FINAL-FORM RULEMAKING
ENVIRONMENTAL QUALITY BOARD
[25 Pa. Code Chapters 225, 227, 227a and 228]

Radiation Safety Requirements for Non-Healing Arts Radiation-producing Devices

The Environmental Quality Board (Board) amends Chapters 225 and 228 (relating to radiation safety requirements for industrial radiographic operations; and radiation safety requirements for particle accelerators), deletes Chapter 227 (relating to radiation safety requirements for analytical X-ray equipment, X-ray gauging equipment, electron microscopes and X-ray calibration systems) and adds Chapter 227a (relating to radiation safety requirements for non-healing arts radiation-producing devices) to read as set forth in Annex A. The amendments include clarification and guidance regarding radiation safety and update the standards for protection against radiation.

There have been important advances in technology and use of X-rays and other ionizing radiation particles over the past 20 years for industrial radiography, non-contact level monitoring, foreign body detection, chemical purification, melting, welding, polymerization, sterilization, and security screening. A new model Suggested State Regulation (SSR) Part H was developed and finalized by the Conference of Radiation Control Program Directors (CRCPD). This SSR reviewed the advances in technology over the past 20 years and is used as reference material with the update to Chapter 227.

This final-form rulemaking was adopted by the Board at its meeting of _____(blank)_____.

A. *Effective Date*

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

B. *Contact Persons*

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C. *Statutory Authority*

This final-form rulemaking is authorized under section 301(c) of the Radiation Protection Act (35 P.S. § 7110.301(c)), which directs 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 Commonwealth's radiological health regulations in 2019 to provide for updates and technological advances in uses of radiation sources for 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 nonmedical 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 the potential health impacts, these amendments address nonmedical X-ray operations and emerging technologies in the industrial field to ensure that exposure to radiation from nonmedical radiation-producing devices is as low as reasonably possible. Some examples of nonmedical X-ray operations and emerging technologies that these regulations apply to include many recent advances in X-ray capabilities for bomb detection, contraband scanning, and advanced welding and detection capabilities.

These amendments affect approximately 1,400 radiation-producing device registrants in this 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 be government offices such as prisons and courthouses, universities and research laboratories. A small number of registrants for radiation-producing devices used in individual security screening are 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 § 227a.52 (relating to radiation-producing devices used in individual security screening). However, all current registrants have obtained this training.

This final-form rulemaking was 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. This final-form rulemaking was introduced to RPAC on March 3, 2022. On March 3, 2022, RPAC voted to concur with the Department's recommendation that this final-form rulemaking move forward in the regulatory process.

E. *Summary of Final-Form Rulemaking and Changes from Proposed to Final-Form Rulemaking*

The amendments to Chapter 225 are intended to separate and more clearly outline requirements applicable to nonmedical X-ray operations and field radiography. Chapter 227, which pertains to radiation safety requirements for analytical X-ray gauging equipment, electron microscopes and X-ray calibration systems, has been deleted and reserved. Regulations in Chapter 227 are moved to Chapter 227a, which outlines radiation requirements for these nonhealing arts radiation-producing devices. The requirements were rewritten and rearranged to incorporate SSR Part H and Part E, and to clarify all the requirements. The regulated community suggested that creating this new chapter would help them to clearly understand their regulatory obligations. Chapter 228 is amended to update a definition to match the United States Nuclear Regulatory Commission's terminology.

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

Unless otherwise indicated, the sections described below were not altered from the proposed rulemaking to this final-form rulemaking.

Chapter 225. Radiation Safety Requirements for Industrial Radiographic Operations

The heading for Subchapter B (relating to radiation-producing machines) is changed to "Radiation-Producing Devices" to more accurately reflect the applicability of the subchapter. Similar changes are included throughout various sections of Chapter 225.

§ 225.71. Definitions

Section 225.71 (relating to definitions) is 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 instead moved to Chapter 227a. The definition of "radiographer trainee" is deleted because, according to the industry, this is not a position. The definition of "industrial radiography" is 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 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 not a position as a radiographer trainee. This is the reason for the deletion of the definition of "radiographer trainee" in § 225.71 as well.

§ 225.74. Training and testing

Subsection (a)(3) is 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 needed to incorporate the training requirement from SSR Part E. Subsection (c) is 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 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 deleted 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 deleted and reserved as these requirements have been moved to the new Chapter 227a.

§ 225.82. Operating requirements

Subsection (a) is 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 included in subsection (c)(4) of this section by switching the placement of a reference to 200 milliroentgen. This switch will equate the Board's regulations to Federal nomenclature and will not change the meaning of the subsection.

§ 225.84. Operating and emergency procedures

Paragraph (9) is amended from radiation-producing machines to radiation-producing devices.

§ 225.85. Surveys and survey records

Subsection (b) is 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 amended from radiation-producing machine to radiation-producing device. This section is 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 amendments are included for subsections (a) and (b)(5) by switching the placement of units of measurement and to correct a typographical error. These amendments do not change the meaning of the subsections. Subsection (c) is 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 made to subsection (d)(1) of this section by switching the placement of a reference to 200 mR. The switch will equate the Department's regulations to Federal nomenclature and will not change the meaning of the subsection. Subsection (d)(3) is amended to lengthen the record retention requirement from 3 years to 5 years to maintain consistency throughout the Commonwealth's radiological health regulations.

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

This section is deleted and reserved. Requirements applicable to cabinet X-ray systems, security screening systems, baggage and package systems are instead addressed under Chapter 227a, as described as follows in section E.

§ 225.101a. Radiographic X-ray systems

This section adds requirements applicable to radiographic X-ray systems. Paragraphs (1)—(7) establish a dose limit measured at a distance of 1 meter of 100 mR in 1 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 (for example, 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) (relating to X-ray detection systems for explosives, weapons and illegal items) but are relocated to this section due to splitting the types of radiography regulated between Chapters 225 and 227a.

Paragraph (8) requires registrants to perform radiation surveys to demonstrate compliance with 10 CFR 20.1301 (relating to dose 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. The 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) requires 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 deleted and reserved. The provisions of subsections (a)—(c) are instead transferred to § 227a.55 (relating to shielded room radiation-producing devices) with minor editorial changes. The exemption provision of existing subsection (d) is deleted, because shielded room radiography is transferred to Chapter 227a and these exemptions are for Chapter 225 for field radiography. Chapter 227a exemptions are in § 227a.3 (relating to exemptions).

§ 225.103. Field radiography

The heading of this section is amended by deleting "site" to make it clear the section applies to field radiography.

Subsection (a) is 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 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, they are split between Chapters 225 and 227a to be consistent with the types of radiography regulated under the respective chapters.

In this final-form rulemaking, the sentence “The area of operation shall be monitored periodically if radiation levels are variable” in subsection (a.6) is deleted in response to comments from the Independent Regulatory Review Commission (IRRC) because it was duplicative of the sentence explaining that a survey should be performed whenever there is a new operating condition.

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

This section is deleted and reserved. Requirements in this section are instead addressed in 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 deleted and reserved. A new Chapter 227a, entitled "Radiation Safety Requirements for Non-Healing Arts Radiation-Producing Devices" and consisting of four subchapters, is added as more fully described as follows. The 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 were in 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

Subsections (a) and (b) establish that Chapter 227a regulates nonhealing arts radiation-producing devices operating between 5 kiloelectron volts and 1 million electron volts and apply to all devices defined in § 227a.2. It clarifies that registrants subject to this chapter would also be subject to the requirements of Chapters 215, 216, 219 and 220. The chapter does not pertain to radiation safety requirements for X-ray equipment covered under Chapters 221 (relating to X-rays in the healing arts), 225 and 228.

Subsections (c)—(f) establish that the provisions in Chapter 227a 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

This section establishes 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).

In this final-form rulemaking, multiple changes were made to § 227a.2 (relating to definitions) in response to comments from IRRC on the proposed rulemaking and to provide clarification.

The term “analytical X-ray equipment” is not used in the regulations in Chapter 227a and has been deleted. The units of measure in the definitions for “general-use system” and “limited-use system” have been corrected to microrem and microsievert. The substantive requirements in the “general-use system” and “limited-use system” definitions were deleted. The “general-use system” substantive provision is redundant with requirements in § 227a.52(3) (relating to radiation-producing devices used in individual security screening). The substantive requirement in the “limited-use system” definition for additional controls and documentation to ensure dose limits are not exceeded has been added to § 227a.52(4). XRF has been spelled out within the “handheld radiation-producing device” definition as it is used only once. In the definition of “radiation-producing device,” the phrase “must be” was replaced with “is” to clarify that there is no substantive requirement in the definition.

§ 227a.3. Exemptions

Subsections (a) and (b) establish that bomb protection radiation equipment and handheld radiation-producing devices are exempt from the posting requirements of § 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.

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 this final-form regulation. In this final-form rulemaking, paragraphs (1)—(3) were revised from the proposed rulemaking to replace the word “providing” with “if” to clarify that the exemption is conditioned upon not exceeding the specified exposure rates, as well as to conform to the *Pennsylvania Code & Bulletin Style Manual* § 6.15(b)(4).

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 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).

Subsection (e) establishes 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 labeling; 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

This section describes how a registrant that is subject to the requirements of Chapter 227a but cannot meet one or more requirements of Chapter 227a shall 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. In this final-form rulemaking, a sentence is added to state the Department may consider an application for exemption to clarify an exemption is not automatic when a request for one is submitted. The words "is subject to the requirements of this chapter and" are unnecessary and are deleted.

Subchapter B. General Technical Requirements

Subchapter B (relating to general technical requirements) outlines general technical requirements applicable to Chapter 227a. Subchapter B includes §§ 227a.10—227a.22.

§ 227a.10. Radiation safety program

This section outlines the requirements for a radiation safety program for registrants intending to use radiation-producing devices. The program includes employee training, normal operating procedures, emergency procedures, monitoring reports, internal review systems and an organizational structure for radiation protection. This requirement ensures the safety of those operating and subjected to radiation-producing devices.

§ 227a.11. Warning devices

This section requires that warning devices be labeled with their purpose to ensure awareness and to have a warning light of a fail-safe design to prevent any failures of the warning light.

§ 227a.12. Labeling

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

In this final-form rulemaking, subsection (a) is amended in response to comments from IRRC. The cross-reference to § 219.159 (relating to posting of radiation-production machines) is deleted as it was unnecessary.

§ 227a.13. Radiation source housing

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.

Subsection (b) requires that the housing be constructed so that the leakage radiation measurement at 5 centimeters distance does not exceed 2.5 millirem 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

This section requires an X-ray generator or high-voltage source to have a protective cabinet that limits leakage radiation to 0.5 millirem per hour at 5 centimeters. Alternative measurement specifications are included 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 provided because different device types have different dose rates associated with them.

§ 227a.15. Surveys

Subsection (a) requires 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 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 an increase over the previous monitoring period or approaches the limits of 10 CFR 20.1201 (relating to occupational dose limits). 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.

In this final-form rulemaking, subsection (a)(7) is changed to “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).” This change is made to clarify the amount of an increase that would indicate something is wrong with the equipment that may not otherwise be apparent except through this dosimetry.

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

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. In this final-form rulemaking, the term “assure” is corrected to “ensure” in response to a comment from IRRC.

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

This section requires 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 1 hour or 100 millirem (1mSv) per year to caution individuals that radiation is produced when the device is energized.

§ 227a.17. Security

This section requires that radiation-producing devices must be secured at all times to be accessible or operated only by authorized personnel to prevent unauthorized use and possible unintended radiation exposure.

§ 227a.18. Operating requirements

Subsection (a) requires 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.

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 were required by § 227.13a and are being transferred to this section.

Subsection (b) also requires that records of bypasses be maintained to ensure proper procedures were followed during the bypass as these procedures will be reviewed during an inspection, and 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 (relating to surveys) 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. In this final-form rulemaking, the Board clarified in subsection (b)(3) that these records must be maintained for 5 years to maintain consistency throughout the radiological health regulations.

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.

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.

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

This section requires that only trained personnel or registered service providers are permitted to install or repair a radiation-producing device. It states 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 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 this personnel while completing the repairs.

§ 227a.20. Testing of safety devices

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.

Subsection (b) requires that if a safety device fails, it must be removed from service until repaired or temporary administrative controls are 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.

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.

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.

Subsection (e) allows for a test to 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.

Subsection (f) states 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

This section outlines training requirements for individuals who operate or maintain 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.

In this final-form rulemaking, the sentence “Before an individual may operate or maintain a radiating-producing device or enter a shielded room, the individual shall receive instruction in and shall demonstrate competence as to the following:” is revised to “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:” in order to clarify how competence is evaluated as suggested by IRRC. The review and inspection of registrants’ and licensees’ training records serves as the performance evaluation, which is a standard action conducted by the Radiation Protection Program.

§ 227a.22. Radiation protection responsibility

Subsection (a) states 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 must 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.

Subsection (b) requires that the registrant's senior management to 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.

In this final-form rulemaking, based on comments from IRRC, subsection (b)(5) is revised to clarify which records must be retained and reference the Federal regulation containing the annual review requirements.

Subchapter C. Closed-Beam Radiation-Producing Devices

Subchapter C (relating to closed-beam radiation-producing devices) is added to establish requirements applicable to closed-beam radiation-producing devices. Subchapter C includes §§ 227a.30—227a.35 as more fully described as follows.

§ 227a.30. System enclosure

This section requires 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 to protect the user from unnecessary radiation exposure.

§ 227a.31. Interlocks

This section requires 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

This section requires a closed-beam radiation-producing device enclosure, sample chamber or similar enclosure to 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 (relating to operating requirements). It requires the interlock to 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

This section requires 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 § 227.12a(b), which is deleted and replaced by this section.

§ 227a.34. Security screening devices

This section 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 0.5 second or greater 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

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.

Subsection (b) requires that 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.

In the proposed rulemaking, subsection (c) was added to specify 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. However, based on comments from IRRC, subsection (c) is removed from this final-form rulemaking as it is duplicative of § 227a.21.

Subchapter D. Open-Beam Radiation-Producing Devices

Subchapter D (relating to open-beam radiation-producing devices) is added to establish requirements applicable to open-beam radiation-producing devices. Subchapter D includes §§ 227a.40—227a.55 as more fully described as follows.

§ 227a.40. Safety device

Subsection (a) requires a registrant to document 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 due to the higher likelihood of radiation exposure associated with an open-beam system compared to a closed beam system.

Subsection (b) requires 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.

Subsection (c) requires 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. The 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. Based on comments from IRRC, in this final-form rulemaking, the justification for using open-beam radiation-producing device is added to the records required to be maintained in subsection (c).

Subsection (d) requires 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 the Commonwealth's radiological health regulations.

Subsection (e) requires that a portable open-beam radiation-producing device without a safety device described in § 227a.40(b) (relating to safety device) 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

This section 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

This section requires each unit to 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" 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 ports

This section 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

This section requires 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

This section requires that radiation emission limits (exclusive of the primary beam) 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).

Based on comments from IRRC, this section is revised in this final-form rulemaking so radiation emission limits must be met at the specified tube rating established by the manufacturer and not set by the registrant as required by the proposed rulemaking, who would not traditionally be expected to set emission limits. Additionally, a reference to “manufacture” was corrected to “manufacturer.”

§ 227a.46. Primary beam attenuation

This section requires 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

This section requires the operator to 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

This section requires 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.

Based on comments from IRRC, this section is revised in this final-form rulemaking to delete the sentence "If the radiation-producing device is not in a restricted area and the radiation-producing device is capable of creating a radiation area or a high radiation area as defined 10 CFR 20.1003 (relating to definitions), the operator shall control access to the radiation-producing device at all times during operation" because the first sentence is broad enough, as written, to cover this scenario.

§ 227a.49. Instruction and training

This section requires 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

This section outlines additional requirements in Chapter 227a applicable to open-beam handheld radiation-producing devices. Paragraph (1) requires a registrant to have operating policies and procedures which ensure: that radiation protection is provided equivalent to that afforded under § 219.51 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) states that in addition to the 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 the 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) explains that the radiation emission limits in §§ 227a.13(b) (relating to radiation source housing) 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

This section establishes 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.

Based on comments from IRRC and for consistency throughout the radiological health regulations, the five-year record retention requirement is added to paragraph (2) in this final-form rulemaking. Paragraph (3) is also revised from the proposed rulemaking to replace the words “from any point when the device is energized during training” with the phrase “to the area in which the device is energized.” This requirement to provide security to prevent entry by individuals when the device is energized must be met at all times, not just during training and is implemented based on the registrant’s operating procedures. This is necessary to ensure no unnecessary exposures to radiation occurs and to protect the workers and anyone else nearby from exposure to radiation. The new language also clarifies which area must be controlled. It will be implemented by physical controls that the registrant uses, such as barriers, doors or warning signs, which can be verified upon inspection.

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

This section establishes additional requirements for radiation-producing devices used in individual security screening. A person requesting Department approval for these devices would be required to submit information addressing the requirements described as follows 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 (rem) 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 rem per screening; 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 18 years of age 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.

Based on comments from IRRC received on the proposed rulemaking, paragraph (4) is revised in this final-form rulemaking to delete the words "and is used with discretion" and the following sentence was added: "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)." This revision is made to provide clarity for the regulated community and ensure exposures are tracked so dosage limits for individual and vehicle security screening devices are not exceeded. Additionally, a spelling error for "preventative" is corrected in paragraph (9).

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

Subsection (a) requires 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 two paragraphs of the discussion of § 227a.52.

Subsection (b) requires 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.

Subsection (c) requires 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 previously) must be used to verify the vehicle is unoccupied if the 500 mrem (5 mSv) limit cannot be assured.

Based on comments from IRRC, subsection (a) is revised in this final-form rulemaking to delete "general-use and limited-use systems" because the cross-reference is for § 227a.52(1)—(5) and

not just (3) and (4). Subsections (b) and (c) are revised in this final-form rulemaking to replace "assure" with "ensure."

§ 227a.54. Permanent radiographic installations

Subsection (a) requires 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 must 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 (relating to surveys and survey records) 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. Subsection (a)(3) is revised in this final-form rulemaking to replace the phrase "provided that" with "if" to clarify that use of the facility without the control device or alarm system is conditional, as well as to conform to the *Pennsylvania Code & Bulletin Style Manual* § 6.15(b)(4).

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

Subsection (a) requires a room used for shielded room X-ray radiography to 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.

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

Subsection (c) states 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

This section 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 included for Chapter 228 in this final-form rulemaking. The definition of "accelerator or particle accelerator" is amended to match the United States Nuclear Regulatory Commission's definition.

F. *Summary of Comments and Responses on the Proposed Rulemaking*

The Board received comments from one public commentator during the public comment period and received additional comments from IRRC.

The public commentator suggested the general-use and limited-use systems reference effective doses in § 227a.52 be consistent with ANSI standards. The Board acknowledges the units of measure are different than the ANSI standards; however, the units were changed for consistency with the Commonwealth's radiological health regulations and the U.S. Nuclear Regulatory Commission's regulations. Therefore, the Board did not modify the units used in this final-form rulemaking.

The public commentator also suggested the phrase "…in a 12-month period" in paragraph (3) of § 227a.52 of the Preamble was an error. The Board reviewed the paragraph and agrees it was an error. The Preamble for this final-form rulemaking has been corrected.

The public commentator also suggested the 8-hour training requirement for the RSO for individual security devices in § 227a.52 is excessive and instead recommended a 4-hour RSO training plus the 2-hour operator training. The Board considered this but did not revise the training requirements in this final-form rulemaking as the individuals receiving this training, such as corrections officers, will likely not have prior knowledge in, or experience with, radiation safety. These machines are being used in settings such as prisons and drug rehabilitation centers to search for contraband. In these settings, employees have not traditionally used radiation-producing devices. This training is important for them to understand and promote the safety of all individuals operating and being screened by the device.

IRRC suggested a variety of editorial changes incorporated by the Board in this final-form rulemaking, including deletion of unnecessary cross references, and unclear or unnecessary regulatory language. IRRC also recommended adding a five-year retention period to multiple subsections to improve clarity and consistency, which the Board incorporated in this final-form rulemaking.

IRRC asked the Board to explain how a registrant would be evaluated for compliance with § 227a.15(d), which allows for a registrant to not perform surveys if it demonstrates compliance another way. The Board notes that compliance is evaluated by reviewing historical radiation survey results shielding calculations, personnel dosimetry reports, area monitoring, and manufacturer literature. Therefore, no change is necessary in this final-form rulemaking.

IRRC questioned how competence would be evaluated for § 227a.21 and if the registrant needs to maintain a record of competence. The Board revised this final-form rulemaking to clarify that competence would be evaluated "through a performance evaluation by the registrant" which would be maintained onsite with the registrant's other training and instruction records.

IRRC reviewed § 227a.22(b)(5) and wondered if all records required in Chapter 227a are safety records and what the radiation protection program annual audit requirements are. The Board considered this and revised this final-form rulemaking to change radiation safety records to all records. The Board notes the annual audit requirement is a federal requirement incorporated by reference in the Department's regulations. *See* 10 CFR 20.1101(c) (relating to Radiation

Protection Programs); incorporated by reference in 25 Pa. Code § 219.5 (relating to incorporation by reference). The Federal code reference and language was added, as was the Pennsylvania Code reference.

IRRC asked how an individual would be evaluated for compliance in § 227a.35(c) and if there is a record of competence. The Board reviewed the subsection and found it is duplicative of § 227a.21 and deleted the subsection from this final-form rulemaking.

IRRC asked why a safety device is not required instead of just being considered in § 227a.40(b) and how this protects the health, safety and welfare of the operators. The Board noted that sometimes a safety device will prevent the device from taking accurate images and in these cases the device can still operate in a manner that protects the operators if it is operated according to policies and procedures designed to minimize the possibility of unnecessary exposure which is required in subsection (d).

IRRC requested the Board explain how paragraph (3) of § 227a.51, regarding the registrant preventing entry when the device is energized during training, in the Preamble of the proposed rulemaking will be implemented. The Board deleted "during training" for this final-form rulemaking, because preventing entry is required at all times when the device is energized. The registrant must provide security to prevent entry.

IRRC requested the Board explain in the RAF if the cost of training is per individual and to update questions 19-21 and 23 in the RAF with estimates for costs for additional devices and operators. The Board notes the training cost is for the RSO. There is one RSO per registrant and that has been clarified in the RAF. The operators are trained by the RSO and, therefore, no revisions are necessary to the cost estimate in the RAF.

IRRC had several comments regarding definitions in § 227a.2. IRRC noted that the term analytical X-ray equipment is not used in the proposed rulemaking and should be deleted; general-use systems and limited-use systems should have less substantive provisions and those provisions should be moved to the appropriate section of the rulemaking, the units of measure should match the units in SSR Part H, and the cross-reference to § 227a.53(e) should be corrected in limited-use systems; and, the acronym XRF should be spelled out in the definition of handheld radiation-producing device. The Board has considered these comments and deleted the definition for analytical X-ray equipment, deleted provisions from general-use and limited-use systems and it was not necessary to add them to § 227a.52, and stated X-ray fluorescence instead of XRF in this final-form rulemaking.

G. *Benefits, Costs and Compliance*

Benefits

This final-form rulemaking affects users of nonmedical radiation-producing devices within this Commonwealth. Users of these devices include prisons, government offices, schools and manufacturers. These users are required to comply with radiation protection standards that not only protect and benefit users and employees but also benefit the general public. This final-form rulemaking ensures 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 made to the fee schedule set forth in Chapter 218 (relating to fees). This final-form rulemaking does require additional training for RSOs and operators of individual security screening devices as described in § 227a.52. Currently, there are no registrants of these devices that have not obtained this training. The additional training requirements are 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 amendments since they are already required under existing regulations.

Compliance assistance plan

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

Paperwork requirements

This final-form rulemaking does not create any new paperwork requirements. However, it extends various existing records retention requirements to a 5-year records retention period. This 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.

H. *Pollution Prevention*

The Pollution Prevention Act of 1990 (42 U.S.C.A §§ 13101—13109) is not applicable to this final-form rulemaking.

I. *Sunset Review*

The Board is not establishing a sunset date for this final-form rulemaking, because it is 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.

J. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on July 14, 2021, the Department submitted a copy of the notice of proposed rulemaking, published at 51 Pa.B. 4845 (August 14, 2021), and a copy of a Regulatory Analysis Form to IRRC and the Chairpersons of the House and Senate Environmental Resources and Energy Committees for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents

when requested. In preparing this final-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act, on ___(blank)___, this final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on ___(blank)___ and approved this final-form rulemaking.

K. *Findings of the Board*

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202), referred to as the Commonwealth Documents Law, and regulations promulgated thereunder at 1 Pa. Code §§ 7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law, and all comments were considered.

(3) This final-form rulemaking does not enlarge the purpose of the proposed rulemaking published at 51 Pa.B. 4845.

(4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in section C of this order.

L. *Order of the Board*

The Board, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 25 Pa. Code Chapters 225, 227, 227a, and 228, are amended to read as set forth in Annex A.

(b) The Chairperson of the Board shall submit this final-form regulation to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form, as required by law.

(c) The Chairperson of the Board shall submit this final-form regulation to the IRRC and the Senate and House Environmental Resources and Energy Committees as required by the Regulatory Review Act.

(d) The Chairperson of the Board shall certify this final-form regulation and deposit it with the Legislative Reference Bureau, as required by law.

(e) This final-form regulation shall take effect 90 days after publication in the *Pennsylvania Bulletin.*

RAMEZ ZIADEH, P.E.,
Acting Chairperson