

**CHAPTER 227a. RADIATION SAFETY REQUIREMENTS FOR
NON-HEALING ARTS RADIATION-PRODUCING DEVICES**

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Authority

The provisions of this Chapter 227a added under sections 301(c) and 302(a) of the Radiation Protection Act (35 P.S. §§ 7110.301(c) and 7110.302(a)); and section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 227a added August 11, 2023, effective 90 days after publication, 53 Pa.B. 4977, unless otherwise noted.

Subchapter A. GENERAL PROVISIONS

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§ 227a.1. Purpose and scope.

(a) This chapter establishes special requirements for non-healing arts radiation-producing devices operating between 5 kiloelectron volts (keV) and 1 million electron volts (MeV). This chapter shall apply to all devices defined in § 227a.2 (relating to definitions). Machines operating at energies greater than 1 MeV are subject to Chapter 228 (relating to radiation safety requirements for particle accelerators).

(b) In addition to this chapter, all registrants are subject to Chapters 215, 216, 219 and 220. This chapter does not pertain to radiation safety requirements for X-ray equipment covered under Chapters 221 and 225 (relating to X-rays in the healing arts; and radiation safety requirements for industrial radiographic operations) and Chapter 228.

(c) Radiography that meets the definition of “cabinet radiography,” including cabinet X-ray systems, is regulated under this chapter.

(d) Radiography that occurs in a “shielded room” is regulated under this chapter.

(e) Radiography equipment that meets the definition of “bomb detection radiation-producing devices” is regulated under this chapter.

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(f) Industrial radiography that is open-beam, and not in a shielded room and not otherwise listed here, is regulated under Chapter 225.

§ 227a.2. Definitions.

The following words and terms, when used in this chapter, have the following meanings unless the context clearly indicates otherwise:

ALARA—As low as reasonably achievable.

Accessible surface—The external or outside surface of the enclosure or housing provided by the manufacturer. The term includes the high-voltage generator, doors, access panels, latches, control knobs and other permanently mounted hardware, including the plane across the exterior edge of any opening.

Beam port—An opening on the X-ray apparatus designed to emit a primary beam. This term does not include an opening on a security screening device.

Bomb detection radiation-producing device—X-ray-generating equipment used solely for the purpose of remotely detecting explosive devices. For the purposes of this chapter, this term does not include hand-held X-ray bomb detection devices.

Cabinet radiography—Industrial radiography using radiation-producing devices not subject to United States Food and Drug Administration performance standards for cabinet X-ray systems, in an enclosed, interlocked cabinet in which the portion of a material being irradiated is contained, and in which all of the following are met:

(i) The radiation-producing device will not operate unless all openings are closed with interlocks activated.

(ii) The cabinet is shielded so that every location on the exterior meets the conditions for an unrestricted area as defined under 10 CFR 20.1003 (relating to definitions).

(iii) The cabinet is constructed or arranged as to exclude the entrance of any part of the body of an individual during irradiation.

Cabinet X-ray system—An X-ray system with the X-ray tube installed in an enclosure which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation and exclude personnel from its interior during generation of radiation. The term does not include an X-ray tube used within a shielded part of a building, or X-ray equipment which may temporarily or occasionally incorporate portable shielding.

Cathode ray tube—A device used to accelerate electrons for demonstration or research purposes, except where the tube is incorporated into a television or display monitor that is subject to, and has met applicable Federal radiation safety performance standards under 21 CFR Part 1010 (relating to performance standards for electronic products: general) and 21 CFR 1020.10 (relating to television receivers).

Certified cabinet X-ray system—A radiation-producing device certified by the manufacturer under 21 CFR 1010.2 (relating to certification) as being manufactured and assembled under the provisions of applicable Federal radiation safety performance standards under 21 CFR Part 1010 and 21 CFR 1020.40 (relating to cabinet X-ray systems).

Closed-beam radiation-producing device—A device in which the beam path cannot be entered by any part of the body during normal operation.

Cold-cathode gas discharge tube—An electronic device in which electron flow is produced and sustained by ionization of contained gas atoms and ion bombardment of the cathode.

Collimator—A device for restricting the useful radiation in one or more directions.

Control panel—A device containing means for regulation and activation of a radiation-producing device or for the preselection and indications of operating factors.

Electron microscope—Equipment using the wave characteristics of electrons that have been accelerated by an electric field to visualize the microscopic structure of material.

Emergency procedure—The written planned steps to be taken in the event of actual or suspected exposure of an individual in excess of an administrative or regulatory limit, including the names and telephone numbers of individuals to be contacted as well as directives for processing the film badge or other personnel monitoring devices.

Fail-safe design—A design in which all realistically anticipated failures of indicators or safety components result in a condition in which individuals are safe from exposure to radiation. For example, the production of X-rays must be prevented if a light indicating “X-RAY ON” fails and the shutter must close if a shutter status indicator fails.

General-use system—An individual screening system that delivers an effective dose equal to or less than 25 μrem (0.25 μSv) per screening.

Handheld radiation-producing device—A portable device designed to operate when held in the hand, such as a hand-held X-ray fluorescence analytical device.

Industrial radiography—An examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.

Interlock—A device or engineered system that precludes access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

kV—Kilovolt.

Leakage radiation—Radiation coming from within the source housing, other than the useful beam.

Limited-use system—An individual screening system that is capable of delivering an effective dose greater than 25 μrem (0.25 μSv) per screening but that cannot exceed an effective dose of 1 mrem (10 μSv) per screening.

Local components—Parts of a radiation-producing device X-ray system, including areas struck by X-rays, such as radiation source housings, beam port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding. The term does not include power supplies, transformers, amplifiers, readout devices or control panels.

Lockout/tagout—A safety procedure that ensures dangerous devices and energy sources are properly shut off and cannot startup unexpectedly while maintenance or service work is being completed.

μrem —Microrem.

μSv —Micro Sievert.

mrem—Millirem.

mSv—Milli Sievert.

Mobile device—Radiation-producing device mounted on a permanent base with wheels or casters, or both, for moving while completely assembled.

Normal operating procedures—Step-by-step instructions necessary to accomplish the task. Examples include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant and data recording procedures, which are related to radiation safety.

Open-beam radiation-producing device—A device in which any part of the body could enter the beam path during normal operations. Examples include X-ray gauges, tabletop and handheld X-ray devices and electron beam welders.

Permanent radiographic installation—A shielded installation or structure designed or intended for radiography in which radiography is regularly performed.

Portable device—Radiation-producing device designed to be hand-carried.

Primary beam—The ionizing radiation coming directly from the radiation source through a beam port into the volume defined by the collimation system.

Qualified expert—The term has the meaning given to it under § 215.2 (relating to definitions).

RSO—radiation safety officer—The term has the meaning given to it under § 215.2.

Radiation-producing device—A radiation-producing device where the apparatus, device, electronic product, system, subsystem or component of any of them may generate X-rays or particle radiation between 5 keV and 1 MeV. The device is not intended for healing arts use for humans or animals. The device is fixed or portable, such as mobile devices, portable devices, stationary equipment or transportable equipment.

Radiation-producing device used in individual security screening—X-ray equipment used on humans for security evaluation.

Radiation source (or X-ray tube) housing—That portion of an X-ray system that contains the X-ray tube or secondary target, or that contains both. Often the housing contains radiation shielding material or inherently provides shielding.

Radiograph—A permanent film or digital image produced on a sensitive surface by a form of radiation other than direct visible light.

Radiography—The process of creating a radiographic image through X-ray radiation.

Registrant—The term has the meaning given to it under § 215.2.

Safety device—A device, interlock or system that prevents the entry of any portion of an individual's body into the primary X-ray beam or that causes the beam to shut off upon entry into its path.

Scattered radiation—Radiation that has been deviated in direction or energy, or both, by passing through matter.

Security screening device—A non-human use open-beam system or cabinet X-ray system with accessible openings designed for the detection of weapons, bombs or contraband concealed in baggage, mail, a package or another commodity or structure.

Shielded room—A room housing a non-healing arts radiation-producing device where, with the radiation-producing device at maximum techniques, the exterior room environs meet the unrestricted area limits of 2 mrem (0.02 mSv) in any 1 hour and 100 mrem (1 mSv) in a year at 30 centimeters from the barrier. The term does not include a room housing a radiation-producing device that meets the definition of cabinet X-ray systems.

Shutter—A moveable device used to block the useful (or primary) beam emitted from an X-ray tube assembly.

Source—The point of origin of the radiation. An example of this term is the focal spot of an X-ray tube.

Stationary equipment—Radiation-producing device equipment that is installed or placed in a permanent or fixed location.

Transportable equipment—Radiation-producing device equipment to be installed in a vehicle or that may be readily disassembled for transport or use in a vehicle.

Warning device—A visible or audible signal that warns individuals of a potential radiation hazard.

X-ray gauge—An X-ray-producing device designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level or interface location.

X-ray generator—That portion of an X-ray system which provides the accelerating high voltage and current for the X-ray tube.

X-ray tube—The term has the meaning given to it under § 221.2 (relating to definitions).

Cross References

This section cited in 25 Pa. Code § 227a.1 (relating to purpose and scope).

§ 227a.3. Exemptions.

(a) A radiation-producing device meeting the definition of “bomb detection radiation-producing device” is exempt from § 227a.16 (relating to posting).

(b) Unless used in a dedicated location, a handheld radiation-producing device is exempt from § 227a.16.

(c) The following devices and equipment are exempt from this chapter:

(1) Domestic television receivers, if the exposure rate at 5 centimeters from any outer surface is less than 0.5 mrem (0.005 mSv) per hour.

(2) Cold-cathode gas discharge tubes, if the exposure rates do not exceed 10 mrem (0.1 mSv) per hour at 30 centimeters from any point on the external surface of the tube.

(3) Other electrical equipment, except electron microscopes, that produces radiation incidental to its operation for other purposes, if the dose rate to the whole body at the point of nearest approach to the equipment when any external shielding not integral to the equipment is removed does not exceed 25 mrem (0.25 mSv) per year. The product testing of any radiation-producing device or factory servicing of the equipment is not exempt.

(d) Equipment described in this section is not exempt from this chapter if it is used or handled in a manner an individual might receive a dose of radiation in excess of the limits specified in Chapter 219 (relating to standards for protection against radiation).

(e) Equipment operating at less than or equal to 50 kV tube voltage and designed to be held by an operator during use is exempt from this chapter except for §§ 227a.12 and 227a.21 (relating to labeling; and instruction and training).

§ 227a.4. Application for exemptions.

The Department may consider an application for exemptions to the requirements of this chapter. A radiation-producing device registrant who cannot meet one or more requirements of this chapter shall submit to the Department a written request for an exemption to the requirements that cannot be met. The exemption request must explain why the provision cannot be met and must demonstrate all of the following to the Department’s satisfaction:

(1) That the use of the radiation-producing device will not result in undue hazard to public health and safety or to property.

(2) That compliance with the provision from which the registrant is seeking exemption would require replacement or substantial modification of the radiation-producing device.

(3) That the registrant will achieve, through other means, radiation protection equivalent to that required by the provision from which the registrant is seeking exemption.

Subchapter B. GENERAL TECHNICAL REQUIREMENTS

- Sec.
227a.10. Radiation safety program.
227a.11. Warning devices.
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227a.14. Generating cabinet or high voltage source radiation emission limits.
227a.15. Surveys.
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227a.20. Testing of safety devices.
227a.21. Instruction and training.
227a.22. Radiation protection responsibility.

Cross References

This subchapter cited in 25 Pa. Code § 227a.50 (relating to handheld radiation-producing devices); 25 Pa. Code § 227a.51 (relating to bomb detection radiation-producing devices); and 25 Pa. Code § 227a.52 (relating to radiation-producing devices used in individual security screening).

§ 227a.10. Radiation safety program.

A registrant who intends to use radiation-producing devices shall have a program for training personnel, written normal operating procedures and emergency procedures, individual monitoring reports required under 10 CFR 20.2206(a)(2) (relating to reports of individual monitoring), an internal review system and an organizational structure for radiation protection which includes specified delegations of authority and responsibility for operation of the program.

§ 227a.11. Warning devices.

(a) *Label.* Warning devices must be labeled so that their purpose is easily identified.

(b) *Warning device light.* An easily visible warning device light labeled with the words “X-RAY ON,” or words having a similar intent, must be located near every switch that energizes an X-ray tube and must be illuminated only when the tube is energized. This warning light must be of a fail-safe design.

Cross References

This section cited in 25 Pa. Code § 227a.41 (relating to X-ray on status).

§ 227a.12. Labeling.

(a) *General rule.* A radiation-producing device must be labeled with a readily visible and discernible sign or signs bearing the radiation symbol and the words: “CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIA-

TION WHEN ENERGIZED,” or words having a similar intent, near every switch that energizes an X-ray tube.

(b) *Devices with designed openings.* For radiation-producing devices with designed openings for object entries, such as baggage units, the following must be posted at or near every opening: “CAUTION—X-RAY HAZARD: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED” or words having similar intent.

Cross References

This section cited in 25 Pa. Code § 227a.3 (relating to exemptions).

§ 227a.13. Radiation source housing.

(a) *Interlock.* When the X-ray tube housing is the primary shielding for the X-ray tube and is intended to be opened for normal use or maintenance, the housing must be equipped with an interlock that shuts off the high voltage to the X-ray tube if the housing is opened.

(b) *Radiation emission limit.* Except as specified elsewhere in this chapter, each X-ray tube housing must be constructed so that, with all shutters closed, the leakage radiation measured at 5 centimeters from the X-ray tube housing surface does not exceed 2.5 mrem (0.025 mSv) per hour. This limit must be met at the maximum tube rating.

Cross References

This section cited in 25 Pa. Code § 227a.50 (relating to handheld radiation-producing devices).

§ 227a.14. Generating cabinet or high voltage source radiation emission limits.

Each X-ray generator or high-voltage source must be supplied with a protective cabinet which limits leakage radiation to 0.5 mrem (5.0 μ Sv) per hour at 5 centimeters measured at the nearest accessible surface. For closed-beam radiation-producing devices, this requirement may be met by complying with § 227a.33 (relating to radiation emission limit). For a radiation-producing device in a shielded room with the high-voltage generator also inside the shielded room, this limit may be met by measuring from any accessible surface outside the room housing the radiation-producing device. For hand-held, open-beam radiation-producing devices, this requirement may be met by complying with the limits under § 227a.50(3) (relating to handheld radiation-producing devices).

Cross References

This section cited in 25 Pa. Code § 227a.50 (relating to handheld radiation-producing devices).

§ 227a.15. Surveys.

(a) *General rule.* Radiation surveys of all radiation-producing devices must be sufficient to show compliance under § 219.51 (relating to radiation dose lim-

its for individual members of the public) and to show compliance with radiation emission requirements of this chapter. The radiation surveys must be sufficient to evaluate the magnitude and extent of radiation emissions and the potential radiological hazards that could be present. Records of these surveys must be maintained for 5 years for inspection by the Department. At a minimum, surveys shall be performed in the following instances:

(1) Upon installation of the equipment and at least once every 12 months thereafter.

(2) Following a change in the initial arrangement, number or type of local components in the system, and prior to returning to service.

(3) Following maintenance requiring the disassembly, removal or repair of a local component in the system, and prior to returning to service.

(4) During the performance of maintenance, calibration and another procedure if the procedure requires the presence of a primary beam while any local component in the system is disassembled or removed.

(5) Following bypass of a safety device or interlock as required by § 227a.18(b) (relating to operating requirements).

(6) When a visual inspection of the local components in the system reveals an abnormal condition.

(7) If a personnel monitoring device shows a radiation exposure that is greater than 25% of the annual occupational dose limit as specified in 10 CFR 20.1201 (relating to occupational dose limits for adults).

(b) *Instrument requirements.* The registrant shall have access to sufficiently calibrated, appropriate and operable radiation survey instruments to make physical radiation surveys as required by this chapter. The instruments must be capable of detecting and measuring the types and levels of radiation involved, including primary, scattered and leakage radiation.

(c) *Maintenance and calibration.* The registrant shall ensure the maintenance and calibration of all monitoring and survey instruments under 10 CFR 20.1501 (relating to general).

(d) *Exception.* Radiation surveys are not required if a registrant otherwise demonstrates compliance under this chapter to the satisfaction of the Department.

Cross References

This section cited in 25 Pa. Code § 227a.18 (relating to operating requirements).

§ 227a.16. Posting.

Each area or room containing a radiation-producing device where an individual may receive 2 mrem (0.02 mSv) in any 1 hour or 100 mrem (1 mSv) per year shall be conspicuously posted with a sign or signs bearing the radiation symbol and “CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED,” or words having a similar intent.

Cross References

This section cited in 25 Pa. Code § 227a.3 (relating to exemptions); and 25 Pa. Code § 227a.51 (relating to bomb detection radiation-producing devices).

§ 227a.17. Security.

A radiation-producing device must be secured to be accessible only to authorized personnel at all times.

Cross References

This section cited in 25 Pa. Code § 227a.51 (relating to bomb detection radiation-producing devices).

§ 227a.18. Operating requirements.

(a) *Procedures.* Normal operating procedures shall be written and available to all radiation-producing device workers. An individual may not operate a radiation-producing device in a manner other than that specified in the normal operating procedures unless the individual has obtained written approval of the RSO.

(b) *Bypassing.*

(1) An individual may not bypass a safety device or interlock, and may not remove shielding, unless the individual has obtained approval of the RSO. The approval shall be limited to a specified period of time.

(2) When a safety device or interlock has been bypassed, a conspicuous sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing and at the control switch.

(3) A record of a bypass of a safety device or interlock shall be maintained for 5 years. The record must contain all of the following information:

- (i) The date the bypass was made.
- (ii) A detailed description of the bypass.
- (iii) The length of time the unit remained in the altered condition.
- (iv) The post bypass survey as noted in § 227a.15 (relating to surveys).
- (v) Other relevant information for the bypass.

(4) A record of a bypass shall be signed by the RSO, the individual who performed the bypass and the individual who restored the unit to its original condition.

(c) *Control panel.*

(1) The radiation-producing device may only be activated from a control panel.

(2) Indicators and controls that control the primary beam must be identifiable and discernible through the use of labels, symbols, software displays or equivalent methods.

(d) *Interlocks.*

(1) An interlock may not be used to de-activate the X-ray tube of a radiation-producing device, except in an emergency or during testing of the interlock system.

(2) After an interlock is triggered, resetting the radiation-producing device to full operation must only be possible from a control panel.

(3) Interlocks must be of a fail-safe design.

(e) *Multiple sources.* If more than one X-ray tube assembly or focal spot can be operated sequentially or simultaneously from a control panel, visual indicators must identify which tube assembly or focal spot has been selected. The selectors must be identified as to their function. If a letter or number is used, a reference card or table explaining the code must be affixed to the control panel.

Cross References

This section cited in 25 Pa. Code § 227a.15 (relating to surveys).

§ 227a.19. Repair or modification of X-ray tube or radiation-producing device.

Only trained personnel or a registered service provider may install, repair or make modifications to a radiation-producing device. An operation involving removal of covers, shielding materials or tube housings, or an operation involving modifications to shutters, collimators or beam stops, may only be performed after ascertaining that the tube is off and will remain off until safe conditions have been restored. The main power switch with a lock-out/tag-out, rather than interlocks, shall be used for routine shutdown in preparation for repairs. The registrant shall ensure that only qualified personnel install, repair and make modifications to a radiation-producing device.

§ 227a.20. Testing of safety devices.

(a) *Testing interval.* Testing of safety devices, such as interlocks, shutters, warning lights and required emergency shut-off switches, shall be conducted on all operable radiation-producing devices at intervals not to exceed 12 months.

(b) *Device failure.* If a safety device fails during testing, the radiation-producing device shall be removed from service until the safety device is corrected or proper temporary administrative controls are established. The RSO shall approve in writing the temporary administrative controls.

(c) *Availability of records.* Records of safety device tests, check dates, findings and corrective actions shall be available for inspection and maintained for 5 years.

(d) *Record requirements.* Records required under this section must include the date of the test, a list of the safety devices tested, survey instrument informa-

tion, the calibration date, the results of the test, the name of the person performing the test and, for safety devices that fail the required test, corrective actions taken.

(e) *Out of service requirements.* Testing of safety devices may be deferred if the unit or installation, or both, are clearly marked and kept out of service. A unit or installation, or both, brought back into service after the 12-month interval specified in subsection (a) shall be tested prior to use.

(f) *Testing constraints.* If testing of a safety device cannot be performed due to manufacturer design, the registrant shall document that the safety device cannot be tested and specify why the safety device cannot be tested.

§ 227a.21. Instruction and training.

The registrant shall document the scope of training required for the radiation-producing device the registrant possesses under this section. An individual may not operate or maintain a radiation-producing device or enter a shielded room without appropriate instruction and training. Records of all required training and instruction shall be maintained onsite and made available for review by the Department for 5 years. Before an individual may operate or maintain a radiation-producing device or enter a shielded room, the individual shall receive instruction in and shall demonstrate competence through a performance evaluation by the registrant, as to the following:

- (1) Types of radiation, identification of radiation hazards associated with the use of the radiation-producing device and associated equipment, and precautions or measures to take to minimize radiation exposure.
- (2) Significance of the various radiation warnings, safety devices and interlocks incorporated into the equipment, or the reasons that warnings, safety devices or interlocks have not been installed on equipment and the extra precautions required in these cases.
- (3) Commensurate with potential hazards of use, biological effects of radiation, radiation risks and recognition of symptoms of an acute localized exposure.
- (4) Normal operating procedures for each type of radiation-producing device and associated equipment, as well as procedures to prevent unauthorized use. Training in normal operating procedures must include hands-on training.
- (5) Emergency procedures for reporting actual or suspected accidental exposure and other radiation safety concerns, such as an unusual occurrence or malfunction that may involve exposure to radiation.
- (6) Radiation survey performance, where applicable.

Cross References

This section cited in 25 Pa. Code § 227a.3 (relating to exemptions); 25 Pa. Code § 227a.49 (relating to instruction and training); and 25 Pa. Code § 227a.50 (relating to handheld radiation-producing devices).

§ 227a.22. Radiation protection responsibility.

(a) *Responsibility.* The registrant's designated senior management shall make the decision to use a radiation-producing device. The registrant shall document the designated senior management responsible for radiation safety and those records shall be available for inspection by the Department and maintained for 5 years.

(b) *RSO designation.* The registrant's senior management shall designate an RSO. This individual shall have direct access to senior management for radiation safety issues. This individual shall have training and experience commensurate with the scope of the radiation safety program to carry out the following responsibilities:

(1) Ensuring that all radiation-producing devices are operated within the limitations of the established radiation safety program and normal operating procedures.

(2) Instructing personnel on safe working practices and ensuring that all personnel are trained in radiation safety commensurate with the hazards of the job.

(3) Investigating all incidents of abnormal operation and of abnormal exposure or suspected overexposure of an individual to determine the cause of the incident, to take remedial action and to report the incident to the proper authority.

(4) Ensuring that safety devices, interlocks, warning signals, labels, postings and signs are functioning and located where required.

(5) Retaining all records required to show compliance with this section, including annual reviews of the radiation protection program content and implementation and the documentation of its findings, as required in § 219.5 (relating to incorporation by reference), and incorporating by reference 10 CFR 20.1101(c) (relating to radiation protection programs), and making the records available for review by the Department for 5 years.

Subchapter C. CLOSED-BEAM RADIATION-PRODUCING DEVICES

Sec.

227a.30. System enclosure.

227a.31. Interlocks.

227a.32. Interlock functions.

227a.33. Radiation emission limit.

227a.34. Security screening devices.

227a.35. Electron microscope devices.

§ 227a.30. System enclosure.

The radiation source, sample or object, detector and analyzing crystal, if used, of a closed-beam radiation-producing device must be enclosed in a chamber or coupled chambers that cannot be entered by any part of the body during normal operation.

§ 227a.31. Interlocks.

Doors and panels accessing the closed-beam radiation-producing device must be interlocked. The interlocks required by this section must be of a fail-safe design.

§ 227a.32. Interlock functions.

The closed-beam radiation-producing device enclosure, sample chamber, or other similar closure must be interlocked with the X-ray tube high voltage supply or a shutter in the primary beam, or both, so that no X-ray beam can enter the sample or object chamber while the chamber is open unless the interlock has been conspicuously and deliberately defeated. The interlock required by this section must be of fail-safe design or have adequate administrative controls to ensure that operations will only continue with a proper functioning interlock.

§ 227a.33. Radiation emission limit.

The radiation emission for a closed-beam radiation-producing device may not exceed a dose rate of 0.5 mrem (0.005 mSv) in 1 hour at 5 centimeters outside any accessible surface.

Cross References

This section cited in 25 Pa. Code § 227a.14 (relating to generating cabinet or high voltage source radiation emission limits).

§ 227a.34. Security screening devices.

Closed-beam security screening devices must have a mechanism to ensure operator presence at the control area in a location that enables surveillance of the openings and doors of the control area during generation of radiation. The following apply:

- (1) During an exposure or preset succession of exposures of 0.5 second or greater duration, the closed-beam radiation-producing device must have a mechanism to enable the operator to terminate the exposure or preset succession of exposures at any time.
- (2) During an exposure or preset succession of exposures of less than 0.5 second duration, the closed-beam radiation-producing device must have a mechanism to allow completion of the exposure in progress but must enable the operator to prevent additional exposures.

§ 227a.35. Electron microscope devices.

(a) *Labeling.* A closed-beam electron microscope device must be labeled with a conspicuous sign bearing the words, “Caution Radiation—This Equipment Produces Radiation When Energized,” or words containing a similar warning.

(b) *Maximum radiation level.* Radiation levels measured 5 centimeters from an accessible surface of a closed-beam electron microscope may not exceed 0.5 mrem (0.005 mSv) per hour.

Subchapter D. OPEN-BEAM RADIATION-PRODUCING DEVICES

Sec.

227a.40. Safety device.

227a.41. X-ray on status.

227a.42. Labeling.

227a.43. Beam ports.

227a.44. Shutters.

227a.45. Radiation emission limits.

227a.46. Primary beam attenuation.

227a.47. Operator attendance.

227a.48. Control of access.

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227a.50. Handheld radiation-producing devices.

227a.51. Bomb detection radiation-producing devices.

227a.52. Radiation-producing devices used in individual security screening.

227a.53. Radiation-producing devices used in vehicle security screening.

227a.54. Permanent radiographic installations.

227a.55. Shielded room radiation-producing devices.

§ 227a.40. Safety device.

(a) *Documentation.* The registrant shall document its justification of the use of an open-beam instead of closed-beam radiation-producing device.

(b) *Open-beam considerations.* If the registrant needs to use an open-beam radiation-producing device, the registrant shall consider a safety device which minimizes the chance of entry of any portion of the operator’s body into the path of the primary beam or which causes the primary beam to be shut off upon entry into its path.

(c) *Records.* If the registrant’s use of an open-beam radiation-producing device does not permit the use of a safety device to minimize the chance of direct body exposure, the registrant shall maintain a written record of the justification required in subsection (a) and a description of the various safety devices that have been evaluated and reasons the devices cannot be used. These records shall be available onsite for inspection as long as this method is used, plus an additional 5 years.

(d) *Alternative methods.* If the registrant's use of the open-beam radiation-producing device does not permit the use of a safety device to minimize the chance of direct body exposure, the registrant shall use alternative methods, such as policies and procedures, to minimize the possibility of unnecessary exposure. The registrant shall document the alternative methods used. The documentation must include information about the absence of safety devices. This documentation shall be available for inspection as long as the methods are used plus an additional 5 years.

(e) *Compliance.* For a portable open-beam radiation-producing device without a safety device described under subsection (b) that is manufactured to be used or potentially used as a handheld device, the safety device requirements under subsections (b)—(d) shall be met by complying with § 227a.50 (relating to handheld radiation-producing devices) prior to use.

Cross References

This section cited in 25 Pa. Code § 227a.49 (relating to instruction and training).

§ 227a.41. X-ray on status.

Open-beam radiation-producing devices must have a conspicuous and active indication of the following, as applicable:

- (1) X-ray tube “on-off” status indicator located near the radiation source housing. The warning lights required under § 227a.11(b) (relating to warning devices), meet this requirement if the warning lights are conspicuous and viewable by anyone near the primary beam.
- (2) Shutter “open-closed” status indicator located at the control panel and near each beam port on the radiation source housing, if the primary beam is controlled with a shutter. The shutter status device must be clearly labeled to indicate whether the shutter is open or closed. The status light at the control panel meets the requirement for the status light at the beam port if the status light at the control panel is conspicuous and viewable by anyone near the primary beam.
- (3) The X-ray tube “on-off” status indicator and the shutter “open-closed” status indicators must be of a fail-safe design.

§ 227a.42. Labeling.

Each unit must be labeled at or near the X-ray exit beam port to identify the location of the beam with the words, “CAUTION—X-RAY BEAM,” “CAUTION—HIGH INTENSITY X-RAY BEAM,” or words having a similar intent.

§ 227a.43. Beam ports.

Unused beam ports on radiation source housings shall be secured in the closed position in a manner which will prevent inadvertent opening.

§ 227a.44. Shutters.

On open-beam radiation-producing device configurations that are designed to accommodate interchangeable components, each beam port on the radiation source housing must be equipped with a shutter that cannot be opened unless a collimator or a component coupling has been connected to the beam port.

§ 227a.45. Radiation emission limits.

Radiation emissions limits, exclusive of the primary beam, must be met at any specified tube rating established by the manufacturer. The local components of an open-beam radiation-producing device must be located, and be arranged and include sufficient shielding or access control to prevent either of the following from occurring:

- (1) Radiation emissions in any area surrounding the local component group which could result in an occupational dose in excess of 10 CFR Part 20 Subpart C (relating to occupational dose limits).
- (2) A dose to an individual in an area surrounding the local component group in excess of the dose limits outlined under § 219.51 (relating to dose limits for individual members of the public).

§ 227a.46. Primary beam attenuation.

In cases where the primary beam is not intercepted by the detector device under all conditions of operation, protective measures, such as auxiliary shielding or administrative procedures, shall be provided to avoid exposure to any individual from the transmitted primary beam.

Cross References

This section cited in 25 Pa. Code § 227a.50 (relating to handheld radiation-producing devices).

§ 227a.47. Operator attendance.

The operator shall be present at all times when the equipment is in operation except when the area is locked, or the equipment is secured to protect against unauthorized or accidental entry.

§ 227a.48. Control of access.

If the radiation-producing device is not in a restricted area as defined in 10 CFR 20.1003 (relating to definitions), the operator shall control access to the radiation-producing device at all times during operation. The following apply:

- (1) Radiation areas must be conspicuously identified. The following apply:
 - (i) The radiation source must be within a conspicuous perimeter, for instance, a rope, tape or other barrier, that identifies the area in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour.

(ii) The area described in subparagraph (i) must be suitably posted with “CAUTION—RADIATION AREA” signs.

(iii) The operator shall ensure that no one is inside and that no one enters the radiation area during operation of the radiation-producing device.

(2) High radiation areas must be conspicuously identified. The following apply:

(i) The radiation source must be within a conspicuous perimeter, for instance, a rope, tape or other barrier, that identifies the area in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour.

(ii) The area described in subparagraph (i) must be suitably posted with “CAUTION—HIGH RADIATION AREA” signs.

(iii) The operator shall ensure that no one is inside or enters the high radiation area during operation of the radiation-producing device.

(3) The operator shall perform a visual check of the controlled area to ensure that it is free of unauthorized personnel immediately prior to activating or exposing the radiation source.

§ 227a.49. Instruction and training.

In addition to meeting the requirements of § 227a.21 (relating to instruction and training), an individual may not operate or maintain an open-beam radiation-producing device unless the individual has received training applicable to the procedures to be performed and the specific equipment used. This training may include more specific and detailed instruction in, and demonstrated competence as to, the following:

- (1) Sources and magnitude of common radiation exposure.
- (2) Units of radiation measurement.
- (3) Radiation protection concepts of time, distance, shielding and ALARA.
- (4) Procedures and rights of a declared pregnancy.
- (5) Regulatory requirements and area postings.
- (6) Worker, embryo/fetus and public dose limits.
- (7) Proper use of survey instruments and dosimetry.
- (8) Policies and procedures required under § 227a.40 (relating to safety device).

Cross References

This section cited in 25 Pa. Code § 227a.50 (relating to handheld radiation-producing devices).

§ 227a.50. Handheld radiation-producing devices.

In addition to the requirements in Subchapter B and this subchapter (relating to general technical requirements; and open-beam radiation-producing devices), the following requirements apply to open-beam, hand-held radiation-producing devices.

(1) *Procedures.* A registrant possessing an open-beam, hand-held radiation-producing device shall have available for review operating policies and procedures that contain measures to ensure that the following are met:

(i) Radiation protection is provided equivalent to that afforded under § 219.51 (relating to dose limits for individual members of the public).

(ii) Radiation protection is provided equivalent to that afforded under § 227a.46 (relating to primary beam attenuation).

(iii) The operator will not hold the sample during operation of the radiation-producing device and that the operator's hands will not approach the primary beam.

(iv) The operator will not aim the primary beam at any individual, including the operator, during the operation of the radiation-producing device.

(v) Operator radiation exposure is as low as reasonably achievable by use of means such as ancillary equipment that will reduce exposure.

(2) *Training.* In addition to the training requirements under §§ 227a.21 and 227a.49 (relating to instruction and training), the registrant shall provide training for all users and operators on the subjects specified under this section. Records shall be maintained for all user and operator training and be made available for review by the Department for 5 years.

(3) *Radiation emission limit.* For hand-held radiation-producing devices, the limits of §§ 227a.13(b) and 227a.14 (relating to radiation source housing; and generating cabinet or high voltage radiation emission limits), excluding the primary beam, shall be met if the radiation emission at any accessible surface of the radiation-producing device does not exceed 2.5 mrem (0.025 mSv) per hour at 5 centimeters.

Cross References

This section cited in 25 Pa. Code § 227a.14 (relating to generating cabinet or high voltage source radiation emission limits); and 25 Pa. Code § 227a.40 (relating to safety device).

§ 227a.51. Bomb detection radiation-producing devices.

In addition to the requirements in Subchapter B (relating to general technical requirements), except § 227a.16 (relating to posting), the following requirements apply to bomb detection radiation-producing devices:

(1) *Control panel security.* In addition to the requirements in § 227a.17 (relating to security), bomb detection radiation-producing devices shall be locked to prevent unauthorized use when not in use.

(2) *Use log.* The registrant shall maintain a use log for each bomb detection radiation-producing device. This log must record the description of the unit, the date removed from storage, the date returned to storage, the identity and signature of the person to whom the device is assigned, the dates of use and the site or sites of use. This use log shall be maintained for 5 years.

(3) *Area control.* The registrant shall provide security to prevent entry by individuals to the area in which the device is energized.

§ 227a.52. Radiation-producing devices used in individual security screening.

In addition to the requirements in Subchapter B (relating to general technical requirements), the following requirements apply to radiation-producing devices used in individual security screening. A person requesting Department approval for a radiation-producing device to be used for individual security screening with intended human exposure to the primary beam for public protection shall submit the following information to the Department for evaluation and approval. The applicant shall state how the dose limits in this section will be met. The applicant shall receive Department approval prior to use.

(1) *Efficacy evaluation.* An evaluation of all known alternate methods that could achieve the goals of the individual security screening program and an explanation of why these methods will not be used in preference to the applicant's proposed approach using ionizing radiation.

(2) *Equipment evaluation.* A device used for individual security screening of humans shall be evaluated by a qualified expert at the following times for optimization of image quality and radiation dose per manufacturer's recommendations and this section:

- (i) Upon installation of the device.
- (ii) After maintenance that affects the radiation shielding, shutter mechanism or X-ray production components.
- (iii) Upon damage to the system.
- (iv) Every 12 months.

(3) *Dose limits for general-use systems.* An effective dose for a single complete screening must be limited to 25 μrem (0.25 μSv) when the system is used without regard to the number of individuals scanned or number of scans per individual in a year.

(4) *Dose limits for limited-use systems.* The effective dose per screening must be less than or equal to 1 mrem (0.01mSv) when equipment is capable of operation greater than 25 μrem (0.25 μSv) per screening. The number of scans per individual must be tracked to ensure the dose does not exceed the limits referenced in paragraph (5) and § 227a.53(c) (relating to radiation-producing devices used in vehicle security screening).

(5) *Dose limits for repeat security screenings.* An individual subject to repeat individual security screenings at a single venue may not receive an

effective dose greater than 25 mrem (0.25 mSv) in a 12-month period at the registrant's or licensee's facility.

(6) *Information available to screening subjects.* At a minimum, the registrant shall make the following information available to screening subjects prior to scanning:

(i) The estimated effective dose from one screening.

(ii) Examples comparing the effective dose with commonly known sources of radiation exposure.

(7) *Training.* Training must include the following:

(i) The RSO shall have 8 hours of training in radiation safety which must include X-ray physics, biological effects, units of measure, safety standards, and protection regulations.

(ii) In addition to X-ray scanner operation training by the manufacturer, an operator shall receive at least 2 hours of radiation safety training.

(iii) Operators and the RSO shall receive annual radiation safety refresher training. Training must include the applicable topics under Chapter 221, Appendix A (relating to determination of competence).

(8) *Scanning of minors and pregnant individuals.* The scanning of an individual under 18 years of age or an individual known or declared pregnant is prohibited without prior departmental approval.

(9) *Preventative maintenance.* The registrant shall follow the manufacturer's recommended preventative maintenance schedule.

(10) *Radiation protection program.* A written radiation safety program must be based on accepted radiation protection principles, including keeping an exposure ALARA. The registrant is responsible to have the program developed, documented and implemented. The RSO shall review the radiation protection program at least annually.

(11) *Records retention.* The registrant shall maintain all records relative to the use of the radiation-producing device for at least 5 years.

Cross References

This section cited in 25 Pa. Code § 227a.53 (relating to radiation-producing devices used in vehicle security screening).

§ 227a.53. Radiation-producing devices used in vehicle security screening.

(a) *Procedure for human exposure.* When the procedures for operation of a mobile or transportable radiation-producing device used for security screening of vehicles includes knowingly exposing human occupants to the primary beam when screening vehicles, structures or containers, the system is subject to the same requirements as provided in § 227a.52(1)—(5) (relating to radiation-producing devices used in individual security screening).

(b) *Minimizing human exposure.* If vehicle occupants are knowingly exposed to the primary beam of a security screening device and the requirements in

§ 227a.52(3)—(5) cannot be met, then there shall be means to ensure the occupied portion of the vehicle is outside of the scan area while the primary beam is emitted or procedures shall be established and implemented to ensure that no occupants are present in the vehicle during screening.

(c) *Dosage limits.* The effective dose to an individual for a single inadvertent exposure to the primary beam must not exceed 500 mrem (5 mSv). The reliability of the procedure used to ensure that a vehicle to be scanned is unoccupied must be commensurate with the potential severity of an inadvertent exposure. A pre-screening with a mode or system that can meet the limits under § 227a.52(3)—(5) shall be used to verify that the vehicle being examined is unoccupied if the 500 mrem (5 mSv) limit cannot be ensured.

§ 227a.54. Permanent radiographic installations.

(a) *Entrance controls.* Permanent radiographic installations having high radiation area entrance controls of the types described in 10 CFR 20.1601 and 20.1902 (relating to control of access to high radiation areas; and posting requirements) must also meet the following requirements:

(1) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation whenever the X-ray source is energized. The audible signal shall be activated when an attempt is made to enter the installation while the X-ray source is energized.

(2) The entrance control device or alarm system shall be tested for proper function prior to beginning operations on each day of use.

(3) The industrial radiographic system may not be used if an entrance control device or alarm system is not operating properly. If an entrance control device or alarm system is not functioning properly, it shall be removed from service and repaired or replaced immediately. If no replacement is available, the facility may continue to be used if the registrant implements the continuous surveillance under 10 CFR 34.51 and 34.53 (relating to surveillance; and posting), § 225.85 (relating to surveys and survey records) and uses an alarming ratemeter. Before the entrance control device or alarm system is returned to service, the RSO or an individual designated by the RSO shall validate the repair.

(b) *Records.* Records of the tests performed under subsection (a) shall be maintained for inspection by the Department for 5 years.

§ 227a.55. Shielded room radiation-producing devices.

(a) *Control of access.* A room used for shielded room X-ray radiography must be shielded so that every location on the exterior meets conditions for an unrestricted area. Access to the room may only be through openings that are interlocked. The openings must be interlocked so that the radiation source cannot

operate unless all openings are securely closed and meet the requirement of 10 CFR 20.1601 (relating to control of access to high radiation areas).

(b) *Physical radiation survey.* The operator shall conduct a physical radiation survey to determine that the radiation source is deenergized prior to each entry into the radiographic exposure area.

(c) *Radiation monitoring system.* The operator may use an independent radiation monitoring system that displays the radiation intensity or displays when radiation levels have returned to their pre-irradiation levels as an alternative to subsection (b).

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