PROPOSED RULEMAKING
ENVIRONMENTAL QUALITY BOARD
[25 PA. CODE CHS. 225, 227, 227A AND 228]

Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices

The Environmental Quality Board (Board) proposes to amend Chapters 225 and 228 (relating to radiation safety requirements for industrial radiographic operations; and radiation safety requirements for particle accelerators), rescind Chapter 227 (relating to radiation safety requirements for analytical X-ray equipment, X-ray gauging equipment, electron microscopes and X-ray calibration systems) and add new Chapter 227a to read as set forth in Annex A. The proposed rulemaking would amend these chapters in Article V (relating to radiological health) to include clarification and guidance regarding radiation safety and update the standards for protection against radiation.

This proposed rulemaking was adopted by the Board at its meeting on [date].

A. *Effective Date*

This proposed rulemaking will be effective 90 days after final-form publication in the *Pennsylvania Bulletin*.

B. *Contact Persons*

For further information, contact John Chippo, Chief, Division of Radiation Control, P.O. Box 8469, Rachel Carson State Office Building, Harrisburg, PA 17105-8469, (717) 783-9730; or Christopher Minott, Assistant Counsel, Bureau of Regulatory Counsel, P.O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-9372. Information regarding submitting comments on this proposed rulemaking appears in Section J of this preamble. Persons with a disability may use the AT&T Relay service, (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This proposed rulemaking is available electronically on the Department of Environmental Protection's (Department) website at www.dep.pa.gov (select "Public Participation," then "Environmental Quality Board (EQB)").

C. *Statutory Authority*

The proposed amendments to Chapters 225, 227, 227a and 228 are authorized under section 301(c) of the Radiation Protection Act (35 P.S. § 7110.301(c)), which requires the Department to develop and conduct comprehensive programs addressing the "registration, licensing, control, management, regulation and inspection of radiation sources and radiation source users," section 302(a) of the Radiation Protection Act (35 P.S. § 7110.302(a)), which requires the Board to "adopt the rules and regulations of the department to accomplish the purposes and carry out the provisions of [the] act," and section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20), which authorizes the Board to promulgate rules and regulations necessary for the performance of the work of the Department.

D. *Background and Purpose*

The Board last updated the radiological health regulations in 2019 to provide for updates and technological advances in uses of radiation sources in medical X-ray operations. However, radiological health regulations related to non-medical X-ray equipment have not been updated since 2009. Since then, advancements in X-rays and other ionizing radiation particles used for non-medical purposes have necessitated updated regulations to ensure the public, workers, and environment are protected from the potentially harmful effects of ionizing radiation. Overexposure to radiation can cause a wide range of potential negative health impacts, such as skin burns, radiation sickness, cancer, and death in the most extreme cases.

Given these potential health impacts, the proposed amendments included in this rulemaking address non-medical X-ray operations and emerging technologies in the industrial field to ensure that exposure to radiation from non-medical radiation-producing devices is as low as reasonably possible. Some examples of non-medical X-ray operations and emerging technologies that these proposed regulations would apply to include many recent advances in X-ray capabilities for bomb detection, contraband scanning, and advanced welding and detection capabilities.

The proposed regulations would affect approximately 1,400 radiation-producing device registrants in the Commonwealth. These registrants include radiographers, drug rehabilitation centers, food manufacturers, primary metal manufacturers, fabricated metal product manufacturers, machinery manufacturers, computer and electronic product manufacturers, and other miscellaneous manufacturers. In addition to these types of businesses, registrants could also be government offices such as prisons and courthouses, universities, and research laboratories. A small number of registrants (currently 3 registrants) for radiation-producing devices used in individual security screening will also be affected by being required to provide training on the use of equipment to staff that do not have formal training or knowledge in radiological sciences or radiation safety. These are the registrants of radiation-producing devices used in individual security screening as described in proposed § 227a.52.

As more fully explained below, the proposed amendments to Chapter 225 are intended to separate and more clearly outline requirements applicable to non-medical X-ray operations and field radiography. It is also proposed that Chapter 227, which pertains to radiation safety requirements for analytical X-ray gauging equipment, electron microscopes and X-ray calibration systems, be rescinded and reserved. All regulations currently in Chapter 227 are proposed to be moved to the new Chapter 227a, which is proposed to be added to outline radiation requirements for these non-healing arts radiation-producing device. The requirements were rewritten and rearranged in order to incorporate Suggested State Regulations (SSR) Part H and Part E, and to clarify all the requirements. The regulated community suggested creating this new chapter would help them to more clearly understand their regulatory obligations. Existing Chapter 228 is also proposed to be amended to update a definition to match the U.S. Nuclear Regulatory Commission's terminology.

These proposed amendments are based on standards for radiation-producing devices set by recognized accrediting bodies and national organizations. Specifically, the proposed amendments incorporate the SSR Part H and the training requirements in SSR Part E that was developed by

the Conference of Radiation Control Program Directors (CRCPD). The American National Standards Association was consulted in developing these amendments. One of CRCPD's goals is to ensure uniformity in Federal and state radiation protection laws and regulations. Typically, Federal agencies develop radiation control regulations and standards, but it is left to the state to implement and enforce those regulations and standards. The CRCPD reviews draft and final Federal regulations and, through various working groups, develops model state regulations called Suggested State Regulations (SSRs). A new SSR could be developed for a given issue or problem, but more often they are updated to reflect new Federal regulations. As with Federal regulations, once new or revised SSRs are complete, they undergo a CRCPD Board and peer review and then are published as draft within the CRCPD Director Members for comment. The draft SSRs are also sent to Federal agencies for concurrence. States may adopt a CRCPD model state SSR as is or modify them to conform to their regulatory frameworks.

The proposed rulemaking was also developed in consultation with the Department's Radiation Protection Advisory Committee (RPAC). Members of RPAC represent the regulated community, including professional health physics and medical physics organizations, as well as environmental, health, science, engineering, business or public interest groups. The proposed rulemaking was introduced to RPAC on October 10, 2019. An RPAC subcommittee, which was comprised of professionals in the industries potentially impacted by these proposed regulations, had further discussions on the draft proposed rulemaking on December 15, 2019, and January 15, 2020. RPAC again reviewed the package with the revisions made as a result of the recommendations of the subcommittee on March 19, 2020. On July 9, 2020, RPAC voted to concur with the Department's recommendation that the proposed rulemaking move forward in the regulatory process.

E. *Summary of Regulatory Requirements*

The heading for Subchapter B, "Radiation-Producing Machines" is proposed to be changed to "Radiation-Producing Devices" to more accurately reflect the applicability of the subchapter. Similar changes are proposed throughout various sections of Chapter 225.

§ 225.71. Definitions

Section 225.71 is proposed to be amended to add a definition for "radiographic X-ray systems" to accommodate the revisions to § 225.101 and to delete the definitions of "cabinet radiography," "cabinet X-ray system," "certified cabinet X-ray system," "permanent radiographic installation," and "shielded room radiography." These deleted definitions are proposed to be moved to Chapter 227a. The definition of "radiographer trainee" is proposed to be deleted because, according to the industry, there is no such position. The definition of "industrial radiography" is proposed to be amended to match the Federal definition: "An examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images."

§ 225.72. Duties of personnel

Subsection (d) is proposed to be deleted and reserved. The prohibition in subsection (d) against a radiographer trainee using radiation-producing devices is not applicable because, according to

the industry, there is no such position as a radiographer trainee. This is also the reason for the proposed deletion of the definition of "radiographer trainee" in § 225.71.

§ 225.74. Training and testing

Subsection (a)(3) is proposed to be amended by adding "at least 160 hours" to the requirement of receiving instruction covering regulatory requirements, operating and emergency procedures, and the use of radiation-producing devices and radiation survey instruments of the registrant or licensee. This amendment is being proposed to incorporate the training requirement from SSR Part E. Subsection (c) is proposed to be amended to lengthen the record retention requirement from 3 years to 5 years to maintain consistency throughout this Commonwealth's radiological health regulations.

§ 225.76. Reporting requirements

Subsection (a)(2) is proposed to be amended by deleting the requirement of paragraph (2) that an interlock failure during shielded room radiography is subject to the reporting requirements of this section. These reporting requirements are being removed from this section because the subject of shielded room radiography has been moved to Chapter 227a. The reporting requirements in subsection (a)(1) are incorporated in subsection (a).

§ 225.81. Permanent radiographic installations

Section 225.81, which outlines entrance and entrance control requirements for permanent radiographic control devices, is proposed to be rescinded and reserved as these requirements have been moved to the new Chapter 227a.

§ 225.82. Operating requirements

Subsection (a) is proposed to be amended to clarify that the operating requirements of this section apply to field radiographic operations rather than at a location other than a permanent radiographic installation. Also, the reference to "radiographer trainee" is deleted.

A minor editorial change is proposed in subsection (c)(4) of this section by switching the placement of a reference to 200 milliroentgen. The proposed switch will equate our regulations to Federal nomenclature and will not change the meaning of the subsection.

§ 225.84. Operating and emergency procedures

Paragraph (9) is proposed to be changed from radiation-producing machines to radiation-producing devices.

§ 225.85. Surveys and survey records

Subsection (b) is proposed to be amended to lengthen the record retention requirement from 3 years to 5 years to maintain consistency throughout this Commonwealth's radiological health regulations.

§ 225.86. Utilization logs

Several provisions are proposed to be changed from radiation-producing machine to radiation-producing device. This section is also proposed to be amended to lengthen the record retention requirement from 3 years to 5 years to maintain consistency throughout this Commonwealth's radiological health regulations.

§ 225.92. Radiation survey meter calibration requirements

Minor editorial changes are proposed for subsections (a) and (b)(5) by switching the placement of units of measurement and to correct a typographical error. The proposed changes will not change the meaning of the subsections. Subsection (c) is proposed to be amended to lengthen the record retention requirement from 3 years to 5 years to maintain consistency throughout this Commonwealth's radiological health regulations.

§ 225.93. Personnel monitoring control

A minor editorial change is proposed for subsection (d)(1) of this section by switching the placement of a reference to 200 mR. The proposed switch will equate the Department's regulations to Federal nomenclature and will not change the meaning of the subsection. Subsection (d)(3) is proposed to be amended to lengthen the record retention requirement from 3 years to 5 years to maintain consistency throughout this Commonwealth's radiological health regulations.

§ 225.101. Cabinet X-ray systems and baggage/package X-ray systems

This section is proposed to be rescinded and reserved. Requirements applicable to cabinet X-ray systems, security screening systems, baggage and package systems are proposed under Chapter 227a, as described later in section E.

§ 225.101a. Radiographic X-ray systems

This section proposes to add requirements applicable to radiographic X-ray systems. Paragraphs (1)–(7) would establish a dose limit measured at a distance of 1 meter of 100 mR in one hour when an X-ray tube is operated at its leakage technique factors and compliance would be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters; require that an X-ray system have a collimator to restrict the useful beam; require that a means be provided to terminate exposure after a preset time, a preset to image receptor, or a preset product of exposure time and tube current; require that the X-ray control have a dead man type exposure switch; require that X-ray controls indicate

technique factors (e.g. kilovoltage, tube current and exposure time); specify labeling requirements, including a requirement for a sign bearing the radiation symbol; and a requirement that an easily visible warning light be located adjacent to an X-ray tube and be illuminated only when the X-ray tube is energized or the shutter is open. These regulations are currently in § 225.104(c) but are proposed to be relocated to this section due to splitting the types of radiography regulated between Chapters 225 and 227a.

Paragraph (8) would require registrants to perform radiation surveys to demonstrate compliance with 10 CFR 20.1301 (relating to does limits for individual members of the public). Additionally, this paragraph includes a record retention requirement of 5 years to maintain consistency throughout this Commonwealth's radiological health regulations. Registrant would be required to maintain records upon acceptance of the equipment, following maintenance requiring the disassembly or removal of any shielding equipment, and when a visual inspection reveals an abnormal condition

Paragraph (9) would require that records of tests of on-off switches, interlocks and safety devices subject to this section be maintained for 5 years rather than the currently required 3 years to ensure consistency in record retention time requirements throughout this Commonwealth's radiological health regulations.

§ 225.102. Shielded room X-ray radiography

This section is proposed to be rescinded and reserved. The provisions of subsections (a)–(c) are proposed to be transferred to proposed § 227a.55 (relating to shielded room radiation-producing devices) with minor editorial changes. The exemption provision of existing subsection (d) is proposed to be deleted, because shielded room radiography is proposed to be transferred to Chapter 227a and these exemptions are for Chapter 225 for field radiography. Chapter 227a exemptions are in proposed § 227a.3.

§ 225.103. Field site radiography.

It is proposed that the heading of this section be revised by deleting "site" to make it clear the section applies to field radiography.

Subsection (a) (relating to field site radiography) is proposed to be amended by requiring that survey results and records of boundary locations be maintained for 5 years rather than 3 years to ensure consistency in record retention time requirements throughout this Commonwealth's radiological health regulations.

Subsections (a.1) through (a.6) are proposed to be added to require surveillance of the exposure area be maintained during operation; require that a suitable calibrated radiation detection instrument be used to verify the radiation sources is in its shielded position or that the X-ray tube has been de-energized; establish that an appropriately designed and calibrated personal alarming dose meter must be worn to approach the work area to detect the source; and that measurements of radiation levels for a radiation survey be performed using an appropriate calibrated radiation survey meter; the radiation levels shall be measured around the perimeter, which shall be

adjusted accordingly, of the controlled area; and, the survey around the perimeter shall be made for each new operating condition. These provisions are incorporated from SSR Part H; however, it is proposed that they be split between Chapters 225 and 227a to be consistent with the types of radiography regulated under the respective chapters.

§ 225.104. X-ray detection systems for explosives, weapons and illegal items

It is proposed that this section be rescinded and reserved. All requirements in this section are instead proposed to be addressed in proposed Chapter 227a.

Chapter 227. Radiation Safety Requirements for Analytical X-ray Equipment, X-ray Gauging Equipment, Electron Microscopes and X-ray Calibration Systems

Chapter 227 is proposed to be rescinded and reserved. A new Chapter 227a, entitled "Radiation Safety Requirements for Non-Healing Arts Radiation-Producing Devices" and consisting of four subchapters, is proposed to be added as more fully described below. The proposed subchapters relate to general provisions, general technical requirements, closed-beam radiation-producing devices and open-beam radiation-producing devices. This new chapter expands upon the explanations of the requirements that are in the current Chapter 227 to provide more clarity to the regulated community and includes emerging technologies in the field.

Chapter 227a. Radiation Safety Requirements for Non-Healing Arts Radiation-Producing Devices

Subchapter A. GENERAL PROVISIONS

§ 227a.1. Purpose and scope

Proposed § 227a.1 establishes that Chapter 227a would regulate non-healing arts radiation-producing devices operating between 5 kiloelectron volts and 1 million electron volts and apply to all devices defined in § 227a.2. It also clarifies that registrants subject to this chapter would also be subject to the requirements of Chapters 215, 216, 219 and 220 (relating to general provisions; registration of radiation-producing machines and radiation-producing machine service providers; standards for protection against radiation; and notices, instructions and reports to workers; inspections and investigations). The proposed chapter would not pertain to radiation safety requirements for X-ray equipment covered under Chapters 221, 225 and 228 (relating to X-rays in the healing arts; radiation safety requirements for industrial radiographic operations; and radiation safety requirements for particle accelerators).

This section would establish that the provisions in proposed Chapter 227a would apply to cabinet radiography, shielded room radiography, bomb detection equipment and open-beam radiography. Open-beam industrial radiography not in a shielded room or specifically listed in this chapter is regulated under Chapter 225.

§ 227a.2. Definitions

Proposed § 227a.2 sets forth the definitions of 55 terms and acronyms which are used in Chapter 227a. These definitions have been incorporated from SSR Part H, except for "electron microscope" which is moved from § 227.2, and "lockout / tagout," "radiation-producing devices used in individual security screening system," "open-beam radiation-producing device," and "permanent radiographic installation", which are new definitions. Additionally, the terms "qualified expert", "radiation safety officer" and "registrant" have been added and are defined by referencing their definitions in § 215.2 (relating to definitions), as well as the definition for "X-ray tube" as defined in § 221.2 (relating to definitions).

§ 227a.3. Exemptions

Proposed subsections (a) and (b) provide that bomb protection radiation equipment and handheld radiation-producing devices are exempt from the posting requirements of proposed § 227a.16 (relating to posting). Posting is unnecessary for these as they are mobile devices and radiation safety of the equipment and devices is under the control of the user.

Proposed subsection (c) describes equipment which is exempt from the requirements of Chapter 227a. Exempt equipment includes domestic television receivers, cold-cathode gas discharge tubes and other electrical equipment, other than electron microscopes that produce radiation incidental to its operation. To be exempt, the referenced equipment must conform to exposure limits specified in the proposed regulation.

Proposed subsection (d) clarifies that the equipment described in this section would not be exempt from the requirements of Chapter 227a if it is used or handled in such a way that an individual might receive a radiation dose in excess of limits specified in Chapter 219 (relating to standards for protection against radiation).

Proposed subsection (e) provides that equipment operating at less than or equal to 50 kiloelectron volts (kV) tube voltage and designed to be held by an operator is exempt from the requirements of Chapter 227a except for those set forth in §§ 227a.12 and 227a.21 (relating to labelling; and instruction and training). This is because the exposure levels are negligible and do not affect the public's health or safety.

§ 227a.4. Application for exemptions

Proposed § 227a.4 describes how a registrant that is subject to the requirements of Chapter 227a but cannot meet one or more requirements of Chapter 227a may request an exemption to those requirements and what information needs to be submitted for the exemption. The information to be submitted would include a demonstration that the use will not result in undue hazard to public health and safety; that compliance with the provision from which exemption is sought would not require replacement or substantial modification of the radiation-producing device; and that radiation protection equivalent to that required by the provision from which the exemption is sought will be achieved.

Subchapter B. GENERAL TECHNICAL REQUIREMENTS

Proposed Subchapter B outlines general technical requirements applicable to proposed Chapter 227a. Proposed subchapter B includes proposed §§ 227a.10—227a.22.

§ 227a.10. Radiation safety program

Proposed § 227a.10 outlines the requirements for a radiation safety program for registrants intending to use radiation-producing devices. The program would include employee training, normal operating procedures, emergency procedures, monitoring reports, internal review systems and an organizational structure for radiation protection. This requirement is added to ensure the safety of those operating and subjected to radiation-producing devices.

§ 227a.11. Warning devices

Proposed § 227a.11 would require that warning devices be labeled with their purpose to ensure awareness and to have a warning light of a fail-safe design in order to prevent any failures of the warning light.

§ 227a.12. Labeling

Proposed subsection (a) prescribes labeling requirements for radiation-producing devices in order to provide the user or anyone near with a visual warning that the equipment may become dangerous when energized. Proposed subsection (b) prescribes labeling requirements for radiation-producing devices with designed openings for object entries, such as baggage units.

§ 227a.13. Radiation source housing

Proposed subsection (a) requires that when an X-ray tube housing is the primary shielding for an X-ray tube, the housing be equipped with an interlock that shuts off the high voltage to the X-ray tube if the housing is opened for normal use or maintenance.

Proposed subsection (b) requires that the housing be constructed so that the leakage radiation measurement at 5 centimeters distance does not exceed 2.5 millirem in order to ensure dose rates are maintained at a rate that is as low as reasonably achievable.

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

Proposed § 227a.14 provides that an X-ray generator or high-voltage source must have a protective cabinet that limits leakage radiation to 0.5 millirem per hour at 5 centimeters. Alternative measurement specifications are proposed for closed-beam radiation-producing devices, radiation-producing devices in a shielded room with the high-voltage generator also inside the room, and for handheld, open-beam radiation-producing devices. These alternative measurement specifications are proposed, because different device types have different dose rates associated with them.

§ 227a.15. Surveys

Proposed subsection (a) provides that radiation surveys must be sufficient to evaluate the radiation emissions and potential hazards and that the survey records be maintained for 5 years to ensure consistency in record retention time requirements throughout this Commonwealth's radiological health regulations. It also specifies that a survey must be performed upon installation and once every 12 months thereafter; after a change in initial arrangement, number or type of local components and prior to returning to service; following maintenance that requires disassembly, removal or repair; during performance of maintenance, calibration and another procedure if it requires the presence of a primary beam while any local component is disassembled or removed; following bypass of a safety device or interlock; when a visual inspection of the local components shows an abnormal condition; and when a personal monitoring device shows a significant increase, as predetermined by the registrant, over the previous monitoring period or approaches the limits of 10 CFR 20.1201 (relating to operating requirements). Surveys after these events are important, because these types of events could involve changes to the major parts of the device and therefore, the resulting beam produced could be altered. The surveys are necessary to make sure the beam is not performing outside of its intended limits.

Proposed subsection (b) provides that a registrant must have access to sufficiently calibrated, appropriate and operable radiation survey instruments in order to make physical radiation surveys required under by Chapter 227a.

Proposed subsection (c) requires that a registrant assure the maintenance and calibration of all monitoring and survey instruments under 10 CFR 20.1501 (relating to general) to ensure the instruments can accurately detect the type of radiation measured.

Proposed subsection (d) provides that radiation surveys are not required if a registrant otherwise demonstrates compliance with Chapter 227a to the Department's satisfaction.

§ 227a.16. Posting

Proposed § 227a.16 provides that signage must be conspicuously posted in each area or room containing a radiation-producing device where an individual may receive 2 millirem (0.02 mSv) in any one hour or 100 millirem (1mSv) per year in order to caution individuals that radiation is produced when the device is energized.

§ 227a.17. Security

Proposed § 227a.17 provides that radiation-producing devices must be secured at all times to be accessible or operated only by authorized personnel in order to prevent unauthorized use and possible unintended radiation exposure.

§ 227a.18. Operating requirements

Proposed subsection (a) would require normal operating procedures to be written and available to all radiation-producing device workers to ensure all workers are properly trained in the correct use of the device, thus preventing unnecessary radiation exposure.

Proposed subsection (b) outlines requirements relating to bypassing. A safety device or interlock may be bypassed only if approved by the radiation safety officer. When there is a bypass, a sign explaining that the safety device is not working must be placed on the radiation source housing and at the control switch. These requirements are from the current § 227.13a and are being transferred to this section.

Proposed subsection (b) would also require that records of bypasses be maintained in order to ensure proper procedures were followed during the bypass as these procedures will be reviewed during an inspection, and also to ensure the safety of those involved in the procedure. Records of bypasses must contain the date and a detailed description of the bypass, length of time the unit was in the altered condition, the post bypass survey noted in § 227a.15 and other relevant information. The records shall be signed by the radiation safety officer, the individual who performed the bypass and the individual who restored the unit.

Proposed subsection (c) outlines requirements relating to the control panel. A radiation-producing device may only be activated from a control panel, and indicators and controls that control the primary beam must be identifiable through the use of labels, symbols, software displays or equivalent methods.

Proposed subsection (d) outlines requirements relating to interlocks. An interlock may only be used to de-activate an X-ray tube in an emergency or during testing of an interlock system. In addition, the resetting of a radiation-producing device must only be possible from the control panel and all interlocks must be of a fail-safe design.

Proposed subsection (e) outlines requirements applicable to multiple sources of radiation being operated from a control panel. Visual indicators must identify which tube assembly or focal spot was selected and if a letter or number is used for identification, a reference card or table explaining the code must be affixed to the control panel.

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

Proposed § 227a.19 (relating to repair or modification of X-ray tube or radiation-producing device) provides that only trained personnel or registered service providers are permitted to install or repair a radiation-producing device. It also provides that certain operations may only be performed after ascertaining that the X-ray tube is off and that a lock-out/tag-out must be used for routine shutdown for repairs. These requirements will ensure that experts are the only individuals able to repair or modify a radiation-producing device and provides for specifications to ensure the safety of such personnel while completing the repairs.

§ 227a.20. Testing of safety devices

Proposed subsection (a) requires that tests of safety devices be conducted at intervals not to exceed 12 months to ensure the proper operation of the safety devices so no unnecessary exposure of radiation could occur.

Proposed subsection (b) provides that if a safety device fails, it must be removed from service until repaired or temporary administrative controls established. Temporary administrative controls must be approved by the radiation safety officer. An example of temporary administrative controls is disconnecting the device from its power source, so that no radiation can be produced until the device can be repaired.

Proposed subsection (c) requires that records of safety device tests, check dates, findings and corrective actions be retained for 5 years to ensure consistency in record retention time requirements throughout this Commonwealth's radiological health regulations.

Proposed subsection (d) specifies that the records must include the date of the tests, a list of safety devices tested, survey instrument information, calibration date, the results of the test, the name of the person performing the test and corrective actions taken if the device fails the test.

Proposed subsection (e) provides that a test may be deferred if the unit or installation is clearly marked and kept out of service. A unit or installation brought back into service after 12-months must be tested prior to use.

Proposed subsection (f) provides that if a safety device test cannot be performed due to manufacturer design, the registrant must document that and specify why the safety device cannot be tested.

§ 227a.21. Instruction and training

Proposed § 227a.21 outlines training requirements for any individual who operates or maintains a radiation-producing device or enters a shielded room. An individual must receive instruction in and demonstrate competence in types of radiation and hazards associated with the use of the device and precautions and measures to minimize radiation exposure; the significance of warnings and safety devices installed on the equipment or reasons that they are not installed; the potential hazards of use, biological effects of radiation, radiation risks and recognition of symptoms of an acute exposure; normal operating procedures, including training, for each type of device and associated equipment; emergency procedures for reporting actual or suspected accidental exposures; and radiation survey performance. Records of all required training and instruction shall be retained onsite and available for the Department to review for 5 years to ensure consistency in record retention time requirements throughout this Commonwealth's radiological health regulations.

§ 227a.22. Radiation protection responsibility

Proposed subsection (a) provides that a registrant's designated senior management is responsible for the ultimate decision to use a radiation-producing device and for radiation safety. The registrant will document the designated senior management responsible for radiation safety and maintain those records for the Department to review for 5 years to ensure consistency in record retention time requirements throughout this Commonwealth's radiological health regulations.

Proposed subsection (b) provides that the registrant's senior management will designate a radiation safety officer. That individual would be responsible for: ensuring devices are operated in accordance with an established radiation safety program and normal operating procedures; instructing personnel in safe working practices; the investigation and reporting of incidents; ensuring safety devices, interlocks, warning signals, labels, postings and signs are functioning and located where required; and for maintaining radiation safety records for 5 years.

Subchapter C. CLOSED-BEAM RADIATION-PRODUCING DEVICES

Subchapter C is proposed to be added to establish requirements applicable to closed-beam radiation-producing devices. Subchapter C includes proposed §§ 227a.30—227a.35 as more fully described below.

§ 227a.30. System enclosure

Proposed § 227a.30 provides that a radiation source, sample or object, detector and analyzing crystal 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 human body during normal operation in order to protect the user from unnecessary radiation exposure.

§ 227a.31. Interlocks

Proposed § 227a.31 provides that the doors and panels of a closed-beam radiation-producing device must be interlocked and the interlock must be of a fail-safe design. These interlocks will not allow the doors or panels of a device to be opened while energized, thus preventing unnecessary exposure to radiation.

§ 227a.32. Interlock functions

Proposed § 227a.32 provides that a closed-beam radiation-producing device enclosure, sample chamber or similar enclosure 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 it is open unless the interlock has been deliberately defeated. An interlock would be deliberately defeated if a bypass was performed as described in § 227a.18. It also provides that the interlock must be of a fail-safe design or have adequate administrative controls to ensure operations can only continue with a proper functioning interlock.

§ 227a.33. Radiation emission limit

Proposed § 227a.33 provides that the radiation dose for closed-beam radiation-producing devices must not exceed 0.5 millirem (0.005 mSv) per hour at 5 centimeters outside any accessible surface. This dose limit was taken from SSR Part H and the current § 227.12a(b), which is proposed to be rescinded and replaced by this section.

§ 227a.34. Security screening devices

Proposed § 227a.34 requires that 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. During an exposure or preset succession of exposures of less than 0.5 second duration, the closed-beam security screening device must have a mechanism to enable the operator to terminate exposure or a preset succession of exposures at any time. The device must also have a mechanism to allow completion of the radiation exposure in progress but must enable the operator to prevent additional exposure during an exposure or preset succession of exposures of less than 0.5 second duration. These requirements ensure that an operator is able to safely monitor and manage an active security screening device.

§ 227a.35. Electron microscope devices

Proposed subsection (a) outlines the labeling requirements for closed-beam electron microscope devices. It must have a conspicuous sign bearing the words, "Caution Radiation—This Equipment Produces Radiation When Energized," or words containing a similar warning.

Proposed subsection (b) provides radiation levels 5 centimeters from an accessible surface of a closed-beam electron microscope device may not exceed 0.5 millirem (0.005 mSv) per hour.

Proposed subsection (c) provides that no individual may operate or conduct maintenance on closed-beam electron microscopes until the individual has a copy of, is instructed in, and has demonstrated an understanding of the normal operating procedures to ensure radiation safety.

Subchapter D. OPEN-BEAM RADIATION-PRODUCING DEVICES

Subchapter D is proposed to be added to establish requirements applicable to open-beam radiation-producing devices. Subchapter D includes proposed §§ 227a.40—227a.55 as more fully described below.

§ 227a.40. Safety devices

Proposed subsection (a) provides that a registrant must documents its justification of the registrant's use of an open-beam radiation-producing device rather than a closed-beam radiation-producing device. This requirement is proposed due to the higher likelihood of radiation exposure associated with an open-beam system compared to a closed beam system.

Proposed subsection (b) provides that if a registrant uses an open-beam radiation-producing device, the registrant must consider the use of a safety device to minimize 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 shut off upon entry into its path.

Proposed subsection (c) provides that if a safety device cannot be used to minimize the chance of direct body exposure, the registrant must maintain a record of the various safety devices evaluated and reasons the devices cannot be used. Such records must be maintained for as long as the method is used plus an additional 5 years to ensure consistency in record retention time requirements throughout this Commonwealth's radiological health regulations.

Proposed subsection (d) provides that if a registrant's use of an open-beam radiation-producing device prevents the use of a safety device, the registrant must use alternative methods, such as policies and procedures, to minimize the possibility of unnecessary exposure. The alternative methods must be documented, and the documentation maintained for as long as the methods are used, plus an additional 5 years to ensure consistency in record retention time requirements throughout this Commonwealth's radiological health regulations.

Proposed subsection (e) provides that a portable open-beam radiation-producing device without a safety device described in § 227a.40(b) that is manufactured to be used as a handheld device will meet the safety device requirements described in subsections (b)—(d) by complying with § 227a.50 (relating to handheld radiation-producing devices) prior to use.

§ 227a.41. X-ray on status

Proposed § 227a.41 requires that open-beam radiation-producing devices must provide a conspicuous and active indication of the following, as applicable; an X-ray tube "on-off" status indicator located near the radiation source; and a shutter "open-closed" status indicator located at the control panel and near each beam port on the radiation source housing. The X-ray tube "on-off" and shutter "open-closed" status indicators must be of a fail-safe design. These requirements ensure the safety of the operator and prevent unnecessary radiation exposure.

§ 227a.42. Labeling

Proposed § 227a.42 provides that each unit must be labeled at or near the X-ray exit beam port in order to identify the location of the beam with the words "CAUTION – X-RAY BEAM" or "CAUTION – HIGH INTENSITY X-RAY BEAM" or words with similar intent. This ensures the safety of the operator and any other users.

*§ 227a.43. Beam port*s

Proposed § 227a.43 requires that unused beam ports on radiation source housing be secured in the closed position to prevent them from being inadvertently used.

§ 227a.44. Shutters

Proposed § 227a.44 provides that for 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. This has been incorporated from SSR Part H and prevents unnecessary radiation being emitted from a port that is not being used.

§ 227a.45. Radiation emission limits

Proposed § 227a.45 provides that radiation emission limits (exclusive of the primary beam), set by the registrant, must be met at any specified tube rating established by the manufacturer. Local components of an open-beam radiation-producing device must be located and arranged and include sufficient shielding or access control so that no radiation emissions exist in any area surrounding the local component group which could result in an occupational radiation dose in excess of that specified in 10 CFR Part 20 Subpart C (relating to occupational dose limits) or a dose to an individual present therein in excess of the radiation dose limits outlined in § 219.51 (relating to dose limits for individual members of the public).

§ 227a.46. Primary beam attenuation

Proposed § 227a.46 provides that in cases where the primary beam is not intercepted by the detector devices under all conditions of operation, protective measures, such as auxiliary shielding or administrative procedures, must be provided to avoid exposure to any individual from the transmitted primary beam.

§ 227a.47. Operator attendance

Proposed § 227a.47 provides that the operator must be present at all times when the equipment is in operation except when the area is locked or the equipment is secured against unauthorized or accidental entry.

§ 227a.48. Control of access

Proposed § 227a.48 provides that if a radiation-producing device is not in a restricted area as defined in 10 CFR 20.1003 (relating to definitions), an operator of a radiation-producing device shall control access to the device at all times during operation. Radiation areas must be conspicuously identified, and the source located within a conspicuous perimeter that identifies where the radiation levels could result in an exposure to an individual in excess of 0.005 rem (0.05 mSv) in 1 hour or 0.1 rem (1 mSv) in 1 hour if it is a high radiation area. In radiation areas and high radiation areas, the perimeter must have a radiation caution sign and the operator must ensure no one enters the area during the operation of the device. In addition, an operator must perform a visual check of the controlled area to ensure that it is free of unauthorized personnel prior to activating or exposing the source.

§ 227a.49. Instruction and training

Proposed § 227a.49 provides that an individual may not operate or maintain an open-beam radiation-producing device unless the individual has met the requirements of § 227a.21 and received training applicable to the procedures to be performed and the equipment used. Applicable training may include instruction and demonstrated competence as to sources and magnitude of common radiation exposure; units of radiation measurement; radiation protection concepts of time, distance, shielding and ALARA (as low as reasonably achievable); procedures and rights of a declared pregnancy; regulatory requirements and area postings; worker embryo/fetus and public dose limits; proper use of survey instruments and dosimetry; and policies and procedures required under § 227a.40.

§ 227a.50. Handheld radiation-producing devices

Proposed § 227a.50 outlines additional requirements in Chapter 227a applicable to open-beam handheld radiation-producing devices. Paragraph (1) would require a registrant to have operating policies and procedures which ensure: that radiation protection is provided equivalent to that afforded under § 219.51 (relating to dose limits for individual members of the public) and § 227a.46; that the operator will not hold the sample during operation of the device and the operator's hands will not approach the primary beam; that the operator will not aim the primary beam at themselves or any individual during operation of the device; and that operator exposure is as low as reasonably achievable by use of means such as ancillary equipment.

With respect to training, paragraph (2) proposes that in addition to the proposed training requirements under §§ 227a.21 and 227a.49, a registrant of handheld radiation-producing devices provide training specified in this section for all users of such devices. This is due to the ease of unnecessary radiation exposure with these devices. Records of all user and operator training would be required to be maintained for 5 years to ensure consistency with record retention time requirements throughout this Commonwealth's radiological health regulations.

With respect to radiation emission limits, paragraph (3) proposes that the radiation emission limits in §§ 227a.13(b) and 227a.14, excluding the primary beam, would be met if the radiation emission on any accessible surface of the device does not exceed 2.5 millirem (0.025mSv) per hour at 5 centimeters.

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

Proposed § 227a.51 sets forth additional requirements applicable to bomb detection radiation-producing devices. The additional requirements are that the device be locked to prevent unauthorized use when not in use; a use log be maintained for each device that includes a description of the unit, date removed from storage, date returned to storage, name and signature of person assigned the device and the dates and sites of use; and that security be provided to prevent entry by individuals when the device is energized during training.

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

Proposed § 227a.52 sets forth additional requirements for radiation-producing devices used in individual security screening. A person requesting Department approval for such devices would be required to submit information addressing the requirements described below and receive Department approval prior to use.

A requester must submit an efficacy evaluation which evaluates all known alternate methods that could achieve the goals of the individual security screening program and explain why these methods will not be used in preference to the applicant's approach using ionizing radiation and an equipment evaluation by a qualified expert upon installation of the individual security screening device; after maintenance that affects the shielding, shutter mechanism or X-ray production components; upon any damage to the system; and every 12 months.

The applicant must show how the radiation dose limits described herein will be met. Dose limits for general use systems must be limited to 25 microrem (μrem) when used without regard to the number of scans per individual per year; dose limits for limited-use systems must be less than or equal to 1 mrem (0.01 mSv) when equipment is capable of operation greater than 25 μrem in a 12-month period at the facility; and dose limits for repeat individual security screenings at a single site may not receive an effective dose greater than 25 mrem (0.25 mSv) in a 12-month period.

Other requirements include: information regarding the effective radiation dose from one screening and example comparing the dose with known sources of radiation exposure be made available to screening subjects; training includes 8 hours of training for the radiation safety officer in radiation safety, 2 hours of training for the operator in radiation safety in addition to operation training provided by the manufacturer and annual refresher training for operators and radiation safety officers; individual security screening is prohibited on an individual under the age of 18 and individuals who have declared pregnancy without prior department approval; a preventive maintenance schedule from the manufacturer be followed; the registrant is responsible to have a written radiation safety program based on accepted radiation protection principles developed and implemented, and that program be reviewed at least annually by the radiation safety officer; and that relevant records be maintained for 5 years.

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

Proposed subsection (a) provides that when procedures for the operation of a mobile or transportable device used for security screening of vehicles includes knowingly exposing human occupants, the system is subject to the same requirements as general-use or limited-use systems in § 227a.52(1)–(5),described in the first 2 paragraphs of the discussion of § 227a.52.

Proposed subsection (b) provides that if the requirements of § 227a.52(1)–(5) cannot be met, then a means must be provided to assure that no occupants are present in the vehicle during screening.

Proposed subsection (c) provides that the effective radiation dose for a single inadvertent exposure to an individual must not exceed 500 mrem (5 mSv) and that a pre-screening with a mode or system that can meet the limits in § 227a.52(3)–(5) (described in the second paragraph of the discussion of § 227a.52 above) must be used to verify the vehicle is unoccupied if the 500 mrem (5 mSv) limit cannot be assured.

§ 227a.54. Permanent radiographic installations

Proposed subsection (a) provides that each entrance for personnel access have visual warning signals for whenever the X-ray source is energized and have audible warning signals when an attempt is made to enter the installation when the source is energized to warn of the presence of radiation.

The entrance control device or alarm system is to be tested prior to beginning operations on each day of use to ensure proper functionality.

If the entrance control device or alarm system is not functioning properly, it shall be removed from service and repaired or replaced immediately. If there is no replacement available, the facility may continue to be used as long as the registrants provide continuous surveillance in accordance with 10 CFR 34.51 and 34.53 (relating to surveillance; and posting) and § 225.85 and uses an alarming ratemeter. These extra requirements are necessary to verify and document that the X-ray source is not energized while also ensuring the safety of the workers.

Proposed subsection (b) requires records of the tests performed to be maintained for 5 years. This ensures consistency with record retention time requirements throughout this Commonwealth's radiological health regulations.

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

Proposed subsection (a) provides that a room used for shielded room X-ray radiography must be shielded so every location on the exterior meet conditions for an unrestricted area and that access to the room may only be through openings that are interlocked.

Proposed subsection (b) requires an operator to conduct a physical radiation survey to determine the source is deenergized prior to entry into the exposure area.

Proposed subsection (c) provides that an operator may use an independent radiation monitoring system that displays when radiation levels have returned to their pre-irradiation levels as an alternative to the survey required in subsection (b).

CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

§ 228.2. Definitions

Section 228.2 contains the definitions applicable to the provisions of Chapter 228. Except for a revision of the definition of "accelerator or particle accelerator" no changes are proposed for

Chapter 228. The definition of "accelerator or particle accelerator" is proposed to be changed to match the U.S. Nuclear Regulatory Commission's definition.

F. *Benefits, Costs and Compliance*

Benefits

The proposed rulemaking will affect users of non-medical radiation-producing devices within this Commonwealth. Users of such devices include prisons, government offices, schools, and manufacturers. These users would be required to comply with radiation protection standards that would not only protect and benefit users and employees but would also benefit the general public. The proposed rulemaking would ensure that operators of radiation-producing devices are trained properly so that both the operator and the public are adequately protected from radiation exposure.

Compliance costs

No changes are proposed to the fee schedule set forth in Chapter 218 (relating to fees). The proposed regulations do require additional training for radiation safety officers and operators of individual security screening devices as described in § 227a.52. Currently, there are 3 registrants of these devices. The additional training requirements are proposed due to operators not having experience or training in radiation protection practices. There could be a cost at start-up for the initial training provided by the vendor installing the device. The cost of initial training is approximately $950. There are no additional requirements for other devices covered by the proposed amendments since they are already required under existing regulations.

Compliance assistance plan

Outreach and support will be provided by regional inspectors and technical staff of the Department's Radiation Control Division. Assistance will be offered to address requirements for new technologies.

Paperwork requirements

The proposed rulemaking does not create any new paperwork requirements. However, it would extend various existing records retention requirements to a 5-year records retention period. This proposed extension was suggested by RPAC, and the Department agrees, to promote consistency in records retention requirements throughout this Commonwealth's radiological health regulations. These records do not need to be in paper format and may be stored electronically.

G. *Pollution Prevention*

Pollution prevention is not applicable to this proposed rulemaking.

H. *Sunset Review*

The Board is not proposing a sunset date for these regulations since they are needed for the Department to carry out its statutory authority. The Department will continue to closely monitor these regulations for their effectiveness and recommend updates to the Board as necessary.

I. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on (date), the Department submitted a copy of this proposed rulemaking and a copy of the Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Environmental Resources and Energy Committees. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria in section 5.2 of the Regulatory Review Act (71 P.S. § 745.5(b)) which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Department, the General Assembly and the Governor of comments, recommendations or objections raised.

J. *Public Comments*

Interested persons are invited to submit written comments, suggestions, support or objections regarding the proposed rulemaking to the Board. Comments, suggestions or objections must be received by the Board by (date).

Comments may be submitted to the Board online, by email, by mail or by express mail as follows:

Comments may be submitted to the Board online by accessing the Board's online comment system at http://www.ahs.dep.pa.gov/eComment.

Comments may be submitted to the Board by email at RegComments@pa.gov. A subject heading of the proposed rulemaking and a return name and address must be included in each transmission.

If an acknowledgement of comments submitted online or by email is not received by the sender within 2 working days, the comments should be retransmitted to the Board to ensure receipt. Comments submitted by facsimile will not be accepted.

Written comments should be mailed to the Environmental Quality Board, P.O. Box 8477, Harrisburg, PA 17107-8477. Express mail should be sent to the Environmental Quality Board, Rachel Carson State Office Building, 16th Floor, 400 Market Street, Harrisburg, PA 17101-2301.

K. *Public Hearings*

If sufficient interest is generated as a result of this publication, a public hearing will be scheduled at an appropriate location to receive additional comments.

PATRICK McDONNELL,
Chairperson