

**CHAPTER 227. RADIATION SAFETY REQUIREMENTS FOR
ANALYTICAL X-RAY EQUIPMENT, X-RAY GAUGING EQUIPMENT,
ELECTRON MICROSCOPES AND X-RAY CALIBRATION SYSTEMS**

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Authority

The provisions of this Chapter 227 issued under section 301 of The Atomic Energy Development and Radiation Control Act (73 P. S. § 1301) (Repealed); and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), unless otherwise noted.

Source

The provisions of this Chapter 227 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212, unless otherwise noted.

Cross References

This chapter cited in 25 Pa. Code § 215.32 (relating to exemption qualifications); 28 Pa. Code § 501.4 (relating to regulations); and 28 Pa. Code § 565.12 (relating to radiology service policy).

GENERAL PROVISIONS**§ 227.1. Purpose and scope.**

This chapter establishes the requirements for the use of analytical X-ray equipment, X-ray gauging equipment, electron microscopes and X-ray calibration sys-

tems. Registrants who use analytical X-ray equipment, X-ray gauging equipment, electron microscopes or X-ray calibration systems shall comply with this chapter. The requirements of this chapter are in addition to, and not in substitution for, other applicable provisions of this article.

Source

The provisions of this § 227.1 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial page (249334).

§ 227.2. Definitions.

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

Analytical X-ray machine—An assembly of components utilizing X-rays to determine the elemental or chemical composition or to examine the microstructure of materials usually by X-ray diffraction or fluorescence.

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

Fail-safe characteristics—A design feature which causes X-ray production to cease, beam port shutters to close or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

Local components—Parts of an analytical X-ray system, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, that contain or are in the path of the X-ray beam. The term does not include power supplies, transformers, amplifiers, readout devices and control panels.

Open-beam configuration—An analytical X-ray system in which the beam is not enclosed or shielded so any portion of an individual's body could accidentally be placed in the beam path during normal operation.

Operating procedures—Step-by-step instructions necessary to accomplish the analysis.

Primary beam—Radiation which passes through an aperture of the source housing by a direct path from the X-ray tube or a radioactive source located in the radiation source housing.

X-ray calibration systems—Radiation-producing machines and equipment used to calibrate radiation detection or measuring devices.

X-ray gauging equipment—A machine utilizing X-rays to detect, measure, gauge or control thickness, density, level or interface location.

Source

The provisions of this § 227.2 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282. Immediately preceding text appears at serial page (249335).

§ 227.3. [Reserved].**Source**

The provisions of this § 227.3 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (119234) and (4919).

ANALYTICAL X-RAY EQUIPMENT**§ 227.11. [Reserved].****Source**

The provisions of this § 227.11 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203996).

§ 227.11a. Equipment requirements.

(a) Open-beam configurations shall have a safety device which either prevents the entry of any portion of an individual's body into the primary X-ray beam path, or causes the beam to be terminated or interrupted upon entry into the path. A registrant may apply to the Department for an exemption from the requirement of a safety device. The application for an exemption shall include the following:

- (1) A description of the various safety devices that have been evaluated.
- (2) The reason each of these safety devices cannot be used.
- (3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(b) Open-beam configurations shall be provided with a readily discernible indication of one or both of the following:

- (1) X-ray tube status (on-off) located near the radiation source housing, if the primary beam is controlled in this manner.
- (2) Shutter status (open-closed) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(c) Warning devices shall be labeled so that their purpose is easily identified. In addition, equipment manufactured after December 17, 1987, shall have fail-safe characteristics.

(d) An easily visible warning light located immediately adjacent to the tube head or port and labeled with the words “X-ray on,” or words containing a similar warning, shall be provided and shall be illuminated when the X-ray tube is energized.

(e) Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

(f) Analytical X-ray equipment shall be labeled with a readily discernible sign bearing the radiation symbol and both of the following:

(1) “CAUTION—HIGH INTENSITY X-RAY BEAM” or words having a similar intent on the X-ray source housing.

(2) “CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED,” or words having a similar intent, near any switch that energizes an X-ray tube.

(g) On equipment with an open-beam configuration manufactured and installed after December 19, 1987, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or coupling has been connected to the port.

(h) Equipment exclusively designed and exclusively used for vacuum spectroscopy where the tube housing and sample chamber is located behind all external surfaces of the unit shall be exempt from the requirements of this section, §§ 227.12a and 227.13a (relating to area requirements; and operating requirements), but shall meet the requirements of § 227.14 (relating to personnel procedures) and the following:

(1) The unit shall be designed so that when the unit is operating at the maximum kilovoltage and current ratings, the leakage radiation will not be in excess of 0.5 milliroentgens (.129 $\mu\text{C}/\text{kg}$) per hour at a distance of 4 centimeters from any external surface.

(2) Radiation surveys using appropriate radiation survey equipment shall be performed on the analytical X-ray unit upon installation, after moving the unit to a new location, and after maintenance or repair requiring the disassembly or removal of a local component or radiation shielding.

(3) Safety and warning devices shall be tested for proper operation at least annually. If the test reveals that a safety or warning device is not working properly, the unit may not be operated until the warning device is repaired or replaced.

(4) Records of all tests and surveys sufficient to show compliance with subsection (h) shall be maintained and kept available for inspection by the Department for 4 years.

(5) A sign bearing the radiation symbol and the words “CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED,” or words of similar intent shall be placed next to any switch or device that activates the X-ray tube.

(6) A sign bearing the radiation symbol and the words “CAUTION—RADIATION,” or words of similar intent shall be placed next to the opening of the sample chamber.

Authority

The provisions of this § 227.11a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 227.11a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (285692) to (285693) and (282433).

§ 227.12. [Reserved].

Source

The provisions of this § 227.12 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (203997).

§ 227.12a. Area requirements.

(a) The source housing construction shall be of a type that when all the shutters are closed and the source is in any possible operating mode, the leakage radiation will not be in excess of 2.5 milliroentgens (.645 $\mu\text{C}/\text{kg}$) per hour at a distance of 5 centimeters from the housing surface.

(b) The X-ray generator shall have a protective cabinet constructed so that the leakage radiation will not be in excess of 0.5 milliroentgen (.129 $\mu\text{C}/\text{kg}$) per hour at a distance of 5 centimeters from the housing surface.

(c) The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control so that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the limits given in 10 CFR 20.1301 (relating to dose limits for individual members of the public). For systems utilizing X-ray tubes, these requirements shall be met at any specified tube rating.

(d) To show compliance with subsections (a)—(c), the registrant shall perform radiation surveys:

- (1) Upon installation of the equipment and at least every 12 months thereafter.
- (2) Following a change in the initial arrangement, number or type of local components in the system.
- (3) Following maintenance requiring the disassembly or removal of a local component in the system.

(4) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary X-ray beam when a local component in the system is disassembled or removed.

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

(6) When personnel monitoring devices show a significant increase in radiation exposure over the previous monitoring period or the readings are approaching the radiation dose limits.

(7) When the machine is operated in a manner other than the routine manner specified in § 227.13a (relating to operating requirements).

(e) The registrant shall test and inspect all safety and warning devices at least annually to insure their proper operation. If a safety or warning device is found to be malfunctioning, the machine shall be removed from service until repairs to the malfunctioning device are completed.

(f) Records of surveys and tests sufficient to show compliance with this chapter shall be maintained for 4 years and kept available for inspection by the Department.

(g) The equipment used to conduct the surveys and tests required in this chapter shall be adequate to measure the radiation produced by the radiation source.

Authority

The provisions of this § 227.12a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 227.12a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (282434) and (249339).

Cross References

This section cited in 25 Pa. Code § 227.11a (relating to equipment requirements); and 25 Pa. Code § 227.14 (relating to personnel requirements).

§ 227.13. [Reserved].

Source

The provisions of this § 227.13 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (203997) to (203998).

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§ 227.13a. Operating requirements.

(a) Operating procedures shall be written and available to the analytical X-ray equipment operators. These procedures shall include instructions for sample insertion and manipulation, equipment alignment, routine maintenance and data recording procedures which are related to radiation safety. An individual may not operate analytical X-ray equipment in a manner other than that specified in the operating procedures unless the individual has obtained written approval from the radiation safety officer.

(b) An individual may not bypass or otherwise circumvent a safety device unless the individual has obtained the prior written approval of the radiation safety officer. The radiation safety officer may grant the permission only if the following conditions are met:

(1) The radiation safety officer establishes administrative controls and procedures to assure the radiation safety of individuals working around the system.

(2) The period for the bypass of the safety device is not more than 30 days unless written permission is obtained from the Department for a longer period.

(3) A readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words containing a similar warning, is placed on the radiation source housing.

(c) Except as specified in subsection (b), an operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators or beam stops may not be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

(d) Emergency procedures shall be written and posted near the equipment and shall list the names and telephone numbers of personnel to contact. The emergency procedures shall also provide information necessary to de-energize the equipment, such as location and operation of the power supply or circuit breakers.

Authority

The provisions of this § 227.13a issued and amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 227.13a adopted October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (249339) to (249340).

Cross References

This section cited in 25 Pa. Code § 227.11a (relating to equipment requirements); and 25 Pa. Code § 227.12a (relating to area requirements).

§ 227.14. Personnel requirements.

(a) An individual may not operate or maintain analytical X-ray equipment unless the individual has received instruction in and demonstrated competence as to:

- (1) Identification of radiation hazards associated with the use of the equipment.
- (2) Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment, and the extra precautions necessary if the devices are absent or bypassed.
- (3) Written operating and emergency procedures for the equipment.
- (4) Symptoms of an acute localized radiation exposure.
- (5) Procedures for reporting an actual or suspected exposure.
- (6) Use of survey and personnel monitoring equipment.
- (7) The applicable regulations of this article and those incorporated by reference.

(b) Finger or wrist personnel monitoring devices shall be provided to and shall be used by:

- (1) Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device as described in § 227.12a(c) (relating to area requirements).
- (2) Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when a local component in the analytical X-ray system is disassembled or removed or when safety devices are bypassed.

(c) Reported dose values may not be used for the purpose of determining compliance with 10 CFR 20.1201 (relating to occupational dose limits for adults) unless they are evaluated by a qualified expert.

(d) The registrant or licensee shall notify the Department within 5 days of a suspected radiation overexposure to an individual from analytical X-ray machines. This notification is required even if subsequent investigation reveals no actual over-exposure actually occurred.

Authority

The provisions of this § 227.14 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. 510-20).

Source

The provisions of this § 227.14 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended November 17, 1995, effective November 18, 1995, 25 Pa.B. 5085; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894; amended July 16, 2004, effective July 17, 2004, 34 Pa.B. 3823. Immediately preceding text appears at serial pages (249340) to (249341).

Cross References

This section cited in 25 Pa. Code § 227.11a (relating to equipment requirements).

§ 227.15. [Reserved].**Source**

The provisions of this § 227.15 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; reserved October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial pages (203999) to (204000).

X-RAY GAUGING EQUIPMENT**§ 227.21. Warnings.**

X-ray gauging equipment shall be labeled with a readily discernable sign or signs bearing the radiation symbol and the words, "Caution Radiation—This Equipment Produces Radiation When Energized," or words containing a similar warning.

Source

The provisions of this § 227.21 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4922).

§ 227.22. Radiation levels.

An X-ray tube housing shall be constructed so that, with the unit in normal operation, the leakage radiation measured 5 centimeters from a surface is no more than 2.5 milliroentgens (645 nC/kg) per hour.

Source

The provisions of this § 227.22 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4922).

§ 227.23. Personnel requirements.

No registrant may permit an individual to operate or conduct maintenance upon X-ray gauging equipment until the individual has received a copy of and instruction in, and demonstrated an understanding of, the operating procedures necessary to ensure radiation safety.

Source

The provisions of this § 227.23 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4922) to (4923).

§ 227.24. [Reserved].**Source**

The provisions of this § 227.24 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4923) to (4924).

§ 227.25. [Reserved].**Source**

The provisions of this § 227.25 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4924) to (4937).

ELECTRON MICROSCOPES**§ 227.31. Warnings.**

An electron microscope shall be labeled with a readily discernable sign bearing the words, "Caution Radiation—This Equipment Produces Radiation When Energized," or words containing a similar warning.

Source

The provisions of this § 227.31 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4937).

§ 227.32. Radiation levels.

Radiation levels measured 5 centimeters from any accessible surface of an electron microscope may not exceed .5 milliroentgen (129 nC/kg) per hour.

Source

The provisions of this § 227.32 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; amended December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4938).

§ 227.33. Personnel requirements.

A registrant may not permit an individual to operate or conduct maintenance upon any electron microscope until the individual has received a copy of, instruction in, and demonstrated an understanding of, the operating procedures necessary to insure radiation safety.

Authority

The provisions of this § 227.33 amended under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302); and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20).

Source

The provisions of this § 227.33 adopted December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235; amended October 2, 1998, effective October 3, 1998, 28 Pa.B. 4894. Immediately preceding text appears at serial page (204002).

§§ 227.41—227.44. [Reserved].**Source**

The provisions of these §§ 227.41—227.44 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4938) to (4941).

§§ 227.51—227.53. [Reserved].**Source**

The provisions of these §§ 227.51—227.53 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4941) to (4942).

§§ 227.61—227.71. [Reserved].**Source**

The provisions of these §§ 227.61—227.71 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4942) to (4948).

§§ 227.81—227.85. [Reserved].**Source**

The provisions of these §§ 227.81—227.85 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial page (4949) to (4951).

§§ 227.91—227.97. [Reserved].**Source**

The provisions of these §§ 227.91—227.97 adopted February 1, 1972, effective February 2, 1972, 2 Pa.B. 212; reserved December 18, 1987, effective December 19, 1987, 17 Pa.B. 5235. Immediately preceding text appears at serial pages (4951) to (4955).

X-RAY CALIBRATION SYSTEMS**§ 227.101. Scope.**

This section and §§ 227.102—227.104 apply to registrants who use X-ray producing machines to calibrate or test radiation detection or measuring devices.

Authority

The provisions of this § 227.101 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 227.101 adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282.

§ 227.102. Area requirements.

A room or enclosure used for testing or calibration shall be shielded so that every location on the exterior meets conditions for an unrestricted area, and the only access to the room or enclosure is through openings which are interlocked so that the radiation source will not operate unless all openings are securely closed and meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).

Authority

The provisions of this § 227.102 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 227.102 adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282.

Cross References

This section cited in 25 Pa. Code § 227.101 (relating to scope).

§ 227.103. Operating requirements.

(a) The operator shall conduct a physical radiation survey to determine that the radiation machine X-ray tube is de-energized prior to each entry of any body part into the X-ray exposure area.

(b) As an alternative to subsection (a), the registrant may use an independent radiation monitoring system that displays the radiation intensity or displays when radiation levels have returned to their pre-irradiation levels.

Authority

The provisions of this § 227.103 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 227.103 adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282.

Cross References

This section cited in 25 Pa. Code § 227.101 (relating to scope).

§ 227.104. Personnel requirements.

A registrant may not permit an individual to operate or conduct maintenance on any X-ray calibration system until the individual has received a copy of, instruction in, and demonstrated an understanding of, the operating procedures necessary to ensure radiation safety.

Authority

The provisions of this § 227.104 issued under sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302).

Source

The provisions of this § 227.104 adopted November 16, 2001, effective November 17, 2001, 31 Pa.B. 6282.

Cross References

This section cited in 25 Pa. Code § 227.101 (relating to scope).

[Next page is 228-1.]

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