

OHIO DEPARTMENT OF HEALTH

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BOB TAFT
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J NICK BAIRD, M.D.
Director of Health

October 29, 2002

Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mrs. Piccone:

Enclosed is a copy of the final revisions to the Ohio Department of Health Chapter 3701:1-52, Radioactive Material Standards - Irradiators effective October 20, 2002. The final regulations correspond to the following equivalent amendments to NRC's regulations: Licensing and Radiation Safety Requirements for Irradiators-Part 36 (RATS ID # 1993-2).

The proposed regulations are being submitted as final regulations without change.

We believe that adoption of these revisions satisfies the compatibility and health and safety categories established in the Office of State and Tribal Programs (STP) Procedure SA-200.

If you have any questions, please feel free to contact me at 614-644-2727.

Sincerely yours,

A handwritten signature in black ink that reads "Roger L. Suppes".

Roger L. Suppes, Chief
Bureau of Radiation Protection

Enclosures:
As stated

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STP-006 *Complete*
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Ohio Administrative Code

Chapter 3701:1-52 Radioactive Material Standards - Irradiators

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3701:1-52-03

Application for a specific license.

A person, as defined in accordance with rule 3701:1-38-01 of the Administrative Code, may file an application for a specific license authorizing the use of sealed sources in an irradiator on an "Application for a License for Radioactive Material" form provided by the department. Each application for a license must be accompanied by the fee prescribed in rule 3701:1-38-02 of the Administrative Code. The application and one copy must be sent to the department. The license application is obtained by contacting:

Ohio Department of Health 246 North High Street Bureau of Radiation Protection/7th Floor, 35 Bldg. Post Office Box 118 Columbus, OH 43216-0118

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3701:1-52-04 Specific licenses for irradiators.

The director 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 chapter.

- (A) The applicant shall satisfy the general requirements specified in rule 3701:1-40-15 of the Administrative Code and the requirements contained in this chapter.
- (B) The application must describe the training provided to irradiator operators as required by rule 3701:1-52-18 of the Administrative Code including:
 - (1) Classroom training;
 - (2) On-the-job or simulator training;
 - (3) Safety reviews;
 - (4) Method employed by the applicant to test each operator's understanding of the department'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 rule 3701:1-52-19 of this chapter 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 rule 3701:1-52-08 of this chapter, the radiation monitors required by rule 3701:1-52-11 of this chapter, the method of detecting leaking sources required by rule 3701:1-52-22 of this chapter 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 department. 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 licensed by the United States nuclear regulatory commission, the department, 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 rule 3701:1-52-23 of this chapter.

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3701:1-52-05

Start of construction.

The applicant may not begin construction of a new irradiator prior to the submission to the department of both an application for a license for the irradiator and the fee required by rule 3701:1-38-02 of the Administrative Code. As used in this chapter, 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 by the department.

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Applications for exemptions.

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 chapter. The director 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.

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3701:1-52-07

Performance criteria for sealed sources.

- (A) The requirements for sealed sources installed after July 1, 1993:
- (1) Must have a certificate of registration issued in accordance with rule 3701:1-46-49 of the Administrative Code or equivalent United States nuclear regulatory commission or agreement state regulations;
 - (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) Must, in prototype testing of the sealed source, have been leak tested and found leak-free after each of the tests described in paragraphs (B) through (G) of this rule.
- (B) The temperature of the test source must be held at minus forty degrees Celsius for twenty minutes, six hundred degrees Celsius for one hour, and then be subjected to a thermal shock test with a temperature drop from six hundred degrees Celsius to twenty degrees Celsius within fifteen seconds.
- (C) The test source must be twice subjected for at least five minutes to an external pressure (absolute) of two million newtons per square meter (290.1 pounds per square inch).
- (D) A two-kilogram (4.4 pound) steel weight, 2.5 centimeters (one inch) in diameter, must be dropped from a height of one meter (3.28 feet) onto the test source.
- (E) The test source must be subjected three times for ten minutes each to vibrations sweeping from twenty-five hertz to five hundred hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source must be vibrated for thirty minutes at each resonant frequency found.
- (F) A fifty gram (1.75 ounce) weight and pin, 0.3 centimeter (0.12 inch) pin diameter, must be dropped from a height of one meter (3.28 feet) onto the test source.
- (G) If the length of the source is more than fifteen times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of two thousand newtons (four hundred fifty pounds-force) at its center equidistant from two support cylinders, the distance between which is ten times the minimum cross-sectional dimension of the source.

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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) 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 rule. 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 in rule 3701:1-38-18 of the Administrative Code. Radiation postings for panoramic irradiators must comply with the posting

requirements in rule 3701:1-38-18 of the Administrative Code 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.

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Shielding.

- (A) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (two millirems) per hour at any location thirty 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 one hundred square centimeters having no linear dimension greater than twenty centimeters. Areas where the radiation dose rate exceeds 0.02 millisievert (two millirems) per hour must be locked, roped off, or posted.
- (B) The radiation dose rate at thirty centimeters over the edge of the containment pool of a pool irradiator may not exceed 0.02 millisievert (two millirems) per hour when the sources are in the fully shielded position.
- (C) The radiation dose rate at one meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (two millirems) per hour and at five centimeters from the shield may not exceed 0.2 millisievert (twenty millirems) per hour.

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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.

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3701:1-52-14 **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.

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3701:1-52-16 Design requirements.

Irradiators whose construction begins after July 1, 1993, must meet the design requirements of this section.

- (A) 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 paragraph (A) of rule 3701:1-52-11 of this chapter. 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.
- (B) For panoramic irradiators the licensee shall:
 - (1) 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 rule 3701:1-52-09 of this chapter. If the irradiator will use more than 2×10^{17} becquerels (five million curies) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources;
 - (2) Design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls;
 - (3) Verify from the design and logic diagram that the access control system will meet the requirements of rule 3701:1-52-08 of this chapter;
 - (4) 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;
 - (5) Verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than ten seconds;
 - (6) 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 as specified in 10 C.F.R. 39.39 (j) as specified in appendix A of this rule, or local building codes, if current;
 - (7) Verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

- (8) 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; and
- (9) 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.

(C) For pool irradiators the licensee shall:

- (1) 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 paragraph (B) of rule 3701:1-52-13 of this chapter, and that metal components are metallurgically compatible with other components in the pool;
- (2) Verify that the design of the water purification system is adequate to meet the requirements of paragraph (E) of rule 3701:1-52-13 of this chapter. The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored;
- (3) 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; and
- (4) If the licensee uses radiation monitors to detect contamination under paragraph (B) of rule 3701:1-52-22 of this chapter, 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.

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§ 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.

3701:1-52-17

Construction monitoring and acceptance testing.

The requirements of this section must be met for irradiators under construction. The requirements must be met prior to loading sources.

(A) For all irradiators the licensee shall:

- (1) Verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by paragraph (A) of rule 3701:1-52-11 of this chapter; and
- (2) 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 rule 3701:1-52-14 of this chapter 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.

(B) For panoramic irradiators the licensee shall:

- (1) Monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete;
- (2) Monitor the construction of the foundations to verify that their construction meets design specifications;
- (3) 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;
- (4) Test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly;
- (5) 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;
- (6) Demonstrate that the source racks can be returned to their fully shielded positions without offsite power;
- (7) 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; and

- (8) Verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

(C) For pool irradiators the licensee shall:

- (1) 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 paragraph (B) of rule 3701:1-52-13 of this chapter;
- (2) Verify that the water purification system, the conductivity meter, and the water level indicators operate properly;
- (3) Verify the proper operation of the radiation monitors and the related alarm if used to meet paragraph (B) of rule 3701:1-52-22 of this chapter; and
- (4) For underwater irradiators, verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by paragraph (B) of rule 3701:1-52-11 of this chapter.

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3701:1-52-18 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, department 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 rules 3701:1-38-08, 3701:1-38-09 and 3701:1-38-10 of the Administrative Code and Chapter 3701:1-52 of the Administrative Code that are relevant to the irradiator;
 - (3) The operation of the irradiator;
 - (4) Those operating and emergency procedures listed in rule 3701:1-52-19 of this chapter 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 rule 3701:1-52-19 of this chapter 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 paragraphs (B) and (J) of rule 3701:1-52-08; paragraph (A) of 3701:1-52-10, paragraphs (A) and (B) of 3701:1-52-11; and paragraph (B) of 3701:1-52-22 of this chapter, shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

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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 rule 3701:1-52-23 of this chapter;
 - (7) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and
 - (8) Inspection of movable shielding required by paragraph (H) of rule 3701:1-52-08 of this chapter, 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 director 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.

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Personnel monitoring.

- (A) Irradiator operators shall wear either a film badge, a thermoluminescent dosimeter (TLD), an optically stimulated luminescent device (OSLD), or other monitoring device accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The monitoring device processor must be accredited by NVLAP for high energy photons in the normal and accident dose ranges as indicated in paragraph (A)(3) of rule 3701:1-38-14 of the Administrative Code. Each monitoring device must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and TLDs and OSLDs must be processed at least quarterly, and other monitoring devices according to the processing schedule approved by NVLAP.
- (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 thirty per cent of the true radiation dose.

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Detection of leaking sources.

- (A) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the United States nuclear regulatory commission, the department, or an agreement state. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of one hundred eighty five becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the United States nuclear regulatory commission, the department, 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 a leak test has been done within the six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within twenty four 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 organization licensed by the United States nuclear regulatory commission, the department, or an agreement state 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 organization licensed by the United States nuclear regulatory commission, the department, or an agreement state 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 accordance with table II, appendix C of rule 3701:1-38-12 of the Administrative Code. (see rule 3701:1-40-20 of the Administrative Code for reporting requirements.)

3701:1-52-22

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3701:1-52-23 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 rule 3701:1-52-08 of this chapter.
- (2) Functioning of the source position indicator required by paragraph (B) of rule 3701:1-52-12 of this chapter.
- (3) Operability of the radiation monitor for radioactive contamination in pool water required by paragraph (B) of rule 3701:1-52-22 of this chapter using a radiation check source, if applicable.
- (4) Operability of the over-pool radiation monitor at underwater irradiators as required by paragraph (B) of rule 3701:1-52-11 of this chapter.
- (5) Operability of the product exit monitor required by paragraph (A) of rule 3701:1-52-11 of this chapter.
- (6) Operability of the emergency source return control required by paragraph (C) of rule 3701:1-52-12 of this chapter.
- (7) A visual inspection of the leak-tightness of systems through which pool water circulates.
- (8) Without turning extinguishers on, operability of the heat and smoke detectors and extinguisher system required by rule 3701:1-52-10 of this chapter.
- (9) Operability of the means of pool water replenishment required by paragraph (C) of rule 3701:1-52-13 of this chapter.
- (10) Operability of the indicators of high and low pool water levels required by paragraph (D) of rule 3701:1-52-13 of this chapter.
- (11) Operability of the intrusion alarm required by paragraph (I) of rule 3701:1-52-08 of this chapter, 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 rule 3701:1-52-14 of this chapter.
- (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 paragraph (B) of rule 3701:1-52-24 of this chapter.

(B) The licensee shall immediately initiate any repair process for malfunctions and defects found during inspection and maintenance checks.

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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 paragraph (G) of rule 3701:1-52-18 of this chapter 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 paragraphs (F) and (G) of rule 3701:1-52-18 of this chapter. Static irradiations may be performed without a person present at the facility.

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3701:1-52-26

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 paragraph (B) of rule 3701:1-52-11 of this chapter is operating with backup power.

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Irradiation of explosive or flammable material.

- (A) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the director. 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 flammable material with a flash point below sixty degrees Celsius, or one hundred forty degrees Fahrenheit, is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the director. 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.

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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 director terminates the license.
- (B) Records of each individual's training, tests, and safety reviews provided to meet the requirements of paragraphs (A), (B), (C), (D), (F), and (G) of rule 3701:1-52-18 of this chapter until three years after the individual terminates work.
- (C) Records of the annual evaluations of the safety performance of irradiator operators required by paragraph (E) of rule 3701:1-52-18 of this chapter for three years after the evaluation.
- (D) A copy of the current operating and emergency procedures required by rule 3701:1-52-19 of this chapter until superseded or the director terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by paragraph (C)(3) of rule 3701:1-52-19 of this chapter retained for three years from the date of the change.
- (E) Personnel dosimetry results required by rule 3701:1-52-20 of this chapter until the director terminates the license.
- (F) Records of radiation surveys required by rule 3701:1-52-21 of this chapter for three years from the date of the survey.
- (G) Records of radiation survey meter calibrations required by rule 3701:1-52-21 of this chapter and pool water conductivity meter calibrations required by paragraph (B) of rule 3701:1-52-24 of this chapter until three years from the date of calibration.
- (H) Records of the results of leak tests required by paragraph (A) of rule 3701:1-52-22 of this chapter and the results of contamination checks required by paragraph (B) of rule 3701:1-52-22 of this chapter for three years from the date of each test.
- (I) Records of inspection and maintenance checks required by rule 3701:1-52-23 of this chapter for three years.
- (J) Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.
- (K) Records of the receipt, transfer and disposal, of all licensed sealed sources as required by rules 3701:1-40-19 and 3701:1-40-21 of the Administrative Code.

(L) Records on the design checks required by rule 3701:1-52-16 of this chapter and the construction control checks as required by rule 3701:1-52-17 of this chapter 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 paragraph (I) of rule 3701:1-40-17 of the Administrative Code.

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