# Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

*INDEPENDENT REGULATORY REVIEW COMMISSION*
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Independent Regulatory Review Commission
IRRC Number: 3311

(1) Agency: Department of Environmental Protection

(2) Agency Number: 7
Identification Number: 555

(3) PA Code Cite: 25 Pa. Code Article V. Radiological Health Chapters 225, 227, 227a, and 228

(4) Short Title: Radiation Safety Requirements for Non-Healing Arts Radiation Producing Devices

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: Laura Griffin, 717.772.3277, laurgriffi@pa.gov
Secondary Contact: Brian Chalfant, 717.783.8073, bchalfant@pa.gov

(6) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- ☒ Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
  - ☐ Certification by the Governor
  - ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The Chapter 227a regulations are intended to address developments in radiation technology in industrial types of radiation-producing devices, which have occurred since the regulations covering these devices were last updated in 2009. Since that time, there have been advances in technology and use of X-rays and other ionizing radiation for non-medical radiography. Parts of Chapter 225 are moved to Chapter 227a to separate field radiography and non-medical X-ray operations. Also, the definition of "accelerators" in Chapter 228 is being amended to reflect the U.S. Nuclear Regulatory Commission's definition.

These final-form rulemaking amendments are based on Suggested State Regulations (SSR) Part H and the training requirements in SSR Part E that were developed by the Conference of Radiation Control Program Directors (CRCPD).

(8) State the statutory authority for the regulation. Include specific statutory citation.

The amendments to Chapters 225, 227, 228, and a new Chapter 227a, are authorized under the following:

- 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 of the Radiation Protection Act, 35 P.S. § 7110.302, which requires the Environmental Quality Board (Board) to "adopt the rules and regulations of the department to accomplish the purposes and carry out the provisions of [the] act."

- Section 1920-A of the Administrative Code, 71 P.S. § 510-20, which authorizes the Board to promulgate rules and regulations necessary for the performance of the work of the Department.

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

This regulation is not mandated by any federal or state law, court order, or federal regulation, and there are no relevant state or federal court decisions. However, the amendments incorporate SSR Part H and the training requirements in SSR Part E that were developed by CRCPD. Moreover, it better aligns the state regulations with the federal requirements under 10 CFR Part 34 (relating to licenses for industrial radiography and radiation safety requirements for industrial radiographic operations).

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

This final-form rulemaking provides an opportunity to update and further clarify and fortify requirements in the regulations for non-medical X-ray equipment used in research and industry and to establish requirements for new equipment that may be marketed in the future.

As set forth in the final-form rulemaking, users of non-medical radiation-producing devices are required to comply with radiation protection standards that not only protect and benefit employees but also protect and benefit the general public from overexposures to radiation. This final-form rulemaking ensures that operators of these devices are trained properly so that both the public and the operator are adequately protected from overexposures to radiation.

The regulated community and all residents of the Commonwealth benefit from these regulations. For example, personnel at the approximately 90 prisons, 120 schools, 1,040 industrial establishments, and 130 county offices and other non-medical offices are registered with the Department to perform numerous scans per day resulting in thousands of scans being done annually, and the final-form rulemaking ensures anyone involved in these scans are protected from overexposures to 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.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

There are no provisions that are more stringent than the federal standards.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

This final-form rulemaking does not put Pennsylvania at a competitive disadvantage. Instead, it aligns Pennsylvania's regulations better with federal regulations (e.g., 10 CFR Part 34) and also national suggested guidance for states (e.g., SSR Part H and Part E) produced by the CRCPD working groups.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No other state regulations will be affected. The Radiation Protection Act, Act of July 10, 1984, P.L. 688, No. 147 (35 P.S. §§ 7110.101—7110.703) gives full authority to DEP regarding radiation protection.

Section 306 of the Act, Conflicting laws, states:

Ordinances, resolutions or regulations now or hereafter in effect of the governing body of any agency or political subdivision of this Commonwealth relating to radiation or radiation sources shall be superseded by this act if such ordinances or regulations are not in substantial conformity with this act and any rules and regulations issued hereunder.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

As required by section 301(c)(14) of the Radiation Protection Act, the Department provided the Radiation Protection Advisory Committee (RPAC) with an opportunity to review the final-form rulemaking and to advise the Department prior to submittal of the final-form rulemaking to the Board. Members represent professional health physics and medical physics organizations, environmental, health, science, engineering, business or public interest groups. One member of the committee is the Executive Director of the Citizens Advisory Council to the Department of Environmental Protection representing the general public.

RPAC reviewed the final-form rulemaking on March 3, 2022. At the conclusion of the March 3, 2022 meeting, RPAC voted to concur with the Department's recommendation that the final-form rulemaking move forward in the regulatory process.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

The final-form rulemaking affects approximately 1,400 radiation-producing device registrants. The Department estimates approximately 600 of these registrants are small businesses in industries including food manufacturers, primary metal manufacturers, fabricated metal product manufacturers, machinery manufacturers, computer and electronic product manufacturers, and other miscellaneous manufacturers.

In addition to the above stated types of businesses, registrants include government offices such as prisons and courthouses, universities, and research laboratories.

Future registrants for radiation-producing devices used in individual security screening are affected by the final-form rulemaking due to new requirements to provide training on the use of equipment to staff that do not have formal training or knowledge in radiological sciences or radiation safety. Currently, all registrants with this requirement have already obtained this training. These are the registrants of radiation-producing devices used in individual security screening as described in § 227a.52.

Many of the registrants already meet the requirements under the current regulations. These current requirements are moved into a new Chapter, Chapter 227a. The requirements were rewritten and rearranged in order to incorporate SSR Part H and Part E, and to clarify all the requirements. These requirements reflect current industry practices, as discovered through Department inspections and through conversations with RPAC members. Therefore, the final-form rulemaking is not expected to impose additional requirements on those registrants.

This final-form rulemaking not only protects and benefits employees but also protects and benefits the general public from overexposures to radiation. The final-form rulemaking ensures that operators of these devices are trained properly so that both the public and the operator are adequately protected from overexposures to radiation.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

Currently, there are approximately 1,400 radiation-producing device registrants that are required to comply with the final-form rulemaking. Approximately 600 of these registrants are considered small businesses and include food manufacturers, primary metal manufacturers, fabricated metal product manufacturers, machinery manufacturers, computer and electronic product manufacturers, and other miscellaneous manufacturers. In addition to the previously stated types of businesses, some registrants are also government offices such as prisons and courthouses, universities, and research laboratories.

All future registrants of non-healing arts radiation-producing devices are required to comply.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The benefit of the amendments to the radiological health regulations include the requirement for users of radiation-producing devices to comply with radiation protection standards that not only protects employees but also protects the general public from overexposures to radiation. The final-form rulemaking ensures that training is provided to operators of these radiation-producing devices, and the operators and the public are adequately protected from the harmful effects of overexposure to radiation.

Overall, there are no financial, economic, or social impacts expected as a result of the final-form rulemaking. There are no changes to the fee schedule in Chapter 218 in this final-form rulemaking, and the new technologies listed in the final-form rulemaking are already complying with these amendments and fees as required by the general administrative provisions of § 215.22 (relating to prohibited uses). A small number of future registrants may experience additional costs due to the new training requirements. These training requirements are added due to operators of certain technologies not having the knowledge or training in any radiation protection practices. Those in need of this training are registrants of radiation-producing devices used in individual security screening as described in § 227a.52. There currently are no registrants that have not already obtained this training.

There are no social impacts associated with the final-form rulemaking.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

There are no adverse effects associated with the final-form rulemaking.

The benefits of the final-form rulemaking include protecting employees and the general public from overexposures to radiation by requiring compliance with radiation protection standards. The final-form rulemaking ensures that training is provided to operators of these radiation-producing devices. The benefit of maintaining adequate radiation protection standards outweigh the cost that a small percentage of registrants may encounter when providing training to the operators of the devices.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

Members of the regulated community that currently have radiation-producing devices used in individual security screenings are already in compliance and will incur no new costs. Any new registrant intending to use a radiation-producing device in individual screenings is required to obtain training to operate the device, which costs approximately $950 per registrant. Each registrant has one Radiation Safety Officer (RSO) to train. This cost was derived by using an estimate by one of the installers that currently provides the training to these operators.

There will be no savings to the regulated community associated with compliance.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

Local governments that currently have radiation-producing devices subject to the requirements in the final-form rulemaking are already in compliance and will incur no new costs. If a local government that does not currently have a radiation-producing device used in individual security screenings elects to use such devices in the future, then that local government's RSO will be required to obtain training to operate the device, which costs approximately $950.

There will be no savings to local governments associated with compliance.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

State agencies that currently have radiation-producing devices used in individual security screenings are already in compliance and will incur no new costs. If a state agency that does not currently have a radiation-producing device used in individual security screenings elects to use such devices in the future, then that agency's RSO will be required to obtain training to operate the device, which costs approximately $950.

There will not be savings to state government associated with compliance.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

The final-form rulemaking changes various records retention requirements to a five-year record retention period. This change was made in order to promote consistency throughout the radiological health regulations. These records do not need to be in paper format and may be stored electronically.

(22a) Are forms required for implementation of the regulation?

No.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here.** If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

There are no forms required to implement the regulation.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

| | Current FY 2021/22 | FY +1 2022/23 | FY +2 2023/24 | FY +3 2024/25 | FY +4 2025/26 | FY +5 2026/27 |
|---|---|---|---|---|---|---|
| **SAVINGS:** | $ | $ | $ | $ | $ | $ |
| **Regulated Community** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Local Government** | 0 | 0 | 0 | 0 | 0 | 0 |
| **State Government** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total Savings** | 0 | 0 | 0 | 0 | 0 | 0 |
| **COSTS:** | | | | | | |
| **Regulated Community** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Local Government** | 0 | 0 | 0 | 0 | 0 | 0 |
| **State Government** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total Costs** | 0 | 0 | 0 | 0 | 0 | 0 |
| **REVENUE LOSSES:** | | | | | | |
| **Regulated Community** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Local Government** | 0 | 0 | 0 | 0 | 0 | 0 |
| **State Government** | 0 | 0 | 0 | 0 | 0 | 0 |
| **Total Revenue Losses** | 0 | 0 | 0 | 0 | 0 | 0 |

(23a) Provide the past three-year expenditure history for programs affected by the regulation.

This amendment has no effect on program expenditures. The DEP Radiation Protection Fund covers all areas of Radioactive Material, Environmental Surveillance, X-Ray / Accelerators, Nuclear Safety and Radon. Decommissioning is also covered to the extent cleanup costs cannot be recovered from responsible parties and are not eligible for funding through other special funds administered by the Department.

| Program | FY -3 2019-20 | FY -2 2020-21 | FY -1 2021-22 | Current FY 2022-23 |
|---|---|---|---|---|
| Radiation Protection Fund | $12,809,000 | $12,140,000 | $12,484,000 | $15,517,000 |

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.

There are approximately 600 small businesses subject to these regulations.

(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.

There is no added reporting, recordkeeping or other administrative requirements that would have a cost.

(c) A statement of probable effect on impacted small businesses.

There are presently no small businesses that are predicted to be affected or adversely impacted by this final-form rulemaking as they are already in compliance as required by the general administrative provisions of § 215.22 (relating to prohibited uses). If a small business that does not currently have a radiation-producing device used in individual security screenings elects to use such a device in the future, then that business's staff will be required to obtain training to operate the device, the impact of which would be a one-time cost for the small business of approximately $950.

(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

There is no less intrusive or less costly alternative method of achieving the purpose of the final-form rulemaking. Much of this final-form rulemaking is moving current requirements to a different chapter. The requirements were rewritten and rearranged in order to incorporate 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. The added requirement in this final-form rulemaking for a new technology, radiation-producing devices used in individual security screening, is already being regulated administratively by the program under the Department's general authority in § 215.22 (relating to prohibited uses) and is just being codified in this chapter specifically regulating non-healing arts radiation-producing devices. The additional training for operators of this technology is necessary, as these operators do not have any knowledge or experience in radiation protection.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

The Department does not anticipate any impacts from this final-form rulemaking to minorities, the elderly, small businesses or farmers that would necessitate special provisions. By adding the requirements for the radiation-producing devices used in individual security screening with defined operator training requirements, the final-form rulemaking helps ensure protection of the public from unnecessary radiation exposure. Therefore, no special provisions have been developed.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory provisions have been considered or rejected for the radiological health amendments since the majority of the amendments are current industry radiation protection practices and are based on SSRs produced by the Conference of Radiation Control Program Directors' working groups.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

a) The establishment of less stringent compliance or reporting requirements for small businesses;
b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
c) The consolidation or simplification of compliance or reporting requirements for small businesses;
d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and
e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

Performance standards for small businesses were not considered to replace design or operation standards required by the final-form rulemaking because the radiation risk level remains the same for small businesses that operate radiation-producing devices. The exemption of small businesses from all or any part of the requirements contained in the final-form rulemaking was also not considered for this same reason.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

Data is not the basis for this regulation. Suggested State Regulations Part H and E were the basis for this final-form rulemaking. They are available at the following link: https://files.dep.state.pa.us/PublicParticipation/Public%20Participation%20Center/PubPartCenterPortalFiles/Environmental%20Quality%20Board/2021/May%2019/01_7-555%20Rad%20Safety/04b_7-555_Radiation%20Safety_Proposed_RAF%20Attachments.pdf.

(29) Include a schedule for review of the regulation including:

| | |
|---|---|
| A. The length of the public comment period: | 30 days |
| B. The date or dates on which any public meetings or hearings will be held: | None held |
| C. The expected date of delivery of the final-form regulation: | Quarter 1, 2023 |
| D. The expected effective date of the final-form regulation: | 90 days after publication in the *Pennsylvania Bulletin* |
| E. The expected date by which compliance with the final-form regulation will be required: | 90 days after publication in the *Pennsylvania Bulletin* |
| F. The expected date by which required permits, licenses or other approvals must be obtained: | Not applicable |

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Department will continue to work with RPAC and other stakeholders to evaluate the effectiveness of this final-form rulemaking after its implementation.

CDL-1

**FACE SHEET**
**FOR FILING DOCUMENTS**
**WITH THE LEGISLATIVE REFERENCE BUREAU**

**(Pursuant to Commonwealth Documents Law)**

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MAR 21 2023

Independent Regulatory Review Commission

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality Attorney General

By: (Deputy Attorney General)

DATE OF APPROVAL

☐ Check if applicable
Copy not approved. Objections attached.

Copy below is hereby certified to be true and correct copy of a document issued, prescribed or promulgated by:

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

(AGENCY)

DOCUMENT/FISCAL NOTE NO. 7-555

DATE OF ADOPTION November 15, 2022

BY

TITLE RAMEZ ZIADEH, P.E.
ACTING CHAIRPERSON

EXECUTIVE OFFICER CHAIRPERSON OR SECRETARY

Copy below is hereby approved as to form and legality Executive or Independent Agencies

BY

11/23/2022
DATE OF APPROVAL

(Deputy General Counsel)
~~(Chief Counsel – Independent Agency)~~
(Strike inapplicable title)

☐ Check if applicable. No Attorney General Approval or objection within 30 days after submission.

NOTICE OF FINAL RULEMAKING

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices

25 Pa. Code Chapters 225, 227, 227a and 228

**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 November 15, 2022.

A. *Effective Date*

This final-form rulemaking will be effective 90 days after 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 Nicholas Pistory, Assistant Counsel, Bureau of Regulatory Counsel, P.O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-9372. Persons with a disability may use the Pennsylvania Hamilton Relay Service by calling (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This final-form rulemaking is available on the Department of Environmental Protection's (Department) web site at www.dep.pa.gov (Select "Public Participation," then "Environmental Quality Board (EQB)" and then navigate to the Board meeting of November 15, 2022).

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) are 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.*

RICHARD NEGRIN,
*Acting Chairperson*

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

**Bureau of Radiation Protection**

# COMMENT AND RESPONSE DOCUMENT

## Radiation Safety Requirements for Non-Healing Arts Radiation Producing Devices

25 Pa. Code Chapters 225, 227, 227a and 228
51 Pa.B. 4845 (August 14, 2021)
Environmental Quality Board Regulation #7-555
(Independent Regulatory Review Commission #3311)

## INTRODUCTION

On May 19, 2021, the Environmental Quality Board (Board or EQB) adopted a proposed rulemaking amending 25 Pa. Code Chapters 225, 227, 227a, and 228 to establish and maintain adequate radiation protection standards and oversight of non-medical X-ray operations and emerging technologies in the industrial field. The proposed amendments are based on standards for radiation-producing devices set by recognized accrediting bodies and national organizations. Specifically, the proposed amendments incorporate the Suggested State Regulations (SSR) Part H and the training requirements in SSR Part E that were developed by the Conference of Radiation Control Program Directors (CRCPD). The American National Standards Association was consulted in developing these amendments. The amendment to Chapter 228 is proposed to update a definition to match the U.S. Nuclear Regulatory Commission's terminology.

The proposed rulemaking was published in the *Pennsylvania Bulletin* on August 14, 2021 (51 Pa.B. 4845) for a 30-day public comment period that closed on September 13, 2021. Comments were received from one public commentator. The Independent Regulatory Review Commission (IRRC) also submitted comments on the proposed rulemaking.

This Comment and Response Document provides responses to all comments received. Copies of all public comments received by the Board are posted on the Department's e-Comment website at https://www.ahs.dep.pa.gov/eComment/. Additionally, copies of all comments are available on IRRC's website at http://www.irrc.state.pa.us by searching for Regulation # 7-555 or IRRC #3311.

## LIST OF COMMENTATORS ON THE PROPOSED RULEMAKING

| Name/Address |
|---|
| 1. William Hoake<br>Boalsburg, PA 16827 |
| 2. Independent Regulatory Review Commission (IRRC)<br>333 Market Street<br>14th Floor<br>Harrisburg, PA 17101 |

## List of Acronyms used in this Comment and Response Document

ANSI – American National Standards Institute
CFR – Code of Federal Regulations
Mrem – millirem
μSv – microsievert
RAF – Regulatory Analysis Form
RSO – Radiation Safety Officer
XRF – X-ray Fluorescence

## COMMENTS AND RESPONSES

**1. Comment:** Regarding § 227a.52 on radiation-producing devices used in individual security screening, a commentator states that paragraph 3 is confusing and should be rewritten to be consistent with ANSI N43.17-2009. Specifically, the commentator recommends the following:

1. For general use systems:
   a. The reference effective dose from a single screening shall not exceed 25 microrem (0.25 μSv).
   b. The reference effective dose received by an individual shall not exceed 25 mrem (250 μSv) in one year.
2. For limited use systems:
   a. The reference effective dose from a single screening shall not exceed 1 mrem (10 μSv)
   b. The reference effective dose received by an individual shall not exceed shall not exceed 25 mrem (250 μSv) in one year.
   c. Documented procedures must be in place to ensure that not individual exceeds 25 mrem (250 μSv) in one year.
3. The statement in paragraph 3 "when equipment is capable of operation greater than 25 rem in a 12-month period at the facility" appears to be an error. The commentator can find no reference to this in either ANSI or the suggested state regulations.
4. Regarding the training requirements for RSOs in paragraph 4, the commentator believes the 8-hour requirement is excessive. The RSO on these units do not perform surveys, dose calculations, dosimetry, etc. In the commentator's experience, 4 hours of training is appropriate with emphasis on regulatory compliance and record keeping requirements. The commentator suggests that an RSO be required to take the 2-hour operator radiation safety class and in addition a 4-hour RSO class. (1)

**Response:** Regarding the amendments to § 227a.52 paragraphs 3 and 4 for general use systems and limited use systems, the Department acknowledges that the units of measurement referenced are not consistent with the ANSI standards. However, the units were changed from the ANSI standards for consistency with the Commonwealth's radiological health regulations and the U.S. Nuclear Regulatory Commission's regulations, who use conventional units first. Therefore, the final-form rulemaking has not been modified as suggested by the commentator.

Regarding the commentator's note about an error in the Preamble to the proposed rulemaking discussing paragraph 3 of § 227a.52, the Department reviewed the paragraph and agrees. Therefore, the Preamble for the final-form rulemaking has been corrected by removing the "in a 12-month period at the facility" language.

Lastly, the Department acknowledges the comment regarding the number of training hours for radiation safety officers (RSO). However, based on the Department's experience with facilities using individual screening devices, individuals receiving this training are unlikely to have prior experience or knowledge in radiation safety as these machines are used in settings where employees have not traditionally used radiation-producing devices, such as prisons and drug rehabilitation centers to search for contraband. Thus, individuals, such as corrections officers,

need a longer timeframe for training to understand the concepts and can protect the health and safety of all individuals involved. Therefore, no changes were made to the training requirements in the final-form rulemaking.

**2. Comment:** IRRC comments that in § 225.103 on field radiography, subsection (a.6) requires an operator to periodically monitor the area of operation when radiation levels are variable. IRRC asks how frequently the operator should monitor radiation levels. Since the term "periodically" is vague, IRRC asks the Board to clarify this provision to establish a standard that is achievable for the regulated community and protects the public health, safety and welfare. (2)

**Response:** After review, the Department finds the sentence regarding periodic monitoring is unnecessary and duplicative of the first sentence as a survey is required to be done for each new operating condition. Therefore, it has been deleted in the final-form rulemaking.

**3. Comment:** IRRC comments that in § 227a.15 on surveys, subsection (a)(7) requires a survey to be performed when "a personnel monitoring device shows a significant increase, as predetermined by the registrant, over the previous monitoring period or readings approach the limits specified in 10 CFR 20.1201 (relating to occupational dose limits for adults)." The Board does not explain in the Preamble what constitutes a significant increase in an occupational dose of radiation and why it is reasonable for the registrant to predetermine the amount. We ask the Board to explain how this provision will be implemented and how it protects the public health, safety and welfare. Further, IRRC asks the Board to consider clarifying this provision to establish a standard that is achievable for the regulated community. (2)

**Response:** For the final-form rulemaking, the Department deleted "significant" and "predetermined by the registrant" and revised the language used in this subsection to specify a radiation exposure of more than 25 percent of the annual occupational dose limit would trigger the need for a survey to be performed. This is an increase that would note something is wrong with the equipment that may not be apparent except through this dosimetry and would ensure the individual would not exceed the annual occupational dose limit.

**4. Comment:** IRRC also comments that in § 227a.15 on surveys, subsection (d) provides that a registrant is not required to perform radiation surveys if it "otherwise demonstrates compliance under this chapter to the satisfaction of the Department" of Environmental Protection (Department). How will the Department evaluate the registrant's compliance with § 219.51 (relating to dose limits for individual members of the public), as required by subsection (a)? IRRC asks the Board to explain how this subsection will be implemented to ensure a registrant is in compliance with radiation dose limits. (2)

**Response:** Evaluating compliance in this scenario would be accomplished by reviewing historical radiation survey results, shielding calculations, personnel dosimetry reports, area monitoring, and manufacturer literature. This information could, in some instances, provide enough information for the Department to determine a radiation-producing device complies with dose limits for individual members of the public without the registrant having to perform a radiation survey.

**5. Comment:** IRRC comments that in § 227a.18 on operating requirements, subsection (b)(3) requires a record of a bypass of a safety device or interlock. This provision does not include a record retention requirement. The Board should consider revising this paragraph to include the 5-year record maintenance requirement for consistency with other radiological health regulations. (2)

**Response:** The five-year retention period language has been added to § 227a.18(b)(3) in the final-form rulemaking.

**6. Comment:** IRRC notes that § 227a.21 states the instruction and training requirements for an individual to operate or maintain a radiation-producing device or enter a shielded room. IRRC inquires how an individual will be evaluated to determine competence with paragraphs (1) – (6) and how a registrant will be required to maintain a record of competence. IRRC asks the Board to explain how this regulation will be implemented and to clarify this section to address these concerns. (2)

**Response:** Standard actions in the Radiation Protection program's inspection procedures are to review training records of the registrant or licensee. The sentence "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 as to the following:" was 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:" to clarify that an individual will be evaluated through a performance evaluation by the registrant to determine competence with paragraphs (1) – (6). As noted in this section, records related to an operator's training and instruction are required to be maintained onsite and made available for review by the Department for 5 years.

**7. Comment:** IRRC notes that in § 227a.22 on radiation protection responsibility, subsection (b)(5) requires the radiation safety officer to maintain "all radiation safety records, including annual audits of the radiation protection program and documentation of its findings." IRRC asks if the Department considers all of the records required under Chapter 227a to be "safety records" and what the requirements are for the annual audit of the radiation protection program. IRRC asks the Board to clarify this paragraph to address these concerns. (2)

**Response:** Subsection (b)(5) of the final-form rulemaking has been revised to clarify which records must be retained and to reference the federal regulation containing the annual review requirements. The annual review 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. Subsection (b)(5) now reads "**Retaining** all records **required to show compliance with this section,** including annual **reviews** of the radiation protection program **content and implementation** and **the** documentation of its findings, **as required in § 219.5 (relating to incorporation by reference) and incorporating by reference 10 CFR 20.1101(c) (relating to radiation protection programs),** and making the records available for review by the Department for 5 years."

**8. Comment:** IRRC notes subsection (c) of § 227a.35 on electron microscope devices states that an individual may not operate or conduct maintenance on a closed-beam electron microscope until they have received instruction "and demonstrated an understanding of the normal operating procedures necessary to ensure radiation safety." Similar to Comment #4, this regulation does not state how an individual's understanding will be evaluated and if there is a record of competence. IRRC questions if this subsection is needed as § 227a.21 requires instruction, training and competence and asks the Board to explain how this regulation will be implemented and why it is needed. (2)

**Response:** The Department agrees that this requirement is duplicative of § 227a.21. Therefore, subsection (c) of § 227a.35 has been deleted from the final-form rulemaking.

**9. Comment:** IRRC comments § 227a.40(a) requires a registrant to document the justification of the use of an open-beam radiation-producing device. The Board should consider adding this document to the records required to be maintained under subsection (c). (2)

**Response:** The first sentence of § 227a.40(c) in the final-form rulemaking has been revised to read "If the registrant's use of an open-beam radiation-producing device does not permit the use of a safety device to minimize the chance of direct body exposure, the registrant shall maintain a written record of **the justification required in subsection (a), and** a description of the various safety devices that have been evaluated and reasons the devices cannot be used."

**10. Comment:** IRRC notes § 227a.40(b) requires a registrant to "consider a safety device" to minimize the chance of a portion of an operator's body from entering into the path of the primary beam or which causes the primary beam to be shut off upon entry into its path. IRRC asks the Board to explain its rationale for requiring a registrant to consider but not require a safety device and why this approach is reasonable. IRRC further asks the Board to explain how this provision protects the health, safety and welfare of operators of these devices. (2)

**Response:** In some circumstances, use of a safety device with an open-beam radiation-producing device is impractical because it will prevent the device from taking an accurate image or analysis of metals. In these circumstances, the device can still be operated in a manner that protects the health, safety, and welfare of operators, without a safety device, as long as the device is operated according to policies and procedures designed to minimize the possibility of unnecessary exposure. As examples, operator training can include instructions that the operator never use their hand or any other body part to hold a sample, and not to point the radiation-producing device at another person. Subsection (c) requires that an operator document the safety devices it considered for the open-beam radiation producing device and the reasons the safety devices could not be used. Subsection (d) requires that an operator document the policies and procedures they will require, in the absence of a safety device, to ensure the radiation-producing device is operated safely.

**11. Comment:** IRRC comments that § 227a.45 allows the registrant to set the radiation emissions limits for an open-beam radiation-producing device. IRRC notes the Preamble does not state why the registrant is given the authority to make this decision and asks the Board to

explain why this provision is reasonable and how it protects the health, safety and welfare of an individual in the area around a device. (2)

**Response:** The words "set by the registrant and" have been deleted in the final-form rulemaking and replaced with the radiation emissions limits that must be met for any specified tube rating should be established by the tube manufacturer.

**12. Comment:** IRRC comments that in § 227a.48, the first sentence requires an operator to control access to a radiation-producing device at all times during operation when it is not in a restricted area. The second sentence requires an operator to control access at all times during operation when the device is not in a restricted area and is capable of creating a radiation area or a high radiation area. The broad condition in the first sentence appears to encompass all radiation-producing devices. IRRC asks the Board to explain why the specific restriction on radiation areas in the second sentence is needed. (2)

**Response:** The Department agrees with this comment, and the second sentence has been deleted in the final-form rulemaking.

**13. Comment:** IRRC comments that paragraph (3) of § 227a.51 specifies that the registrant shall prevent entry when the device is energized during training. The Preamble does not explain how this paragraph will be implemented and why it is needed. IRRC asks the Board to explain the implementation procedures in the Preamble to the final-form regulation. (2)

**Response:** The Department agrees with this comment, and the words "during training" were deleted from the final-form rulemaking. This requirement is always necessary, not just during training, to ensure no unnecessary exposures to radiation occurs and to protect the workers and anyone else nearby from exposure to radiation. It will be implemented by physical controls that the registrant uses, such as barriers, doors or warning signs, which can all be verified upon inspection.

**14. Comment:** IRRC notes that § 227a.51(2) requires a registrant to maintain a use log for each bomb detection radiation-producing device. This provision does not include a record retention requirement. The Board should consider revising this paragraph to include the 5-year record maintenance requirement for consistency with other radiological health regulations. (2)

**Response:** The 5-year retention period language has been added to § 227a.51(2) of the final-form rulemaking.

**15. Comment:** IRRC notes that paragraph (4) of § 227a.52 addresses individual security screening with limited-use systems that are "used with discretion." This phrase lacks the clarity to set a binding norm. IRRC asks the Board to revise this provision to establish a standard that is achievable for the regulated community. (2)

**Response:** Paragraph (4) has been clarified by deleting "and is used with discretion" and adding the following sentence: "The number of scans per individual must be tracked to ensure the dose does not exceed the limit referenced in paragraph (5)."

**16. Comment:** IRRC comments that in response to RAF Questions #19 – 21, the Board states training to operate a radiation-producing device "costs approximately $950." Is this cost estimate for one individual? Further, the response to RAF Question #23 addresses three local governments. However, it does not include an estimate of costs for new registrations or registrants who may utilize additional devices and additional individuals who may need to be trained. IRRC asks the Board to explain if the cost of training is per individual and update the cost estimates accordingly, as well as to provide an estimate of costs for additional devices and operators in RAF Questions #19 – 21 and 23 or explain why it is not possible to do so. (2)

**Response:** The training cost is for the Radiation Safety Officer (RSO), and there is one RSO per registrant. This has been clarified in the RAF. There is no additional training cost for additional devices. The RSO training cost would apply any time there is a change of the facility's RSO and cannot be predicted by the Department. The operators are trained by the RSO. Therefore, the cost estimate of $950 in the RAF is accurate. Subsequent to delivery of the proposed rulemaking package to IRRC on July 14, 2021, the three local governments identified in the response to RAF Questions #20 and #23 have completed the RSO training. The cost estimates for those two questions have been updated accordingly.

**17. Comment:** IRRC comments in § 227a.2 the term "analytical X-ray equipment" is not used in the regulations. This definition should be deleted under Section 2.11(c) of the Pennsylvania Code & Bulletin (Style Manual). (2)

**Response:** The term and definition of "analytical X-ray equipment" has been deleted in the final-form rulemaking.

**18. Comment:** IRRC comments in § 227a.2, for the definitions of "general-use system" and "limited-use system," the units of measure for the effective dose should be corrected to microrem and microsievert to reflect the definitions in Suggested State Regulation Section H.4 (relating to definitions). (2)

**Response:** The units of measure in these definitions have been corrected in the final-form rulemaking.

**19. Comment:** IRRC comments that the definitions of "general-use system" and "limited-use system" in § 227a.2 contain substantive provisions in the second sentences regarding screening an individual and dose limits, respectively. Section 2.11(e) of the Style Manual states that substantive provisions may not be contained in a definition section. IRRC recommends moving these requirements to the body of the regulations. (2)

**Response:** The Department agrees that the sentences IRRC identified are substantive provisions that should not be included in definitions. "Given proper justification and certain restrictions, general-use systems may be operated without specific controls that would limit the number of individuals scanned or the number of scans per individual in a year" has been deleted from the definition of "general-use system." This provision is redundant and unnecessary because

§ 227a.52(3) already provides the restriction of an effective dose limit of 25 μrem (0.25 μSv) for a single complete screening when using a general-use system.

"A limited-use system requires additional controls and documentation to ensure that annual individual dose limits required under § 227a.53(c) (relating to radiation-producing devices used in vehicle security screening) are not exceeded" has been deleted from the definition of "limited-use system." The requirement to track the number of scans to ensure dose limits in § 227a.53(c) are not exceeded has been added to § 227a.52(4).

**20. Comment:** IRRC comments that in § 227a.2 in the definition of "handheld radiation-producing device," the acronym "XRF" should be stated in full as it is only used one time. (2)

**Response:** This acronym is now spelled out in the final-form rulemaking.

**21. Comment:** IRRC comments that in § 227a.2 in the definition of "limited-use system," the cross-reference to § 227a.53(e) (relating to radiation-producing devices used in vehicle security screening) should be corrected to § 227a.53(c). (2)

**Response:** The Department agrees with this comment. However, the sentence containing the incorrect cross-reference has since been deleted from the definition of "limited-use system" in response to IRRC's other comment on this definition. Please see Comment #19.

**22. Comment:** IRRC comments that in § 227a.12(a) (relating to labeling), the cross-reference to § 219.159 (relating to posting of radiation-producing machines) is not needed and should be deleted. (2)

**Response:** This cross-reference has been deleted from the final-form rulemaking.

**23. Comment:** IRRC comments that in § 227a.15(a)(5) (relating to surveys), subsection (d) should be added to the cross-reference to § 227a.18(b) (relating to operating requirements). (2)

**Response:** The § 227a.18(d) cross-reference is not necessary as § 227a.18(b) is sufficient to require a survey for bypassing a safety device or interlock.

**24. Comment:** IRRC suggests that in § 227a.15(c), "assure" should be revised to "ensure." (2)

**Response:** This has been corrected in the final-form rulemaking.

**25. Comment:** IRRC suggests that the explanation of § 227a.34 (relating to security screening devices) in the Preamble should be revised to refer to exposures of greater than 0.5 second. (2)

**Response:** The Preamble has been revised to correct the explanation of § 227a.34(1).

**26. Comment:** IRRC notes that § 227a.45 (relating to radiation emission limits) should be revised to refer to ratings established by the "manufacturer." (2)

**Response:** "Manufacture" has been corrected to "manufacturer" in the final-form rulemaking.

**27. Comment:** IRRC comments that the cross-reference in § 227a.53 to § 227a.52 (relating to radiation-producing devices used in individual security screening) should be reviewed and revised for consistency. In addition, the explanation of § 227a.53 in the Preamble should be revised accordingly. (2)

**Response:** The terms "as general use or limited-use systems" have been deleted from subsection 227a.53(a) in the final-form rulemaking and, as a result, the cross-reference to § 227a.52 does not need to be corrected.

**Annex A**

**TITLE 25. ENVIRONMENTAL PROTECTION**

**PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION**

**Subpart D. ENVIRONMENTAL HEALTH AND SAFETY**

**ARTICLE V. RADIOLOGICAL HEALTH**

**CHAPTER 225. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS**

**Subchapter B. RADIATION-PRODUCING [MACHINES] DEVICES**

**GENERAL ADMINISTRATIVE REQUIREMENTS**

**§ 225.71. Definitions.**

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

**[*Cabinet radiography*—Industrial radiography conducted in an enclosure or cabinet (not a room) so shielded that doses to individual members of the public at every location on the exterior meet the limitations specified in 10 CFR 20.1301 (relating to dose limits for individual members of the public).**

***Cabinet X-ray system*—An X-ray system with the X-ray tube installed in an interlocked enclosure or cabinet, designed to exclude personnel from its interior during operation.**

**(i) Included are all X-ray systems designed primarily for the inspection of baggage or packages.**

**(ii) An X-ray tube used within a shielded part of a building or X-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet X-ray system.**

***Certified cabinet X-ray system*—An X-ray system which has been certified under 21 CFR 1010.2 (relating to certification) as being manufactured and assembled under 21 CFR 1020.40 (relating to cabinet x-ray systems).]**

*DRD—Direct reading dosimeter*—

(i) As used in this subchapter, means an "individual monitoring device" (see 10 CFR 20.1003 (relating to definitions)) that does not require additional processing to measure an individual's dose.

(ii) The term also includes the direct reading personnel (individual) monitoring devices known as pocket dosimeter, pocket ionization chamber and electronic personal dosimeter (EPD).

*Field radiography*—A location where radiographic operations are conducted (onsite or offsite) other than those designated as a permanent radiographic facility.

*Industrial radiography*—**[An examination of the structure of materials by nondestructive methods, including fluoroscopy, which utilizes radiation producing machines to make radiographic images]** **An examination of the structure of materials by nondestructive methods, utilizing ionizing radiation to make radiographic images.**

*NVLAP*—National Voluntary Laboratory Accreditation Program.

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

*Personal supervision*—The provision of guidance and instruction to a radiographer's assistant given by a radiographer who is:

(i) Physically present at the site.

(ii) In visual contact with the radiographer's assistant while the assistant is using radiation sources.

(iii) In proximity so that immediate assistance can be given if required.

*Personnel dosimeter*—As used in this subchapter, means any of the "individual monitoring devices" (see 10 CFR 20.1003) that shall be processed and evaluated to generate a permanent record of an individual's dose, for example, a film badge, thermoluminescent dosimeter (TLD) or optically stimulated luminescent dosimeter (OSLD).

*RSO—radiation safety officer*—An individual who ensures that, in the daily operation of the registrant's or licensee's radiation safety program, activities are being performed in accordance with approved procedures and are in compliance with Department requirements.

*Radiographer*—An individual who performs radiographic operations or an individual in attendance at a site where **[radiation producing machines]** **radiation-producing devices** are being used who personally supervises industrial radiographic operations.

*Radiographer's assistant*—An individual who, under the personal supervision of a radiographer, uses **[radiation producing machines]** **radiation-producing devices** or radiation survey instrumentation.

**[*Radiographer trainee*—An individual who is in the process of becoming a radiographer's assistant or a radiographer.]**

*Radiographic operations*—The activities associated with a **[radiation producing machine]** **radiation-producing device** during use of the **[machine]** **device**, to include surveys to confirm adequacy of boundaries, setting up equipment and any activity inside restricted area boundaries.

***Radiographic X-ray systems*—A system utilizing a radiation generating device for quality assurance, materials detection or nondestructive testing used in industrial settings.**

*Safety device*—As applied to radiation-producing **[machines]** **devices** in this subchapter, a device or component that causes the unit to de-energize or interrupt the beam.

**[*Shielded room radiography*—Industrial radiography that is conducted in an enclosed room, the interior of which is not occupied during radiographic operations.]**

**§ 225.72. Duties of personnel.**

(a) The RSO shall assure that the radiation safety program of the registrant or licensee is implemented and suspend or terminate operations that are not being conducted in accordance with approved procedures or the Department's requirements.

(b) The radiographer is responsible to the registrant or licensee for following the procedures of the registrant or licensee and for complying with the Department's requirements while industrial radiographic operations are being conducted.

(c) The radiographer's assistant shall only use **[radiation producing machines]** **radiation-producing devices** or radiation survey instrumentation under the personal supervision of a radiographer.

(d) **[The radiographer trainee is not permitted to operate radiation producing machines or radiation survey instrumentation]** **(Reserved).**

**§ 225.74. Training and testing.**

(a) The registrant may not permit an individual to act as a radiographer until that individual has:

(1) Been instructed in the subjects outlined in Appendix A.

(2) Received copies of this chapter, Chapters 219 and 220 (relating to standards for protection against radiation; and notices, instructions and reports to workers; inspections and investigations), and copies of the license or certificate of registration and the operating and emergency procedures of the registrant or licensee.

(3) Received **at least 160 hours of** instruction covering regulatory requirements, operating and emergency procedures and the use of radiation-producing **[machines]** **devices** and radiation survey instruments of the registrant or licensee.

(4) Demonstrated competency and understanding of the information in this subsection to the satisfaction of the registrant or licensee as evidenced by the successful completion of a written test and a field examination.

(b) The registrant or licensee may not permit an individual to act as a radiographer's assistant until that individual has:

(1) Received copies of, and instruction in, the applicable operating and emergency procedures and has been instructed in the use of sources of radiation and radiation survey instruments of the registrant or licensee.

(2) Demonstrated that, under direct personal supervision of a radiographer, the individual is competent to use sources of radiation and radiation survey instruments as evidenced by the successful completion of a written or oral test and a field examination on the subjects relevant to being an assistant radiographer.

(c) Records of the training required under subsections (a) and (b), including copies of written tests, dates of oral tests and field examinations, shall be maintained for inspection by the Department for **[3]** 5 years following termination of employment by the individual or until the registration or license is terminated.

**§ 225.76. Reporting requirements.**

(a) In addition to the reporting requirements in §§ 219.221 and 219.222 (relating to reports of stolen, lost or missing licensed or registered sources of radiation; and notification of incidents and reportable events), each registrant or licensee shall provide to the Department, within 30 days of its occurrence, a written report on **[any of the following incidents involving machines or equipment used in radiographic operations:]** **an incident involving the inability to terminate irradiation from a radiation-producing device.**

(1) **[The inability to terminate irradiation from a radiation producing machine]** **(Reserved)**.

(2) **[An interlock failure during shielded room radiography]** **(Reserved)**.

(b) The registrant or licensee shall include the following information in each report submitted under subsection (a):

(1) A description of the equipment problem.

(2) The cause of the incident, if known or determined.

(3) The manufacturer and model number of the equipment involved.

(4) The place, date and time of the incident.

(5) Actions taken to reestablish normal operations.

(6) Corrective actions taken or planned to prevent reoccurrence.

(7) The names and qualifications of personnel involved.

(c) Reports of overexposures, required under 10 CFR 20.2202 (relating to notification of incidents) or of excessive exposures, required under 10 CFR 20.2203 (relating to reports of exposures, radiation levels and concentrations of radioactive material exceeding the limits) which involve the failure of safety components of radiography equipment shall also include, to the extent known, the information specified under subsection (b). Complete information required in subsection (b) shall be available in the 30-day follow-up report rule under 10 CFR 20.2203(a).

## GENERAL TECHNICAL REQUIREMENTS

**§ 225.81. [Permanent radiographic installations] (Reserved).**

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

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

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

**(3) The radiographic exposure system may not be used if an entrance control device or alarm system is not operating properly. If an entrance control device or alarm system is not functioning properly, it shall be removed from service and repaired or replaced immediately. If no replacement is available, the facility may continue to be used provided that the registrant implements the continuous surveillance under 10 CFR 34.51 and 34.53 (relating to surveillance; and posting), § 225.83 (relating to records required at field radiography sites) and uses an alarming ratemeter. Before the entrance control device or alarm system is returned to service, the radiation safety officer or an individual designated by the radiation safety officer shall validate the repair.**

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

**§ 225.82. Operating requirements.**

(a) When **field** radiographic operations are performed **[at a location other than a permanent radiographic installation]**, a minimum of two radiographic personnel shall be present to operate the X-ray device. At least one of the radiographic personnel shall be qualified as a radiographer.

The other individual may be either a radiographer[ , ] or a radiographer's assistant **[or a radiographer trainee]**.

(b) Other than a radiographer, or a radiographer's assistant who is under the personal supervision of a radiographer, an individual may not manipulate the controls or operate the equipment used in industrial radiographic operations.

(c) At each job site, the following shall be supplied by the registrant or licensee:

(1) The appropriate barrier ropes and warning signs.

(2) At least one operable, calibrated radiation survey instrument.

(3) For each worker requiring monitoring, an individual personnel dosimeter that is processed and evaluated by an NVLAP processor.

(4) An operable, calibrated direct reading dosimeter with a range of zero to **[51.6 µC/kg (200 milliroentgen)]** **200 milliroentgen (51.6 µC/kg)** for each worker requiring monitoring.

(d) An industrial radiographic operation may not be performed if any of the items in subsection (c) is not available at the job site or is inoperable.

**§ 225.84. Operating and emergency procedures.**

The operating and emergency procedures of the registrant or licensee shall include instruction in at least the following:

(1) Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation in excess of the limits established in Chapter 219 (relating to standards for protection against radiation).

(2) Methods and occasions for conducting radiation surveys and the proper use of survey meters.

(3) Methods for controlling access to areas where radiographic operations are being conducted.

(4) Methods and occasions for locking and securing sources of radiation.

(5) Personnel monitoring and the use of individual monitoring devices, including steps that are to be taken immediately by radiographic personnel when a direct reading dosimeter is found to be off-scale.

(6) Methods and procedures for minimizing exposure to individuals in the event of an accident.

(7) The procedure for notifying proper personnel in the event of an accident.

(8) Maintenance of records required by the Department.

(9) The inspection and maintenance of radiation-producing **[machines]** **devices** and survey meters.

**§ 225.85. Surveys and survey records.**

(a) A survey with a calibrated radiation survey instrument shall be made after each radiographic exposure to determine that the emission of radiation has terminated.

(b) Records of the surveys required by subsection (a) shall be maintained (for inspection by the Department) for **[3]** **5** years. If the survey has been used to determine an individual's exposure, the records of the survey shall be maintained until the Department terminates the registration or license.

**§ 225.86. Utilization logs.**

A registrant or licensee shall maintain current logs, which shall be kept available for inspection by the Department for **[3]** **5** years from the date of the event, showing for each radiation-producing **[machine]** **device**, the following applicable information:

(1) The identity (name and signature) of the operator to whom the radiation-producing **[machine]** **device** is assigned.

(2) The model and serial number of the radiation-producing **[machine]** **device**.

(3) The locations and dates of use.

(4) The technique factors (tube kilovoltage, tube current, exposure time) used for each radiographic exposure.

## RADIATION SURVEY INSTRUMENT AND PERSONNEL MONITORING REQUIREMENTS

**§ 225.92. Radiation survey meter calibration requirements.**

(a) In addition to the requirements of § 225.91 (relating to survey meter requirements), instruments required by this chapter shall have a range so that **[0.516 µC/kg (2 mR)]** **2 mR (0.516 µC/kg)** per hour through **[258 µC/kg (1 R)]** **1 R (258 µC/kg)** per hour can be measured.

(b) Each radiation instrument shall be calibrated:

(1) At energies appropriate for use.

(2) At intervals not to exceed 6 months.

(3) After each instrument servicing, other than battery replacement.

(4) To within an accuracy of +/− 20%.

(5) At two points located approximately one-third and two-thirds of full scale on each scale of linear scale instruments; at mid-range of each decade and at two points of at least 1 decade for logarithmic scale instruments; and for digital instruments, at three points between **[(2 mR) 0.516 µC/kg] 2 mR (0.516 µC/kg)** and **[(1000 mR) 258 µC/kg] 1,000 mR (258 µC/kg)** per hour.

(6) By a person authorized by the Department, the NRC or an agreement state.

(c) Calibration records shall be maintained for inspection by the Department for **[3] 5** years after the date of calibration.

**§ 225.93. Personnel monitoring control.**

(a) The registrant or licensee may not permit an individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operations, each individual wears a direct reading dosimeter and a personnel dosimeter that is processed and evaluated by an NVLAP processor.

(1) Personnel monitoring devices used to determine compliance with dose limits for the whole body shall be worn on the trunk of the body over the area most likely to receive exposure.

(2) This does not relieve the registrant or licensee from providing peripheral monitoring devices such as ring finger TLDs when appropriate.

(3) Each personnel monitoring device shall be assigned to and worn by only one individual.

(b) Film badges shall be replaced at intervals not to exceed 1 month. Other personnel dosimeters processed and evaluated by an accredited NVLAP processor shall be replaced at intervals not to exceed 3 months.

(c) Direct reading dosimeters shall meet the criteria as in ANSI N13.5-1972, "Performance Specifications for Direct Reading and Indirect Reading Pocket Dosimeters for X- and Gamma-Radiation" published in 1972, exclusive of subsequent amendments or additions.

(d) The use of DRDs is subject to the following requirements:

(1) DRDs shall have a range of zero to **[(200 mR) 51.6 µC/kg] 200 mR (51.6 µC/kg)** and shall be rezeroed at the start of each work shift.

(2) As a minimum, at the beginning and the end of each worker's shift involving the use of a source of radiation, DRDs shall be read and the exposure values recorded.

(3) Direct reading dosimeters shall be checked for correct response to radiation at periods not to exceed 1 year. A dosimeter may not be used for personnel monitoring unless the response is accurate within +/- 20% of the true radiation exposure. Records of dosimeter response checks shall be maintained for inspection by the Department for **[3] 5** years.

(4) If an individual's DRD indicates exposure that is "off-scale" beyond the range it can measure, industrial radiographic operations by that individual shall cease immediately and the individual's personnel dosimeter shall be sent immediately for processing. The individual may not use any sources of radiation until the individual's radiation dose has been determined.

(c) Data on personnel exposure reported or recorded from personnel monitoring devices shall be kept for inspection by the Department until the certificate of registration or license is terminated or until the Department authorizes their disposition, in writing, following a determination by the Department that the records contain inaccurate personnel monitoring information.

## RADIATION-PRODUCING [MACHINE] DEVICE REQUIREMENTS

**§ 225.101. [Cabinet X-ray systems and baggage/package X-ray systems] (Reserved).**

**[(a) Cabinet and baggage/package X-ray systems that are certified under 21 CFR Chapter I, Subchapter J (relating to radiological health) shall also meet the requirement of 21 CFR 1020.40 (relating to cabinet X-ray systems).**

**(b) A cabinet X-ray system may not be energized unless all openings are securely closed and exposure to radiation from the system does not exceed the limits in 10 CFR 20.1301 (relating to dose limits for individual members of the public). Each access door to the cabinet shall have an interlock that terminates the exposure whenever the door is opened. The enclosure shall be shielded so that every location on the exterior meets the conditions for an unrestricted area.**

**(c) A registrant may not permit an individual to operate a cabinet X-ray system until the individual has received a copy of, and instruction in, the operating procedures for the X-ray system and has demonstrated competency in the use of the cabinet X-ray system and an understanding of the operating procedures.**

**(d) The registrant shall perform radiation surveys to demonstrate compliance with 10 CFR 20.1301 and maintain records of these surveys for inspection by the Department for 3 years:**

**(1) Upon installation of the equipment.**

**(2) Following maintenance requiring the disassembly or removal of any shielding component.**

**(3) When a visual inspection reveals an abnormal condition.**

**(e) The registrant shall test on-off switches, interlocks and safety devices at intervals not exceeding 1 year and make repairs as necessary to maintain all safety features including warning labels. Records of these tests shall be maintained for inspection by the Department for 3 years.**

**(f) Cabinet X-ray systems and baggage/package X-ray systems are exempt from all other provisions of this chapter.]**

(*Editor's Note*: The following section is proposed to be added and printed in regular type to enhance readability.)

**§ 225.101a. Radiographic X-ray systems.**

Radiographic X-ray systems shall conform to the following:

(1) The leakage radiation from the source assembly measured at a distance of 1 meter in any direction from the source may not exceed 100 mR (25.8 μc/kg) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(2) The X-ray system shall be equipped with collimators which are capable of restricting the useful beam to the area of interest. Collimators shall provide the same degree of protection required in subsection (1).

(3) A means shall be provided to terminate the exposure after a preset time, a preset to image receptor or a preset product of exposure time and tube current.

(4) The X-ray control shall have a dead-man type exposure switch.

(5) The X-ray controls shall indicate the technique factors, such as kilovoltage, tube current and exposure time or the product of tube current and exposure time.

(6) The X-ray system shall be labeled with a readily discernible sign bearing the radiation symbol and the words "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or words having a similar intent, near any switch that energizes the X-ray tube.

(7) For X-ray systems, an easily visible warning light shall be located adjacent to the X-ray tube and labeled with the words "X-RAY ON" or words having a similar intent. The warning light shall be illuminated only when the X-ray tube is energized or only when the shutter is open.

(8) The registrant shall perform radiation surveys to demonstrate compliance with 10 CFR 20.1301 (relating to dose limits for individual members of the public) and maintain records of these surveys for inspection by the Department for 5 years:

(i) upon acceptance of the equipment;

(ii) following maintenance requiring the disassembly or removal of any shielding component; and

(iii) when a visual inspection reveals an abnormal condition.

(9) The registrant shall test on-off switches, interlocks and safety devices at intervals not exceeding 1 year and make repairs as necessary to maintain all safety features including warning labels. Records of these tests shall be maintained for inspection by the Department for 5 years.

**§ 225.102. [Shielded room X-ray radiography] (Reserved).**

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

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

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

**(d) With the exception of the provisions in §§ 225.4a, 225.76 and 225.84 (relating to radiation safety program; reporting requirements; and operating and emergency procedures), shielded room radiography is exempt from all other provisions of this chapter.]**

**§ 225.103. Field [site] radiography.**

(a) The operator shall conduct a physical radiation survey to determine that the radiation source is de-energized prior to each entry into the radiographic exposure area. Survey results and records of the boundary location shall be maintained and kept available for inspection by the Department for [3] 5 years.

**(a.1) Surveillance of the exposure area shall be maintained during operation, either by visual or by other reliable means, to ensure that no person enters the area.**

**(a.2) With the exception of hand-held X-ray systems, when approaching the radiation source, following the conclusion of an exposure, the operator shall use a suitable calibrated and operable radiation detection instrument to verify that the radiation source is in its fully shielded condition or that the X-ray tube has been de-energized.**

(a.3) A personal alarming dose rate meter shall also be worn to approach the work area if the device is appropriately designed and calibrated for the type of X-ray emitted, either pulse or continuous, set at an appropriate level to detect the presence of the source, for example 2 mrem (0.02 mSv) per hour and has been source-checked prior to use. The radiation in the work area must be reasonably uniform so that the device responds to radiation exposure to any part of the body. It may not be used to measure radiation levels, nor may it be used to indicate the presence of the source for potential non-uniform exposure, such as may occur during device maintenance or work in a radiation-producing device target area.

(a.4) Measurement of radiation levels for a radiation survey shall be performed using an appropriately calibrated radiation survey meter. A radiation survey meter shall also be used when there is potential for non-uniform exposure to personnel, such as may occur during device maintenance or work in a radiation-producing device target area.

(a.5) During the initial exposure, the radiation levels shall be measured around the perimeter of the controlled area. The perimeter shall be adjusted accordingly to meet the access control requirement for radiation areas or high radiation areas.

(a.6) The survey around the perimeter shall be made for each new operating condition and the perimeter adjusted accordingly. ~~The area of operation shall be monitored periodically if radiation levels are variable.~~

(b) Mobile or portable **[radiation producing machines]** radiation-producing devices shall be physically secured to prevent tampering or removal by unauthorized personnel.

**§ 225.104. [X-ray detection systems for explosives, weapons and illegal items]** (Reserved).

**[(a) This section applies to X-ray systems that produce an image that may be used to screen for the presence of explosive devices or components, weapons, contraband or prohibited items. This section does not apply to cabinet and baggage/package X-ray systems covered under § 225.101 (relating to cabinet X-ray systems and baggage/package X-ray systems).**

**(b) An X-ray system used for detection of explosives, weapons or illegal items may not be used on human beings or animals without specific permission of the Department. X-ray systems that irradiate human beings for medical diagnosis are covered under Chapter 221 (relating to human use of X-ray machines). X-ray systems that irradiate animals for diagnosis or therapy are covered under Chapter 223 (relating to veterinary medicine).**

**(c) Radiographic X-ray detection systems shall conform to the following:**

**(1) The leakage radiation from the source assembly measured at a distance of 1 meter in any direction from the source may not exceed 25.8 μc/kg (100 mR) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by**

**measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.**

**(2) Portable X-ray systems shall be equipped with collimators which are capable of restricting the useful beam to the area of interest. Collimators shall provide the same degree of protection required in paragraph (1).**

**(3) A means shall be provided to terminate the exposure after a preset time, a preset to image receptor or a preset product of exposure time and tube current.**

**(4) The X-ray control shall have a dead-man type exposure switch.**

**(5) The X-ray controls shall indicate the technique factors, (that is, kilovoltage, tube current and exposure time or the product of tube current and exposure time).**

**(6) The X-ray machine shall be labeled with a readily discernible sign bearing the radiation symbol and the words, "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or words having a similar intent, near any switch that energizes the X-ray tube.**

**(7) For fixed radiographic equipment, an easily visible warning light shall be located adjacent to the X-ray tube and labeled with the words "X-RAY ON" or words having a similar intent. The warning light shall be illuminated only when the X-ray tube is energized or only when the shutter is open.**

**(d) Fluoroscopic X-ray detection systems shall conform to the following:**

**(1) The leakage radiation from the source assembly measured at a distance of 1 meter in any direction from the source may not exceed 25.8 μc/kg (100 mR) in 1 hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.**

**(2) The X-ray machine shall be labeled with a readily discernible sign bearing the radiation symbol and the words, "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" or words having a similar intent, near any switch that energizes the X-ray tube.**

**(3) To the extent practicable, the X-ray system (X-ray tube, imaging system and the object being irradiated) shall be completely enclosed so that every location on the exterior meets conditions for an unrestricted area and the only access to the room or enclosure is through openings which are interlocked so that the radiation source will not operate unless all openings are securely closed and meet the requirements of 10 CFR 20.1601 (relating to control of access to high radiation areas).**

**(4) The equipment shall be constructed so that, under conditions of normal use, the entire cross-section of the useful beam shall be attenuated by a primary protective barrier permanently incorporated into the equipment.**

**(5) The X-ray control shall have a dead-man type exposure switch. Activation of the X-ray beam shall be possible only by continuous pressure on the exposure switch.**

**(6) An easily visible warning light shall be located adjacent to the X-ray tube or on the outside of the enclosure and be labeled with the words "X-RAY ON" or words having a similar intent. This light shall be illuminated only when the X-ray tube is energized or only when the shutter is open.**

**(e) Operating procedures for portable radiographic X-ray detection systems are as follows:**

**(1) To the extent practicable, portable X-ray tube heads shall be supported by a stand.**

**(2) To the extent practicable, supporting or positioning devices for the image receptor shall be used during radiation exposures.**

**(3) Individuals, other than those whose presence is necessary to conduct the X-ray procedure, shall be located at least 2 meters away from the X-ray tube and the object being irradiated during exposures.**

**(4) An individual may not be regularly employed to support the image receptor or object during radiation exposures.**

**(f) Operating procedures for fixed radiographic X-ray detection systems are as follows:**

**(1) A registrant shall test the safety and warning devices, including interlocks, at intervals not to exceed 12 months. Test records shall be maintained for inspection by the Department for 3 years after the test has been conducted.**

**(2) Safety or warning devices that do not function properly shall be repaired in a timely manner.**

**(3) If an X-ray detection system is required to be operated while in need of repair, procedures shall be modified to maintain the design level equivalent of safety or else the equipment may not be used.]**

## CHAPTER 227. [RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT, X-RAY GAUGING EQUIPMENT, ELECTRON MICROSCOPES AND X-RAY CALIBRATION SYSTEMS] (Reserved)

## [GENERAL PROVISIONS]

**§ 227.1. [Purpose and scope] (Reserved).**

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

**§ 227.2. [Definitions] (Reserved).**

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

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

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

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

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

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

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

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

**_X-ray calibration systems_—Radiation-producing machines and equipment used to calibrate radiation detection or measuring devices.**

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

**[ANALYTICAL X-RAY EQUIPMENT]**

**§ 227.11a. [Equipment requirements] (Reserved).**

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

**(1) A description of the various safety devices that have been evaluated.**

**(2) The reason each of these safety devices cannot be used.**

**(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.**

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

**(1) X-ray tube status (on-off) located near the radiation source housing, if the primary beam is controlled in this manner.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**(i) Analytical X-ray equipment operating at less than or equal to 50 kV tube voltage and designed to be held by an operator during use are exempt from the requirements of this section and § 227.12a(b), but shall meet the requirements of subsection (f)(2) and §§ 227.13a(a) and 227.14(a).]**

**§ 227.12a. [Area requirements] (Reserved).**

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

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

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

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

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

**(2) Following a change in the initial arrangement, number or type of local components in the system.**

**(3) Following maintenance requiring the disassembly or removal of a local component in the system.**

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

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

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

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

**(e) The registrant shall test and inspect all safety and warning devices at least annually to insure their proper operation. If a safety or warning device is found to be**

**malfunctioning, the machine shall be removed from service until repairs to the malfunctioning device are completed.**

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

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

**§ 227.13a. [Operating requirements] (Reserved).**

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

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

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

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

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

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

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

**§ 227.14. [Personnel requirements] (Reserved).**

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

**(1) Identification of radiation hazards associated with the use of the equipment.**

**(2) Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment, and the extra precautions necessary if the devices are absent or bypassed.**

**(3) Written operating and emergency procedures for the equipment.**

**(4) Symptoms of an acute localized radiation exposure.**

**(5) Procedures for reporting an actual or suspected exposure.**

**(6) Use of survey and personnel monitoring equipment.**

**(7) The applicable regulations of this article and those incorporated by reference.**

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

**(1) Analytical X-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device as described in § 227.12a(c) (relating to area requirements).**

**(2) Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when a local component in the analytical X-ray system is disassembled or removed or when safety devices are bypassed.**

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

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

## [X-RAY GAUGING EQUIPMENT]

**§ 227.21. [Warnings] (Reserved).**

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

**§ 227.22. [Radiation levels] (Reserved).**

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

**§ 227.23. [Personnel requirements] (Reserved).**

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

## [ELECTRON MICROSCOPES]

**§ 227.31. [Warnings] (Reserved).**

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

**§ 227.32. [Radiation levels] (Reserved).**

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

**§ 227.33. [Personnel requirements] (Reserved).**

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

## [X-RAY CALIBRATION SYSTEMS]

**§ 227.101. [Scope] (Reserved).**

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

**§ 227.102. [Area requirements] (Reserved).**

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

**§ 227.103. [Operating requirements] (Reserved).**

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

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

**§ 227.104. [Personnel requirements] (Reserved).**

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

(*Editor's Note*: Chapter 227a is proposed to be added and is printed in regular type to enhance readability.)

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

**Subchap.**

## Subchapter A. GENERAL PROVISIONS

Sec.



### § 227a.1. Purpose and scope.

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

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

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

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

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

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

### § 227a.2. Definitions.

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

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

*ALARA*—As low as reasonably achievable.

~~*Analytical X-ray equipment*—Equipment that generates, by electronic means, and uses ionizing radiation for the purpose of examining the microstructure of materials, namely diffraction and spectroscopy, including fluorescence.~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*General-use system*—An individual screening system that delivers an effective dose equal to or less than 25 ~~rem~~ **µREM** (0.25 µSv) per screening. ~~**Given proper justification and certain restrictions, general-use systems may be operated without specific controls that would limit the number of individuals scanned or the number of scans per individual in a year.**~~

*Handheld radiation-producing device*—A portable device designed to operate when held in the hand, such as a hand-held ~~**XRF**~~ **X-RAY FLUORESCENCE** analytical device.

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

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

*kV*—Kilovolt.

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

*Limited-use system*—An individual screening system that is capable of delivering an effective dose greater than 25 ~~rem~~ **µREM** (0.25 µSv) per screening but that cannot exceed an effective dose of 1 mrem (10 µSv) per screening. ~~**A limited-use system requires additional controls and documentation to ensure that annual individual dose limits required under § 227a.53(e) (relating to radiation-producing devices used in vehicle security screening) are not exceeded.**~~

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

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

*μrem*—Microrem.

*μSv*—Micro Sievert.

*mrem*—Millirem.

*mSv*—Milli Sievert.

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

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

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

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

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

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

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

*RSO—Radiation Safety Officer*—The term has the meaning given to it under § 215.2.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**§ 227a.3. Exemptions.**

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

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

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

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

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

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

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

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

**§ 227a.4. Application for exemptions.**

**THE DEPARTMENT MAY CONSIDER AN APPLICATION FOR EXEMPTIONS TO THE REQUIREMENTS OF THIS CHAPTER.** A radiation-producing device registrant who ~~is subject to the requirements of this chapter and~~ cannot meet one or more requirements of this chapter shall submit to the Department a written request for an exemption to the requirements that cannot be met. The exemption request must explain why the provision cannot be met and must demonstrate all of the following to the Department's satisfaction:

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

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

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

## Subchapter B. GENERAL TECHNICAL REQUIREMENTS

Sec.



### § 227a.10. Radiation safety program.

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

### § 227a.11. Warning devices.

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

(b) *Warning device light.* An easily visible warning device light labeled with the words "X-RAY ON," or words having a similar intent, must be located near every switch that energizes an

X-ray tube and must be illuminated only when the tube is energized. This warning light must be of a fail-safe design.

**§ 227a.12. Labeling.**

(a) *General rule.* A radiation-producing device must be labeled with a readily visible and discernible sign or signs bearing the radiation symbol ~~as defined under § 219.159 (relating to posting of radiation-producing machines)~~ and the words: "CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near every switch that energizes an X-ray tube.

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

**§ 227a.13. Radiation source housing.**

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

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

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

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

**§ 227a.15. Surveys.**

(a) *General rule.* Radiation surveys of all radiation-producing devices must be sufficient to show compliance under § 219.51 (relating to radiation dose limits for individual members of the public) and to show compliance with radiation emission requirements of this chapter. The radiation surveys must be sufficient to evaluate the magnitude and extent of radiation emissions and the potential radiological hazards that could be present. Records of these surveys must be

maintained for 5 years for inspection by the Department. At a minimum, surveys shall be performed in the following instances:

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

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

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

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

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

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

(7) ~~When~~ **IF** a personnel monitoring device shows ~~a significant increase, as predetermined by the registrant, over the previous monitoring period or readings approach the limits~~ **A RADIATION EXPOSURE THAT IS GREATER THAN 25% OF THE ANNUAL OCCUPATIONAL DOSE LIMIT AS** specified in 10 CFR 20.1201 (relating to occupational dose limits for adults).

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

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

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

**§ 227a.16. Posting.**

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

**§ 227a.17. Security.**

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

**§ 227a.18. Operating requirements.**

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

(b) *Bypassing.*

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

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

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

(i) The date the bypass was made.

(ii) A detailed description of the bypass.

(iii) The length of time the unit remained in the altered condition.

(iv) The post bypass survey as noted in § 227a.15 (relating to surveys).

(v) Other relevant information for the bypass.

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

(c) *Control panel.*

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

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

(d) *Interlocks.*

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

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

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

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

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

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

**§ 227a.20. Testing of safety devices.**

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

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

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

(d) *Record requirements.* Records required under this section must include the date of the test, a list of the safety devices tested, survey instrument information, the calibration date, the results of the test, the name of the person performing the test and, for safety devices that fail the required test, corrective actions taken.

(e) *Out of service requirements.* Testing of safety devices may be deferred if the unit or installation, or both, are clearly marked and kept out of service. A unit or installation, or both,

brought back into service after the 12-month interval specified in subsection (a) shall be tested prior to use.

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

**§ 227a.21. Instruction and training.**

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

(1) Types of radiation, identification of radiation hazards associated with the use of the radiation-producing device and associated equipment, and precautions or measures to take to minimize radiation exposure.

(2) Significance of the various radiation warnings, safety devices and interlocks incorporated into the equipment, or the reasons that warnings, safety devices or interlocks have not been installed on equipment and the extra precautions required in these cases.

(3) Commensurate with potential hazards of use, biological effects of radiation, radiation risks and recognition of symptoms of an acute localized exposure.

(4) Normal operating procedures for each type of radiation-producing device and associated equipment, as well as procedures to prevent unauthorized use. Training in normal operating procedures must include hands-on training.

(5) Emergency procedures for reporting actual or suspected accidental exposure and other radiation safety concerns, such as an unusual occurrence or malfunction that may involve exposure to radiation.

(6) Radiation survey performance, where applicable.

**§ 227a.22. Radiation protection responsibility.**

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

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

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

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

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

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

(5) ~~Maintaining~~ **RETAINING** all ~~radiation safety~~ records **REQUIRED TO SHOW COMPLIANCE WITH THIS SECTION**, including annual ~~audits~~ **REVIEWS** of the radiation protection program **CONTENT AND IMPLEMENTATION** and **THE** documentation of its findings, **AS REQUIRED IN § 219.5 (RELATING TO INCORPORATION BY REFERENCE), AND INCORPORATING BY REFERENCE 10 CFR 20.1101(c) (RELATING TO RADIATION PROTECTION PROGRAMS)**, and making the records available for review by the Department for 5 years.

## Subchapter C. CLOSED-BEAM RADIATION-PRODUCING DEVICES

Sec.



### § 227a.30. System enclosure.

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

### § 227a.31. Interlocks.

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

**§ 227a.32. Interlock functions.**

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

**§ 227a.33. Radiation emission limit.**

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

**§ 227a.34. Security screening devices.**

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

(1) During an exposure or preset succession of exposures of 0.5 second or greater duration, the closed-beam radiation-producing device must have a mechanism to enable the operator to terminate the exposure or preset succession of exposures at any time.

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

**§ 227a.35. Electron microscope devices.**

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

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

~~**(c) *Operation.* A registrant may not permit an individual to operate or conduct maintenance upon any closed-beam electron microscope until the individual has received a copy of, instruction in, and demonstrated an understanding of the normal operating procedures necessary to ensure radiation safety.**~~

## Subchapter D. OPEN-BEAM RADIATION-PRODUCING DEVICES

Sec.



### § 227a.40. Safety device.

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

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

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

(d) *Alternative methods.* If the registrant's use of the open-beam radiation-producing device does not permit the use of a safety device to minimize the chance of direct body exposure, the registrant shall use alternative methods, such as policies and procedures, to minimize the possibility of unnecessary exposure. The registrant shall document the alternative methods used.

The documentation must include information about the absence of safety devices. This documentation shall be available for inspection as long as the methods are used plus an additional 5 years.

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

**§ 227a.41. X-ray on status.**

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

(1) X-ray tube "on-off" status indicator located near the radiation source housing. The warning lights required under § 227a.11(b) (relating to warning devices), meet this requirement if the warning lights are conspicuous and viewable by anyone near the primary beam.

(2) Shutter "open-closed" status indicator located at the control panel and near each beam port on the radiation source housing, if the primary beam is controlled with a shutter. The shutter status device must be clearly labeled to indicate whether the shutter is open or closed. The status light at the control panel meets the requirement for the status light at the beam port if the status light at the control panel is conspicuous and viewable by anyone near the primary beam.

(3) The X-ray tube "on-off" status indicator and the shutter "open-closed" status indicators must be of a fail-safe design.

**§ 227a.42. Labeling.**

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

**§ 227a.43. Beam ports.**

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

**§ 227a.44. Shutters.**

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

**§ 227a.45. Radiation emission limits.**

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

(1) Radiation emissions in any area surrounding the local component group which could result in an occupational dose in excess of 10 CFR Part 20 Subpart C (relating to occupational dose limits).

(2) A dose to an individual in an area surrounding the local component group in excess of the dose limits outlined under § 219.51 (relating to dose limits for individual members of the public).

**§ 227a.46. Primary beam attenuation.**

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

**§ 227a.47. Operator attendance.**

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

**§ 227a.48. Control of access.**

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

(1) Radiation areas must be conspicuously identified. The following apply:

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

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

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

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

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

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

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

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

**§ 227a.49. Instruction and training.**

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

(1) Sources and magnitude of common radiation exposure.

(2) Units of radiation measurement.

(3) Radiation protection concepts of time, distance, shielding and ALARA.

(4) Procedures and rights of a declared pregnancy.

(5) Regulatory requirements and area postings.

(6) Worker, embryo/fetus and public dose limits.

(7) Proper use of survey instruments and dosimetry.

(8) Policies and procedures required under § 227a.40 (relating to safety device).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) *Area control.* The registrant shall provide security to prevent entry by individuals ~~from any point when the device is energized during training~~ **TO THE AREA IN WHICH THE DEVICE IS ENERGIZED**.

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

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

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

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

(i) Upon installation of the device.

(ii) After maintenance that affects the radiation shielding, shutter mechanism or X-ray production components.

(iii) Upon damage to the system.

(iv) Every 12 months.

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

(4) *Dose limits for limited-use systems.* The effective dose per screening must be less than or equal to 1 mrem (0.01mSv) when equipment is capable of operation greater than 25 µrem (0.25 µSv) per screening ~~and is used with discretion~~. **THE NUMBER OF SCANS PER INDIVIDUAL MUST BE TRACKED TO ENSURE THE DOSE DOES NOT EXCEED THE LIMITS REFERENCED IN PARAGRAPH (5) AND § 227a.53(c) (RELATING TO RADIATION-PRODUCING DEVICES USED IN VEHICLE SECURITY SCREENING).**

(5) *Dose limits for repeat security screenings.* An individual subject to repeat individual security screenings at a single venue may not receive an effective dose greater than 25 mrem (0.25 mSv) in a 12-month period at the registrant's or licensee's facility.

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

(i) The estimated effective dose from one screening.

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

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

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

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

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

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

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

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

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

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

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

(b) *Minimizing human exposure.* If vehicle occupants are knowingly exposed to the primary beam of a security screening device and the requirements in § 227a.52(3)—(5) cannot be met, then there shall be means to ~~assure~~ **ENSURE** the occupied portion of the vehicle is outside of the scan area while the primary beam is emitted or procedures shall be established and implemented to assure that no occupants are present in the vehicle during screening.

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

**§ 227a.54. Permanent radiographic installations.**

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

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

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

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

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

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

(a) *Control of access.* A room used for shielded room X-ray radiography must be shielded so that every location on the exterior meets conditions for an unrestricted area. Access to the room may only be through openings that are interlocked. The openings must be interlocked so that the

radiation source cannot operate unless all openings are securely closed and meet the requirement of 10 CFR 20.1601 (relating to control of access to high radiation areas).

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

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

## CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

### GENERAL PROVISIONS

### § 228.2. Definitions.

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

*Accelerator* or *particle accelerator*—A radiation-producing machine **[that imparts kinetic energies of one of the following:**

**(i) One-tenth of one MeV or greater to electrons if the electron beam is brought out of the evacuated region of the unit.**

**(ii) One MeV or greater to electrons if the electrons are utilized for X-ray production.**

**(iii) One-tenth of one MeV or greater to other particles.]**

**capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt (MeV).**

*Applicator*—A structure which determines the extent of the treatment field at a given distance from the virtual source.

* * * * *

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

March 21, 2023

David Sumner
Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17120

Re: Final Rulemaking: Radiation Safety Requirements for Non-Healing Arts Radiation-producing Devices (#7-555 / IRRC # 3311)

Dear Mr. Sumner:

Pursuant to Section 5.1(a) of the Regulatory Review Act (RRA), please find enclosed the Radiation Safety Requirements for Non-Healing Arts Radiation-producing Devices (#7-555) final-form rulemaking for review by the Independent Regulatory Review Commission (IRRC). The Environmental Quality Board (EQB or Board) adopted this rulemaking at its November 15, 2022, meeting.

The Board adopted the proposed rulemaking on May 19, 2021. On August 14, 2021, the proposed rulemaking was published in the *Pennsylvania Bulletin* at 51 Pa.B. 4845 for a 30-day public comment period that closed on September 13, 2021. The Department received one public comment. The Board provided the Environmental Resources and Energy Committees and IRRC with copies of all comments received in compliance with Section 5(c) of the RRA.

The Department will provide assistance as necessary to facilitate IRRC's review of the enclosed rulemaking under Section 5.1(e) of the Regulatory Review Act.

Please contact me by e-mail at laurgriffi@pa.gov or by telephone at 717.772.3277 if you have any questions or need additional information.

Sincerely,

Laura Griffin
Regulatory Coordinator

Enclosures

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT**

**I.D. NUMBER:** 7-555

**SUBJECT:** Radiation Safety Requirements for Non-Healing Arts Radiation-producing Devices

**AGENCY:** DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

**TYPE OF REGULATION**

RECEIVED
MAR 21 2023
Independent Regulatory Review Commission

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

**FILING OF REGULATION**

| DATE | SIGNATURE | DESIGNATION |
|---|---|---|
| | | *HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY* |
| 3/21/23 | | MAJORITY CHAIR Representative Greg Vitali |
| 3/21/23 | | MINORITY CHAIR Representative Martin Causer |
| | | *SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY* |
| 3/21/23 | electronic submittal | MAJORITY CHAIR Senator Gene Yaw |
| 3/21/23 | electronic submittal | MINORITY CHAIR Senator Carolyn Comitta |
| | | *INDEPENDENT REGULATORY REVIEW COMMISSION* |
| | | *ATTORNEY GENERAL* (for Final Omitted only) |
| | | *LEGISLATIVE REFERENCE BUREAU* (for Proposed only) |

March 21, 2023

**Shani Shenk**

**From:** Eyster, Emily <Emily.Eyster@pasenate.com>
**Sent:** Tuesday, March 21, 2023 11:08 AM
**To:** Troutman, Nick; Griffin, Laura
**Cc:** Chalfant, Brian; Reiley, Robert A.; Nezat, Taylor
**Subject:** Re: Delivery of Final Rulemaking - Radiation Safety Requirements for Non-Healing Arts Radiation-producing Devices (7-555)



Received. Thank you!

Emily Eyster
Legislative Director, Office of Senator Carolyn T. Comitta
Executive Director, Senate Environmental Resources and Energy Committee
Cell: (717) 756-4702
Phone: (717) 787-5709
www.pasenatorcomitta.com

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**From:** Troutman, Nick <ntroutman@pasen.gov>
**Sent:** Tuesday, March 21, 2023 10:55:40 AM
**To:** Griffin, Laura <laurgriffi@pa.gov>; Eyster, Emily <Emily.Eyster@pasenate.com>
**Cc:** Chalfant, Brian <bchalfant@pa.gov>; Reiley, Robert A. <rreiley@pa.gov>; Nezat, Taylor <tnezat@pa.gov>
**Subject:** RE: Delivery of Final Rulemaking - Radiation Safety Requirements for Non-Healing Arts Radiation-producing Devices (7-555)

■ EXTERNAL EMAIL ■

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Received by Senator Yaw's Office. Thanks Laura

**From:** Griffin, Laura <laurgriffi@pa.gov>
**Sent:** Tuesday, March 21, 2023 10:53 AM
**To:** Troutman, Nick <ntroutman@pasen.gov>; Emily.Eyster@pasenate.com
**Cc:** Chalfant, Brian <bchalfant@pa.gov>; Reiley, Robert A. <rreiley@pa.gov>; Nezat, Taylor <tnezat@pa.gov>
**Subject:** Delivery of Final Rulemaking - Radiation Safety Requirements for Non-Healing Arts Radiation-producing Devices (7-555)
**Importance:** High



Good morning,

Pursuant to Section 5.1(a) of the Regulatory Review Act, please find attached the Radiation Safety Requirements for Non-Healing Arts Radiation-producing Devices final rulemaking (#7-555) for review by the Senate Environmental Resources and Energy Committee. The rulemaking documents are attached in a compressed folder and the cover letters for Senators Yaw and Comitta are attached separately.

Also attached is the transmittal sheet showing delivery to the House Environmental Resources and Energy Committee this morning.

Please confirm receipt of this rulemaking by replying to all recipients.

Thank you,
Laura



**Laura Griffin** | Regulatory Coordinator
*she/her/hers*
Department of Environmental Protection | Policy Office
Rachel Carson State Office Building
400 Market Street | Harrisburg, PA 17101
Phone: 717.772.3277| Fax: 717.783.8926
Email: laurgriffi@pa.gov
www.dep.pa.gov

Connect with DEP on: Twitter | Facebook | LinkedIn | YouTube | Instagram

**Shani Shenk**

**From:** Troutman, Nick <ntroutman@pasen.gov>
**Sent:** Tuesday, March 21, 2023 10:56 AM
**To:** Griffin, Laura; Eyster, Emily
**Cc:** Chalfant, Brian; Reiley, Robert A.; Nezat, Taylor
**Subject:** RE: Delivery of Final Rulemaking - Radiation Safety Requirements for Non-Healing Arts Radiation-producing Devices (7-555)



Received by Senator Yaw's Office. Thanks Laura

**From:** Griffin, Laura <laurgriffi@pa.gov>
**Sent:** Tuesday, March 21, 2023 10:53 AM
**To:** Troutman, Nick <ntroutman@pasen.gov>; Emily.Eyster@pasenate.com
**Cc:** Chalfant, Brian <bchalfant@pa.gov>; Reiley, Robert A. <rreiley@pa.gov>; Nezat, Taylor <tnezat@pa.gov>
**Subject:** Delivery of Final Rulemaking - Radiation Safety Requirements for Non-Healing Arts Radiation-producing Devices (7-555)
**Importance:** High



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Thank you,
Laura

**Laura Griffin** | Regulatory Coordinator
*she/her/hers*
Department of Environmental Protection | Policy Office
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