator as required by § 30.35(g).

[58 FR 7728, Feb. 9, 1993, as amended at 65 FR 63752, Oct. 24, 2000]

§ 36.83 Reports.

(a) In addition to the reporting requirements in other parts of NRC regulations, the licensee shall report the following events if not reported under other parts of NRC 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 the cable or drive mechanism used to move the source racks.

(5) Inoperability of the access control system.

(6) Detection of radiation source by the product exit monitor.

(7) Detection of radioactive contamination attributable to licensed radioactive material.

(8) Structural damage to the pool liner or walls.

(9) Abnormal water loss or leakage from the source storage pool.

(10) Pool water conductivity exceeding 100 microsiemens per centimeter.

(b) The report must include a telephone report within 24 hours as described in § 30.50(c)(1), and a written report within 30 days as described in § 30.50(c)(2).

Subpart F--Enforcement

§ 36.91 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§ 36.93 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for

willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 36 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 36 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 36.1, 36.2, 36.5, 36.8, 36.11, 36.13, 36.17, 36.19, 36.91, and 36.93.