Regulatory Analysis Form

(Completed by Promulgating Agency)

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

(1) Agency: Department of Environmental Protection

(2) Agency Number: 7

Identification Number: 555

IRRC Number: 3311

(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):

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(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 proposed to be 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.

The proposed 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 proposed 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 proposed amendments incorporate SSR Part H and the training requirements in SSR Part E that were developed by the Conference of Radiation Control Program Directors (CRCPD). Moreover, it will better align the state regulations with the federal requirements under 10 CFR Part 34.

(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.

The proposed 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 provide for requirements of new equipment that may be marketed in the future.

As set forth in the proposed rulemaking, users of non-medical radiation-producing devices would be required to comply with radiation protection standards that would not only protect and benefit employees but would also protect and benefit the general public from overexposures to radiation. The proposed rulemaking would ensure 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 citizens of the Commonwealth will benefit from these proposed regulations. For example, personnel at the approximately 90 prisons, 120 schools, 1,040 industrial establishments, and 130 county offices and other non-medical offices registered with the Department perform numerous scans per day resulting in thousands of scans being done annually, and the proposed regulations would ensure 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 proposal will not put Pennsylvania at a competitive disadvantage. Instead, it will align 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, provides:

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 proposed rulemaking and to advise the Department prior to submittal of the proposed regulation 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 proposed regulations on October 10, 2019, and appointed a subcommittee comprised of professionals in this specific industry. The subcommittee held two conference calls from October 2019 through February 2020. RPAC again reviewed the package with the revisions made as a result of the recommendations of the subcommittee on March 19, 2020. At the conclusion of the July 9, 2020 meeting, RPAC voted to concur with the Department's recommendation that the proposed 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 proposed regulations affect approximately 1,400 radiation-producing device registrants. We estimate 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.

Three local government registrants for radiation-producing devices used in individual security screening will additionally be affected by the proposed 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. 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 being 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. The proposed requirements reflect current industry practices, as discovered through Department inspections and through conversations with RPAC members. Therefore, the proposed regulations are not expected to impose additional requirements on those registrants.

This proposed rulemaking would not only protect and benefit employees but would also protect and benefit the general public from overexposures to radiation. The proposed rulemaking would ensure 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 would be required to comply with the proposed regulations. 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 will also be 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 would not only protect employees but would also protect the general public from overexposures to radiation. The proposed rulemaking would ensure 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 proposed rulemaking. There are no changes to the fee schedule in Chapter 218 in this proposed rulemaking, and the new technologies listed in the proposed rulemaking are already complying with these proposed amendments and fees as required by the general administrative provisions of § 215.22 (relating to prohibited uses) . A small number of registrants may experience additional costs due to the new proposed 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. The current number of these registrants is three local government registrants.

There are no social impacts associated with the proposed rulemaking.

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

There are no adverse effects associated with the proposed rulemaking.

The benefits of the proposed rulemaking include protecting employees and the general public from overexposures to radiation by requiring compliance with radiation protection standards. The proposed rulemaking would ensure 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 hoping to use a radiation-producing device in individual screenings would be required to obtain training to operate the device, which costs approximately $950 per registrant. 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.

There are three (3) local governments that have yet to provide the training required as part of compliance with the proposed regulation. Based on the estimate that this training will cost $950 per registrant, compliance will cost the three local governments approximately $2,850 in total. 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 staff will be required to obtain training to operate the device, which again 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 staff 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 proposed rulemaking would change 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 2020/21	FY +1 2021/22	FY +2 2022/23	FY +3 2023/24	FY +4 2024/25	FY +5 2025/26
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	$2,850	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Costs	$2,850	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 will have 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 2017-18	FY -2 2018-19	FY -1 2019-20	Current FY 2020-21
Radiation Protection Fund	$11,639,000	$11,975,000	$12,809,000	$14,936,000

(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 these proposed regulations 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 proposed regulations. Much of this proposed regulation 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 proposal is 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 proposed 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 proposed regulations will help 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 proposed rulemaking because the radiation risk level remains the same for small businesses which operate radiation-producing devices. The exemption of small businesses from all or any part of the requirements contained in the proposed 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 <u>in detail</u> 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 proposed rulemaking. They are attached to this package.

(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 scheduled
C. The expected date of delivery of the final-form regulation:	Quarter 1, 2022
D. The expected effective date of the final-form regulation:	90 days after publication in the *PA Bulletin*
E. The expected date by which compliance with the final-form regulation will be required:	90 days after publication in the *PA 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 Board is not proposing a sunset date for these regulations since they are needed for the Department to carry out its statutory authority. The Department will continue to closely monitor these regulations for their effectiveness and recommend updates to the Board as necessary.

PART E

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Sec. E.1 - Purpose. This Part prescribes requirements for the issuance of licenses or registrations for the industrial use of sources of radiation and radiation safety requirements for persons using these sources of radiation in industrial radiography.

Sec. E.2 - Scope. The provisions and requirements of this Part are in addition to, and not in substitution for, other requirements of these regulations. In particular, the general requirements and provisions of Parts A, B, C, D, J, T, and V of these regulations apply to applicants, licensees and registrants subject to this Part. Parts C and T of these regulations apply to licensing and transportation of radioactive material and Part B of these regulations applies to the registration of radiation machines. Except for sections which are applicable only to sealed radioactive sources, radiation machines and sealed radioactive sources are both covered by this Part. This regulation does not apply to medical uses of sources of radiation which are addressed in Parts G and X of these regulations.

Sec. E.3 - Definitions. As used in this Part, the following definitions apply:

"Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review shall include, as a minimum, any results of internal inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review shall also provide opportunities for employees to ask safety questions.

"ANSI" means the American National Standards Institute.

"Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head)

"Certifying entity" means an independent certifying organization meeting the requirements in Appendix A of this Part or an Agreement State meeting the requirements in Appendix A, Parts II and III of this Part.

"Collimator" means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

"Control cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

"Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.

"Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

"Drive cable" see "Control cable".

"Exposure head" means a device that locates the gamma radiography sealed source in the selected working position.*/

"Field station" means a facility from which sources of radiation may be stored or used and from where equipment is dispatched.

"Guide tube" means a flexible or rigid tube, or "J" tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

"Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process, and includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, transportation of radiography equipment, posting of records and radiation area surveillance, etc., as applicable. Excessive time spent in only one or two of these areas, such as film development or radiation area surveillance, should not be counted toward the 2000 hours of hands-on experience required for a radiation safety officer in E.16a.ii. or the hands-on experience for a radiographer as required by E.17a.

"Independent certifying organization" means an independent organization that meets all of the criteria of Appendix A of this Part.

"Industrial radiography" means an examination of the structure of materials by the nondestructive method of utilizing ionizing radiation to make radiographic images.

["Lay-barge radiography" (for States that authorize this activity) means industrial radiography performed on any water vessel used for laying pipe.]

["Offshore platform radiography" (for States that authorize this activity) means industrial radiography conducted from a platform over a body of water.]

"Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

"Pigtail" see "Source assembly".

"Practical examination" means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

"Radiation safety officer for industrial radiography" means an individual with the responsibility for the

*/ An exposure head is also known as a source stop.

overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of E.16.

"Radiographer" means any individual who performs or who, in attendance at the site where the sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of the Agency's regulations and the conditions of the license or registration.

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

["Radiographer's assistant" (for States who authorize this activity) means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools, or radiation survey instruments in industrial radiography.]

"Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

"Radiographic operations" means all activities associated with the presence of radioactive sources in a radiographic exposure device, or with a radiation machine. Activities include using, transporting except by common or contract carriers, or storing at a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries. Transporting a radiation machine is not considered a radiographic operation.

"Radiography" see "Industrial radiography."

"S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

"Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

"Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may include a ballstop to secure the source in the shielded position.

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices. They may also be used for transporting and storing sealed sources.

"Storage area" means any location, facility, or vehicle that is used to store and secure a radiographic exposure device, a radiation machine, sealed source or a storage container when it is not used for radiographic operations. Storage areas are locked or have a physical barrier to prevent accidental exposure, tampering, or unauthorized removal of the device, machine, or container.

"Storage container" means a container in which sealed sources or radiation machines are secured and stored.

"Temporary jobsite" means a location where radiographic operations are performed and where sources of radiation may be stored other than the location(s) of use authorized on the license or registration.

["Underwater radiography" (for States that authorize this activity) means industrial radiography performed when the radiographic exposure device or radiation machine and/or related equipment are beneath the surface of the water.]

Sec. E.4 - Reserved.

Sec. E.5 - Licensing and Registration Requirements for Industrial Radiography Operations. The Agency will approve an application for a specific license for the use of licensed material or a registration for use of radiation machines if the applicant meets the following requirements:

a. The applicant satisfies the general requirements specified in Part B for radiation machine facilities or Part C for radioactive material, as applicable, and any special requirements contained in this Part;

b. The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of E.17. The applicant need not describe the initial training and examination program for radiographers in the subjects outlined in E.17g;

c. The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;

d. The applicant submits written operating and emergency procedures as described in E.18;

e. The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed 6 months as described in E.17e.;

f. The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;

g. The applicant submits the qualifications of the individual(s) designated as the radiation safety officer as described in E.16a and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures;

h. If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test. If the applicant intends to analyze its own wipe samples, the applicant must include a description of the procedures to be followed. The description must include the:

    i. Methods of collecting the samples;

ii. Qualifications of the individual who analyzes the samples;

iii. Instruments to be used; and

iv. Methods of analyzing the samples.

i. If the applicant intends to perform calibrations of survey instruments and alarming ratemeters, the applicant must describe methods to be used and the experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in E.9 and E.20g.iv.;

j. The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations;

k. The applicant identifies the location(s) where all records required by this and other Parts of these regulations will be maintained;

l. [(For States that authorize this activity) If a license application includes underwater radiography, a description of:

i. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;

ii. Radiographic equipment and radiation safety equipment unique to underwater radiography; and

iii. Methods for gas-tight encapsulation of equipment; and]

m. [(For States that authorize this activity) If an application includes offshore platform and/or lay-barge radiography, a description of:

i. Transport procedures for radioactive material to be used in industrial radiographic operations;

ii. Storage facilities for radioactive material; and

iii. Methods for restricting access to radiation areas.]

Sec. E.6 - Performance Requirements for Industrial Radiography Equipment. Equipment used in industrial radiographic operations must meet the following minimum criteria:

a. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard Institute, N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981); This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd

Street, New York, New York 10036; Telephone: (212) 642–4900. Copies of the document are available for inspection at the Nuclear Regulatory Commission Library, 11545 Rockville Pike, Rockville, Maryland 20852. A copy of the document is also on file at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*;

b. In addition to the requirements specified in E.6a., the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources;

i. The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

(1) Chemical symbol and mass number of the radionuclide in the device;

(2) Activity and the date on which this activity was last measured;

(3) Model or product code and serial number of the sealed source;

(4) Name of the manufacturer of the sealed source; and

(5) Licensee's name, address, and telephone number.

ii. Radiographic exposure devices intended for use as Type B packages must meet the applicable transportation requirements of Part T of these regulations.

iii. Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

c. In addition to the requirements specified in E.6a. and E.6b., the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers;

i. The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

ii. The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

iii. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device

must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

iv. Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

"DANGER -- RADIOACTIVE"

The label may not interfere with the safe operation of the exposure device or associated equipment.

v. The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

vi. Guide tubes must be used when moving the source out of the device.

vii. An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiography operations.

viii. The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

ix. Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

d. All radiographic exposure devices and associated equipment must comply with the requirements of this section; and

e. As an exception to E.6a., equipment used in industrial radiographic operations need not comply with § 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can reasonably exert on the lever or crankshaft of the drive mechanism.

Sec. E.7 - Limits on External Radiation Levels From Storage Containers and Source Changers. The maximum exposure rate limits for storage containers and source changers are 2 millisieverts (200 mrem) per hour at any exterior surface, and 0.1 millisieverts (10 mrem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

Sec. E.8 - Locking Sources of Radiation, Storage Containers and Source Changers.

a. Each radiographic exposure device must have a lock or outer locked container designed to prevent

unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked[**] when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in E. 22. In addition, during radiographic operations, the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

b. Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked[***] when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

c. For x-ray machines whose design output is greater than or equal to 1MeV, the control panel of each radiation machine shall be equipped with a lock that will prevent the unauthorized use of an x-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or a radiographer's assistant.

Sec. E.9 - Radiation Survey Instruments.

a. The licensee or registrant shall keep sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make the radiation surveys required by this Part and by Part D of these regulations. Instrumentation required by this section must be capable of measuring a range from 0.02 millisieverts (2 mrem) per hour through 0.01 sievert (1 rem) per hour.

b. The licensee or registrant shall have each radiation survey instrument required under E.9a. calibrated:

   i. At energies appropriate for use and at intervals not to exceed 6 months or after instrument servicing, except for battery changes;

   ii. At energies appropriate for use:

      (1) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale;

      (2) For logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour;

   iii. So that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.

[**] If a keyed lock, the key must be removed at all times.

c. The licensee or registrant shall maintain records of the results of the instrument calibrations in accordance with E.26.

Sec. E.10 - Leak Testing and Replacement of Sealed Sources.

a. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed by persons authorized to do so by the Agency, the Nuclear Regulatory Commission, or an Agreement State.

b. The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Agency, the Nuclear Regulatory Commission, or an Agreement State.

c. Testing and recordkeeping requirements.

i. Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source must be performed using a method approved by the Agency, the Nuclear Regulatory Commission, or by an Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 becquerel (0.005 microcuries) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the Nuclear Regulatory Commission, or an Agreement State to perform the analysis.

ii. The licensee shall maintain records of the leak tests in accordance with E.27.

iii. Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for leakage and the test results received. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the storage interval exceeds 6 months.

d. Any test conducted pursuant to E.10c. that reveals the presence of 185 becquerels (0.005microcuries) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall have it decontaminated and repaired or disposed of in accordance with Agency regulations. A report must be filed with the Agency within 5 days of any test with results that exceed the threshold in this paragraph, describing the equipment involved, the test results, and the corrective action taken.

e. Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 becquerels (0.005 microcuries) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the Nuclear Regulatory Commission, or an Agreement State to perform the analysis. Should such

testing reveal the presence of 185 becquerel (0.005 microcuries) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while not in use and in storage. Before using or transferring such a device, however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak-test must be made in accordance with E.27.

Sec. E.11 - Quarterly Inventory.

a. Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation, and for devices containing depleted uranium received and possessed under the license.

b. The licensee or registrant shall maintain records of the quarterly inventory in accordance with E.28.

Sec. E.12 - Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

a. The licensee or registrant shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that:

   i. The equipment is in good working condition;

   ii. The sources are adequately shielded; and

   iii. Required labeling is present.

b. Survey instrument operability must be performed using check sources or other appropriate means.

c. If equipment problems are found, the equipment must be removed from service until repaired.

d. Each licensee or registrant shall have written procedures for performance of inspection and routine maintenance of radiation machines (producing x-rays greater than or equal to 1 MeV), radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed 3 months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired. Replacement components shall meet design specifications.

e. The licensee's inspection and maintenance program must include written procedures for inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of

compliance or other approval.

f. Records of equipment problems and of any maintenance performed under E.12 must be made in accordance with E.30.

Sec. E.13 - Permanent Radiographic Installations.

a. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

i. An entrance control of the type described in Part D.1601 of these regulations that causes the radiation level upon entry into the area to be reduced; or

ii. Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed or the machine is energized. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed or the machine is energized.

b. The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry as designated in E.13a.i.must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within 7 calendar days. The facility may continue to be used during this 7-day period, provided the licensee or registrant implements the continuous surveillance requirements of E.22 and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarms must be maintained in accordance with E.31.

Sec. E.14 - Labeling, Storage, and Transportation.

a. The licensee may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol in conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

CAUTION *
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES [or "NAME OF COMPANY"]

* --- or "DANGER"

b. The licensee may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in Part T.

c. Radiographic exposure devices, source changers, storage containers, and radiation machines

machines (of greater than or equal to 1 MeV), must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner that will minimize danger from explosion or fire.

d. The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

Radiation Safety Requirements

Sec. E.15 - Conducting Industrial Radiographic Operations.

a. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of E.17c. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

b. All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation unless otherwise specifically authorized by the Agency.

c. [(For States who authorize this activity) a licensee or registrant may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Agency, the Nuclear Regulatory Commission, or by an Agreement State.]

Sec. E.16 - Radiation Safety Officer. The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

a. The minimum qualifications, training, and experience for radiation safety officers for industrial radiography are as follows:

   i. Completion of the training and testing requirements of E.17a.;

   ii. 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

   iii. Formal training in the establishment and maintenance of a radiation protection program.

b. The Agency will consider alternatives when the radiation safety officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

c. The specific duties and authorities of the radiation safety officer include:

i. Establishing and overseeing all operating, emergency, and ALARA procedures as required by Part D of these regulations and reviewing them regularly to ensure that they conform to Agency regulations and to the license or registration conditions;

ii. Overseeing and approving the training program for radiographic personnel to ensure that appropriate and effective radiation protection practices are taught;

iii. Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;

iv. Ensuring that personnel monitoring devices are calibrated, if applicable, and used properly; that records are kept of the monitoring results; and that timely notifications are made as required by Part D of these regulations; and

v. Ensuring that operations are conducted safely and for implementing corrective actions including stopping radiographic operations when necessary.

Sec. E.17 - Training.

a. The licensee or registrant may not permit any individual to act as a radiographer until the individual has received training in the subjects outlined in E.17g., in addition to on-the-job training consisting of hands-on experience under the supervision of a radiographer and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A of this Part. The on-the-job training shall include a minimum of 2 months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or 1 month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on-the-job training (3 months or 480 hours).

b. In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:

i. Has received copies of and instruction in the requirements described in the regulations contained in this Part, and applicable sections of Parts C, D, J, and T of these regulations, in the license or registration under which the radiographer will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

ii. Has demonstrated an understanding of items in E.17b.i. by successful completion of a written examination;.

iii. Has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

iv. Has demonstrated understanding of the use of the equipment described in E.17b.iii. by successful completion of a practical examination.

c. [(For States that authorize this activity), the licensee or registrant may not permit any individual to act as a radiographer's assistant until the individual:

i. Has received copies of and instruction in the requirements described in the regulations contained in this Part, and applicable sections of Parts C, D, J, and T of these regulations, in the license or registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

ii. Has demonstrated an understanding of items in E.17c.i. by successful completion of a written examination;

iii. Has developed competence to use, under the personal supervision of the radiographer, the radiation machines and/or radiographic exposure devices, sealed sources, associated equipment, and the radiation survey instruments that the assistant will use; and

iv. Has demonstrated understanding of the use of the equipment described in E.17c.iii. by successful completion of a practical examination.]

d. The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

e. Except as provided in E.17e.iii., the radiation safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Agency's regulations, license or registration requirements, and operating and emergency procedures are followed.

i. The inspection program must:

(1)Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

(2) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of E.17b.iii. and the radiographer's assistant must demonstrate knowledge of the training requirements of E.17c.iii. by a practical examination before these individuals can next participate in a radiographic operation.

ii. The Agency may consider alternatives in those situations where the individual serves as both radiographer and radiation safety officer.

iii. In those operations where a single individual serves as both radiographer and radiation safety officer, and performs all radiography operations, an inspection program is not required.

f. The licensee or registrant shall maintain records of the above training to include certification documents, written, and practical examinations, refresher safety training and inspections of job performance in accordance with E.32.

g. The licensee or registrant shall include the following subjects required in E.17a.:

i. Fundamentals of radiation safety including:

(1) Characteristics of gamma and x-radiation;

(2) Units of radiation dose and quantity of radioactivity;

(3) Hazards of exposure to radiation;

(4) Levels of radiation from licensed and registered sources of radiation; and

(5) Methods of controlling radiation dose (time, distance, and shielding);

ii. Radiation detection instruments including:

(1) Use, operation, calibration, and limitations of radiation survey instruments;

(2) Survey techniques; and

(3) Use of personnel monitoring equipment;

iii. Equipment to be used including:

(1) Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails);

(2) Operation and control of radiation machines;

(3) Storage, control, and disposal of sources of radiation; and

(4) Inspection and maintenance of equipment.

iv. The requirements of pertinent state and federal regulations; and

v. Case histories of accidents in radiography.

Sec. E.18 - Operating and Emergency Procedures.

a. Operating and emergency procedures must include, as a minimum, instructions in the following:

i. Appropriate handling and use of sources of radiation so that no person is likely to be exposed to radiation doses in excess of the limits established in Part D of these regulations;

ii. Methods and occasions for conducting radiation surveys;

iii. Methods for posting and controlling access to radiographic areas;

iv. Methods and occasions for locking and securing radiographic exposure devices, transport and storage containers and sealed sources;

v. Personnel monitoring and the use of personnel monitoring equipment;

vi. Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when required, and control of the equipment during transportation as described in Part T of these regulations;

vii. The inspection, maintenance, and operability checks of radiographic exposure devices, radiation machines, survey instruments, alarming ratemeters, transport containers, storage containers and associated equipment;

viii. Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly;

ix. The procedure(s) for identifying and reporting defects and noncompliance, as required by E.38;

x. The procedure for notifying proper persons in the event of an accident or incident;

xi. Minimizing exposure of persons in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;

xii. Source recovery procedure if licensee will perform source recoveries; and

xiii. Maintenance of records.

b. The licensee or registrant shall maintain copies of current operating and emergency procedures in accordance with E.33 and E.37.

[Sec. E.19 - (For States who authorize this activity.) Supervision of Radiographer's Assistants. The radiographer's assistant shall be under the personal supervision of a radiographer when using radiographic exposure devices, associated equipment, or a sealed source, or while conducting radiation surveys required by E.21b. to determine that the sealed source has returned to the shielded position or the radiation machine is off after an exposure. The personal supervision must include:

a. The radiographer's physical presence at the site where the sources of radiation are being used;

b. The availability of the radiographer to give immediate assistance if required; and

c. The radiographer's direct observation of the assistant's performance of the operations referred to in this section.]

Sec. E.20 - Personnel Monitoring.

a. The licensee or registrant may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an alarming ratemeter, and personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. At permanent radiographic installations where other appropriate alarming or warning devices are in routine use, or during radiographic operations using radiation machines, the use of an alarming ratemeter is not required.

   i. Pocket dosimeters must have a range from zero to 2 millisieverts (200 mrem) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

   ii. Each personnel dosimeter must be assigned to and worn by only one individual.

   iii. Personnel dosimetry must be exchanged at periods not to exceed one month.

   iv. After replacement, each personnel dosimeter must be processed as soon as possible.

b. Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with E.34.

c. Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with E.34. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

d. If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than 2 millisieverts (200 mrem), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within 24 hours. In addition, the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination must be included in the records maintained in accordance with E.34.

e. If a personnel dosimeter is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in

the records maintained in accordance with E.34.

f. Reports received from the accredited NVLAP personnel dosimeter processor must be retained in accordance with E.34.

g. Each alarming ratemeter must:

i. Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift;

ii. Be set to give an alarm signal at a preset dose rate of 5 millisieverts (500 mrem) per hour; with an accuracy of plus or minus 20 percent of the true radiation dose rate;

iii. Require special means to change the preset alarm function; and

iv. Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarming ratemeter calibrations in accordance with E.34.

Sec. E.21 - Radiation Surveys. The licensee or registrant shall:

a. Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of E.9;

b. Conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment. Radiation machines shall be surveyed after each exposure to determine that the machine is off;

c. Conduct a survey of the radiographic exposure device whenever the source is exchanged and whenever a radiographic exposure device is placed in a storage area as defined in E.3, to ensure that the sealed source is in its shielded position; and

d. Maintain records in accordance with E.35.

Sec. E.22 - Surveillance. During each radiographic operation, the radiographer, or the other individual present as required by E.15, shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in Part A of these regulations, except at permanent radiographic installations where all entryways are locked and the requirements of E.13 are met.

Sec. E.23 - Posting. All areas in which industrial radiography is being performed must be conspicuously posted as required by Part D.1902 of these regulations. The exceptions listed in Part D.1903 of these regulations do not apply to industrial radiographic operations.

Recordkeeping Requirements

Sec. E.24 - Records for Industrial Radiography. Each licensee or registrant shall maintain a copy of its license or registration, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Agency, or until the Agency terminates the license or registration.

Sec. E.25 - Records of Receipt and Transfer of Sources of Radiation.

a. Each licensee or registrant shall maintain records showing the receipts and transfers of sealed sources, devices using DU for shielding, and radiation machines, and retain each record for 3 years after it is made.

b. These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

Sec. E.26 - Records of Radiation Survey Instruments. Each licensee or registrant shall maintain records of the calibrations of its radiation survey instruments that are required under E.9 and retain each record for 3 years after it is made.

Sec. E.27 - Records of Leak Testing of Sealed Sources and Devices Containing DU. Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of becquerels (microcuries). The licensee shall retain each record for 3 years after it is made or until the source in storage is removed.

Sec. E.28 - Records of Quarterly Inventory.

a. Each licensee or registrant shall maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by E.11, and retain each record for 3 years after it is made.

b. The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

Sec. E.29 - Utilization Logs.

a. Each licensee or registrant shall maintain utilization logs showing for each source of radiation the following information:

    i. A description, including the make, model, and serial number of the radiation machine or the radiographic exposure device, transport, or storage container in which the sealed source is located;

    ii. The identity and signature of the radiographer to whom assigned;

iii. The location and dates of use, including the dates removed and returned to storage; and

iv. For permanent radiographic installations, the dates each radiation machine is energized.

b. The licensee or registrant shall retain the logs required by E.29a. for 3 years.

Sec. E.30 - Records of Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

a. Each licensee or registrant shall maintain records specified in E.12 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for 3 years after it is made.

b. The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

Sec. E.31 - Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations. Each licensee or registrant shall maintain records of alarm system and entrance control device tests required by E.13 and retain each record for 3 years after it is made.

Sec. E.32 - Records of Training and Certification. Each licensee or registrant shall maintain the following records for 3 years:

a. Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, the names of individuals conducting and receiving the oral and practical examinations, and a list of items tested and the results of the oral and practical examinations; and

b. Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliance observed by the radiation safety officer.

Sec. E.33 - Copies of Operating and Emergency Procedures. Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the Agency terminates the license or registration. Superseded material must be retained for 3 years after the change is made.

Sec. E.34 - Records of Personnel Monitoring. Each licensee or registrant shall maintain the following exposure records specified in E.20:

a. Direct reading dosimeter readings and yearly operability checks required by E.20b. and E.20c. for

3 years after the record is made;

b. Records of alarming ratemeter calibrations for 3 years after the record is made;

c. Personnel dosimeter results received from the accredited NVLAP processor until the Agency terminates the license or registration; and

d. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged personnel dosimeters, until the Agency terminates the license or registration.

Sec. E.35 - Records of Radiation Surveys. Each licensee shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in E.21c. Each record must be maintained for 3 years after it is made.

Sec. E.36 - Form of Records. Each record required by this Part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

Sec. E.37 - Location of Documents and Records.

a. Each licensee or registrant shall maintain copies of records required by this Part and other applicable Parts of these regulations at the location specified in E.5k.

b. Each licensee or registrant shall also maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite;

   i. The license or registration authorizing the use of sources of radiation;

   ii. A copy of Parts A, D, E & J of these regulations;

   iii. Utilization logs for each source of radiation dispatched from that location as required by E.29.

   iv. Records of equipment problems identified in daily checks of equipment as required by E.30a.;

   v. Records of alarm system and entrance control checks required by E.31, if applicable;

   vi. Records of dosimeter readings as required by E.34;

   vii. Operating and emergency procedures as required by E.33;

viii. Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by E.26;

ix. Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by E.34;

x. Survey records as required by E.35 and Part D.2103 of these regulations as applicable, for the period of operation at the site;

xi. The shipping papers for the transportation of radioactive materials required by Part T of these regulations; and

xii. When operating under reciprocity pursuant to Part C of these regulations, a copy of the applicable State license or registration, or Nuclear Regulatory Commission license authorizing the use of sources of radiation.

Notifications

Sec. E.38 - Notifications.

a. In addition to the reporting requirements specified in Part D of these regulations, each licensee or registrant shall provide a written report to the Agency within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

i. Unintentional disconnection of the source assembly from the control cable;

ii. Inability to retract the source assembly to its fully shielded position and secure it in this position;

iii. Failure of any component, which is critical to safe operation of the device, to properly perform its intended function; or

iv. An indicator on a radiation machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate x-ray production.

b. The licensee or registrant shall include the following information in each report submitted under E.38a., and in each report of overexposure submitted under Part D.2203 of these regulations which involves failure of safety components of radiography equipment:

i. Description of the equipment problem;

ii. Cause of each incident, if known;

iii. Name of the manufacturer and model number of equipment involved in the incident;

iv. Place, date, and time of the incident;

v. Actions taken to establish normal operations;

vi. Corrective actions taken or planned to prevent recurrence; and

vii. Names and qualifications of personnel involved in the incident.

c. Any licensee or registrant conducting radiographic operations or storing sources of radiation at any location not listed on the license or registration for a period in excess of 180 days in a calendar year, shall notify the Agency prior to exceeding the 180 days.

Radiographer Certification

[Sec. E.39 - (For States that authorize this activity) Application and Examinations.

a. Application

i. An application for taking the examination shall be on forms prescribed and furnished by the Agency.

ii. A non-refundable fee of $XX.XX shall be submitted with the application to cover certification administrative costs, such as the examination, training documentation review, and issuance of certification.

ii. The application and the non-refundable and non-transferable application fee shall be submitted to the Agency on or before the dates specified by the Agency.

iii. Applicants who fail to appear at a scheduled exam and do not reschedule 48 hours prior to their assigned exam session shall apply for a future exam session in accordance with Section E.39.a.

iv. An individual whose certification ID card has been suspended or revoked shall obtain written approval from the Agency to apply to retake the examination.

b. Examination. The examination shall be given for the purpose of determining the qualifications of applicants.

i. A written examination shall be held at times and places determined by the Agency. The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the Agency. The examination will assess the applicant's knowledge to safely use sources of radiation and related equipment and the applicant's knowledge of Parts D, E and T of these regulations.

ii. The examination will be administered by the Agency or persons authorized by the

Agency.

iii. A candidate failing an examination may apply for re-examination in accordance with E.39a. and will be re-examined. A candidate shall not retake the same version of the examination.

iv. The examination will be held at dates, times and locations designated by the Agency.

v. The examination will be in English.

vi. To take the examination, an individual shall have a picture identification card, such as a driver's license, at the time of the examination.

vii. Calculators will be permitted during the examination. However, calculators or computers with preprogrammed data or formulas, including exposure calculators, will not be permitted during the examination.

viii. The examination will be a "closed book" examination.

ix. Any individual observed by an Agency proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet, and any work paper. Such individual will not be allowed to complete the examination, will forfeit the examination fee, and will leave the examination site to avoid disturbing other examinees. Such individual must wait 90 days and must resubmit a new application and an additional $XX.XX fee before taking a new examination.

x. Examination material shall be returned to the Agency at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by any individual of the contents of any examination prior to its administration is prohibited.

xi. The names and scores of individuals taking the examination shall be a public record.]

[Sec. E.40 - (For States that authorize this activity) Certification Identification (ID) Card.

a. A certification ID card shall be issued to each person who successfully completes the requirements of E.17a and the examination prescribed in E.39b.

i. Each person's certification ID card shall contain their photograph. The Agency will take the photograph at the time the examination is administered.

ii. The certification ID card remains the property of the Agency and may be revoked or suspended.

iii. Any individual who wishes to replace their certification ID card shall submit to the Agency a written request for a replacement certification ID card, stating the reason a

replacement certification ID card is needed. A non-refundable fee of $XX.XX shall be paid to the Agency for each replacement of a certification ID card. The prescribed fee shall be submitted with the written request for a replacement certification ID card. The individual shall maintain a copy of the request in their possession while performing industrial radiographic operations until a replacement certification ID card is received from the Agency.

b. Each certification ID card is valid for a period of five years, unless revoked or suspended in accordance with E.40d. Each certification ID card expires at the end of the day, in the month and year stated on the certification ID card.

c. Renewal of Certification ID card.

i. Applications for examination to renew a certification ID card shall be filed in accordance with E.39a.

ii. The examination for renewal of a certification ID card shall be administered in accordance with E.39b.

iii. A renewal certification ID card shall be issued in accordance with E.40a.

d. Revocation or suspension of a certification ID card.

i. Any radiographer who violates these regulations, equivalent State or Nuclear Regulatory Commission regulations, or any applicable statutory requirements may be required to show cause at a formal hearing why their certification ID card should not be revoked or suspended in accordance with E.40d.ii. of these regulations.

ii. When an Agency order has been issued for an industrial radiographer to cease and desist from the use of sources of radiation or the Agency revokes or suspends their certification ID card, the industrial radiographer shall surrender the certification ID card to the Agency until the order is changed or the suspension expires.]

Sec. E.41 - Reciprocity.

a. All reciprocal recognition of licenses and registrations by the Agency will be granted in accordance with Part C of these regulations.

b. Reciprocal recognition by the Agency of an individual radiographer certification will be granted provided that:

i. The individual holds a valid certification in the appropriate category issued by a certifying entity, as defined in E.3;

ii. The requirements and procedures of the certifying entity issuing the certification affords the same or comparable certification standards as those afforded by E.17a.;

iii. The applicant presents the certification to the Agency prior to entry into the state; and

iv. No escalated enforcement action is pending with the Nuclear Regulatory Commission or in any other state.

c. Certified individuals who are granted reciprocity by the Agency shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of E.17a.

Sec. E.42 - Specific Requirements for Radiographic Personnel Performing Industrial Radiography.

a. At a job site, the following shall be supplied by the licensee or registrant:

i. At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

ii. A current whole body personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor for each person;

iii. An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens assigned to each person performing radiographic operations. Each dosimeter must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters;

iv. An operable, calibrated, alarming ratemeter assigned to each person performing radiographic operations using a radiographic exposure device; and

v. The appropriate barrier ropes and signs.

b. Each radiographer at a job site shall have on their person a valid certification ID card issued by a certifying entity.

c. Industrial radiographic operations shall not be performed if any of the items in E.42a. and E.42b. are not available at the job site or are inoperable.

d. During an inspection, the Agency may terminate an operation if any of the items in E.42a. and E.42b. are not available or operable, or if the required number of radiographic personnel are not present. Operations shall not be resumed until all required conditions are met.

PART E

APPENDIX A

I. Requirements for an Independent Certifying Organization.

An independent certifying organization shall:

1. Be an organization such as a society or association, whose members participate in, or have an interest in, the field of industrial radiography;

2. Make its membership available to the general public nationwide. Membership shall not be restricted because of race, color, religion, sex, age, national origin or disability;

3. Have a certification program open to nonmembers, as well as members;

4. Be an incorporated, nationally recognized organization that is involved in setting national standards of practice within its fields of expertise;

5. Have an adequate staff, a viable system for financing its operations, and a policy and decision-making review board;

6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;

10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

12. Exchange information about certified individuals with the Nuclear Regulatory Commission and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and

13. Provide a description to the Nuclear Regulatory Commission of its procedures for choosing examination sites and for providing an appropriate examination environment.

II. Requirements for Certification Programs.

All certification programs must:

1. Require applicants for certification to:

   (a) Receive training in the topics set forth in E.17g. or equivalent State or Nuclear Regulatory Commission regulations, and

   (b) Satisfactorily complete a written examination covering these topics.

2. Require applicants for certification to provide documentation that demonstrates that the applicant has:

   (a) Received training in the topics set forth in E.17g. or equivalent State or Nuclear Regulatory Commission regulations;

   (b) Satisfactorily completed a minimum period of on-the-job training as specified in E.17a.; and

   (c) Received verification by a State licensee or registrant or a Nuclear Regulatory Commission licensee that the applicant has demonstrated the capability of independently working as a radiographer.

3. Include procedures to ensure that all examination questions are protected from disclosure;

4. Include procedures for denying an application and revoking, suspending, and reinstating a certification;

5. Provide a certification period of not less than 3 years nor more than 5 years;

6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and

7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

III. Requirements for Written Examinations

All examinations must be:

1. Designed to test an individual's knowledge and understanding of the topics listed in E.17g. or equivalent State or Nuclear Regulatory Commission requirements;

2. Written in a multiple-choice format; and

3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in E.17g.

PART H

RADIATION SAFETY REQUIREMENTS FOR NON-HEALING ARTS RADIATION GENERATING DEVICES (RGD)

Sec. H.1 - Purpose. This Part provides special requirements for non-healing arts radiation generating devices (RGDs) operating between 5 kiloelectron volts (keV) and 1 million electron volts (MeV). For machines operating at energies greater than 1 MeV, see Part I, (Radiation Safety Requirements for Particle Accelerators) of these regulations.

Sec. H.2 - Scope.

a. In addition to the requirements of this Part, all registrants are subject to the requirements of Parts A, B, D, and J of these regulations. This Part does not pertain to radiation safety requirements for x-ray equipment that is explicitly covered in other sections of these regulations (e.g., Diagnostic Machines [Part F], Particle Accelerators [Part I], and Radiation Safety Requirements for Industrial Radiographic Operations [Part E]).

b. Radiography that meets the definition of "cabinet radiography" (H.4) shall be regulated under this Part. This includes certified cabinet x-ray systems.

c. Radiography that occurs in a "shielded room" as defined in H.4 shall be regulated under this Part.

d. Using Radiography equipment that meets the definition of "bomb detection radiation equipment" (H.4) shall be regulated under this Part.

e. Industrial radiography that is open-beam, and not in a shielded room and not otherwise listed here, shall be regulated under Part E (Radiation Safety Requirements for Industrial Radiographic Operations) of these regulations.

Sec. H.3 - Intent. RGDs are a broad class of equipment that generate x-rays or particle radiation having energies between 5 keV and 1 MeV, and not intended for medical use on humans. If applicable, all RGDs shall comply with FDA performance standards as defined in Title 21 Code of Federal Regulations, parts 1010 thru 1050. Examples of RGDs include, but are not limited to: open and closed analytical x-ray equipment (table top and hand-held), x-ray gauges, cabinet x-ray radiography, security screening units, quality control application devices, ion implantation devices, electron beam welders, non-human use x-ray fluoroscopy, x-ray bomb detection and x-ray irradiators. The intent here is not to define safety parameters by what type of work the x-ray unit performs (analytical, gauge, radiography, etc.), but to classify by hazard (open-beam versus closed-beam) or dose rate. All other non-enclosed beam industrial radiography shall be regulated under Part E of these Regulations (Radiation Safety Requirements for Industrial Radiographic Operations).

Sec. H.4 - Definitions. As used in this Part, the following definitions apply:

"Accessible surface" means the external or outside surface of the enclosure or housing provided by the manufacturer. This includes the high-voltage generator, doors, access panels, latches, control

knobs, and other permanently mounted hardware and including the plane across the exterior edge of any opening.

"Analytical x-ray equipment" means equipment that generates (by electronic means) and uses ionizing radiation for the purpose of examining the microstructure of materials, i.e. diffraction and spectroscopy (including fluorescence).

"Baggage unit". See "Security Screening Unit".

"Beam-port" means an opening on the x-ray apparatus designed to emit a primary beam. This does not include openings on baggage units.

"Bomb detection radiographic equipment" means x-ray generating equipment used solely for the purpose of remotely detecting explosive devices. This definition does not include hand-held x-ray bomb detection equipment for the purposes of this Part.

"Cabinet radiography" means industrial radiography using radiation machines not subject to FDA performance standard for cabinet x-ray systems, in an enclosed, interlocked cabinet in which the portion of a material being irradiated is contained, and in which:

i. The radiation machine will not operate unless all openings are closed with interlocks activated;

ii. The cabinet is shielded such that every location on the exterior meets the conditions for an unrestricted area as defined in Part D of these regulations; and

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" means 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 x radiation. 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 a cabinet x-ray system.

"Cathode ray tube" means any device used to accelerate electrons for demonstration or research purposes, except where such cathode ray tube is incorporated into a television or display monitor that is subject to, and has met applicable federal radiation safety performance standards in 21 CFR 1010 and 1020.10.

"Certified cabinet x-ray system" means a RGD certified by the manufacturer in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of applicable federal radiation safety performance standards 21 CFR 1010 and 1020.40.

"Certifiable cabinet x-ray system" means an existing uncertified RGD that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

"Closed-beam x-ray equipment" means a system in which the beam path cannot be entered by any part of the body during normal operation.

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

"Collimator" means a device for restricting the useful radiation in one or more directions.

"Control panel" means a device containing means for regulation and activation of a RGD or for the preselection and indications of operating factors.

"Emergency procedure" means the written pre-planned steps to be taken in the event of actual or suspected exposure of an individual in excess of administrative or regulatory limits. This procedure shall include 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" means 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, if a light indicating "X-RAY ON" fails, the production of x-rays shall be prevented, or if a shutter status indicator fails, the shutter shall close.

"General-use system" means a personnel screening system that delivers an effective dose equal to or less than 0.25 μSv (25 μrem) 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.

"Hand-held x-ray system" means a portable instrument that is designed to operate when held in the hand, e.g., hand-held XRF analytical devices.

"Industrial radiography" means an examination of the structure of materials by nondestructive methods utilizing ionizing radiation to make radiographic images.

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

"Leakage radiation" means all radiation coming from within the source housing, except the useful beam.

"Limited-use system" means a personnel screening system that is capable of delivering an effective dose greater than 0.25 μSv (25 μrem) per screening but cannot exceed an effective dose of 10 μSv (1 mrem) per screening. Limited-use systems require additional controls and documentation to ensure that annual individual dose limits required by H.12e. are not exceeded.

"Local components" means parts of a RGD x-ray system and include areas that are struck by x-rays such as radiation source housings, beam port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Mobile equipment". See "Radiation generating device."

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

"Open-beam x-ray equipment" means an open-beam x-ray system in which the beam path could be entered by any part of the body at any time.

"Personnel security screening system" means any x-ray equipment used on humans for security evaluation.

"Portable equipment". See "Radiation generating device."

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

"Qualified expert" means an individual as defined in Part A of these regulations.

"Radiation generating device (or RGD)" means any system, device, subsystem, or component thereof, which may generate x-rays or particle radiation between 5 keV and 1 MeV, and not intended for healing arts use for humans or animals. A RGD may be fixed or portable, such as:

i. Mobile means RGD equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;

ii. Portable means RGD equipment designed to be hand-carried;

iii. Stationary means RGD equipment that is installed or placed in a fixed location; or

iv. Transportable means RGD equipment to be installed in a vehicle or that may be readily disassembled for transport or use in a vehicle.

"Radiation Safety Officer (RSO)" means an individual as defined in Part A of these regulations.

"Radiation source (or x-ray tube) housing" means that portion of an x-ray system which contains the x-ray tube and/or secondary target. Often the housing contains radiation shielding material or inherently provides shielding.

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

"Radiography" is the process of creating radiographic images.

"Safety device" means 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" means radiation that has been deviated in direction and / or energy by passing through matter.

"Security screening unit" means a non-human use open-beam or cabinet x-ray system with accessible openings designed for the detection of weapons, bombs, or contraband concealed in baggage, mail, packages or other commodities or structure.

"Shielded room" means a room housing a RGD where, with the RGD at maximum techniques, the exterior room environs meets the unrestricted area limits of 0.02 mSv (2 mrem) in any one hour and 1 mSv (100 mrem) in a year at 30 cm from the barrier. A shielded room does not include a RGD which meet the definition of cabinet x-ray systems.

"Shutter" means a moveable device used to block the useful (or primary) beam emitted from an x-ray tube assembly.

"Source" means the point of origin of the radiation, for example, the focal spot of an x-ray tube.

"Stationary equipment". See "Radiation generating device."

"Stray radiation" means the sum of leakage and scatter radiation.

"Warning device" means a visible or audible signal that warns individuals of a potential radiation hazard.

"X-ray generator" means that portion of an x-ray system which provides the accelerating high voltage and current for the x-ray tube.

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

Sec. H.5 - Exemptions.

a. RGDs meeting the definition of "bomb detection radiation equipment," as defined under H.4, are exempt from the requirements of H.6f. (Posting), of the General Regulatory Provisions of this Part.

b. Unless utilized in a dedicated location, hand-held RGDs are exempt from the requirements of H.6f Posting of the General Regulatory Provisions of this Part.

c. The following machines and equipment are exempt from these regulations:

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

   ii. Cold-cathode gas discharge tubes, providing the exposure rates shall not exceed 0.1 mSv (10 mrem) per hour at a distance of thirty (30) centimeters from any point on the external surface of the tube.

iii. Other electrical equipment that produces radiation incidental to its operation for other purposes, providing the dose rate to the whole body at the point of nearest approach to such equipment when any external shielding not integral to the equipment is removed does not exceed 0.25 mSv (25 mrem) per year. The production testing or factory servicing for such equipment shall not be exempt.

iv. Equipment described in this subsection shall not be exempt if it is used or handled in such a manner that any individual might receive a dose of radiation in excess of the limits specified in Part D of these regulations.

Sec. H.6 - General Regulatory Provisions. Unless otherwise provided in this Part, this Section applies to all RGDs. Certified and Certifiable Cabinet X-ray Systems as defined in this Part shall also meet the requirements of 21 CFR 1020.40.

a. Warning Devices.

i. Warning devices shall be labeled so that their purpose is easily identified.

ii. An easily visible warning device light labeled with the words "X-RAY ON," or words having a similar intent, shall be located near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized. This warning light shall be of a fail-safe design.

b. Labeling.

i. All RGD equipment shall be labeled with a readily visible and discernible sign or signs bearing the radiation symbol (defined in Part D.1901 of these regulations) and the words: "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube.

ii. For RGDs with designed openings, for object entries (such as baggage units), the following shall be posted at or near each opening: "CAUTION – X-RAY HAZARD: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED", or words having similar intent.

c. Radiation Source Housing. Each x-ray tube housing shall be subject to the following requirements:

i. 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 shall be equipped with an interlock that shuts off the high voltage to the x-ray tube if the housing is opened; and

ii. Radiation Emission Limit. Each x-ray tube housing shall be so constructed that, with all shutters closed, the leakage radiation measured at a distance of 5 centimeters from the x-ray tube housing surface does not exceed 0.025 mSv (2.5 mrem) per hour. This limit shall be met at the maximum tube rating. For closed-beam systems, this

requirement can be met by complying with Section H.7d. Radiation Emission Limit. For a RGD in a shielded room, this limit can be met by measuring from any accessible surface outside the room housing the RGD. For hand-held, open-beam RGDs, this requirement can be met by complying with the limits in H.9c. Radiation Emission Limit.

d. Generator Cabinet or High Voltage Source Radiation Emission Limits. Each x-ray generator or high-voltage source shall be supplied with a protective cabinet which limits leakage radiation to 2.5 μSv (0.25 mrem) per hour at a distance of 5 centimeters measured at the nearest accessible surface. For closed-beam systems, this requirement can be met by complying with Section H.7d. Radiation Emission Limit. For a RGD in a shielded room with the high-voltage generator also inside the shielded room, this limit can be met by measuring from any accessible surface outside the room housing the RGD. For hand-held, open-beam RGDs, this requirement can be met by complying with the limits in H.9c. Radiation Emission Limit.

e. Surveys.

i. Radiation surveys of all RGDs shall be sufficient to show compliance with radiation emission requirements of this Part, and as required by Part D.1201 (Occupational Dose Limits for Adults) and Part D.1301 (Dose Limits for Individual Members of the Public) of these regulations. The radiation surveys shall be sufficient to evaluate the magnitude and extent of radiation emissions and the potential radiological hazards that could be present. At a minimum, surveys shall be performed:

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

(2) Following any change in the initial arrangement, number, or type of local components in the system;

(3) Following any maintenance requiring the disassembly, removal, or repair of a local component in the system;

(4) During the performance of maintenance, calibration and other procedures if the procedures require the presence of a primary x-ray beam while any local component in the system is disassembled or removed;

(5) Post bypass of a safety device or interlock as required by H.6.h.ii;

(6) Any time a visual inspection of the local components in the system reveals an abnormal condition;

(7) Whenever a personnel monitoring device shows a significant increase over previous monitoring period or readings are approaching the limits specified in Part D.1201 (Occupational Dose Limits for Adults) of these regulations.

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

iii. The registrant shall assure the maintenance and calibration of all monitoring and survey instruments per Part D.1501 of these regulations.

iv. Radiation survey measurements shall not be required if a registrant can otherwise demonstrate compliance with the requirements of this Part to the satisfaction of the Agency.

f. Posting. Each area or room containing an RGD where an individual may receive 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) per year shall be conspicuously posted with a sign or signs bearing the radiation symbol (as defined in Part D.1901 of these regulations) and the words "CAUTION - X-RAY EQUIPMENT," "CAUTION – RADIATION GENERATING DEVICE" or words having a similar intent.

g. Security. RGDs shall be secured in such a way as to be accessible to, or operable by, only authorized personnel when not in operation.

h. Operating Requirements.

i. Procedures. Normal operating procedures shall be written and available to all RGD workers. No individual shall be permitted to operate a RGD in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

ii. Bypassing.

(1) No individual shall bypass a safety device, interlock, or remove shielding unless such individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time.

(2) When a safety device or interlock has been bypassed, a readily discernible 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 any bypass of a safety device or interlock shall be maintained; the record shall contain such information as the date the alteration was made, type of alteration, length of time the unit remained in the altered condition, post bypass survey and signed by the RSO, individual who made the alteration, and the individual who restored the unit to original condition.

iii. Control Panel.

(1) The RGD can only be activated from a control panel.

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

iv. Interlocks.

(1) An interlock shall not be used to de-activate the x-ray tube or RGD, except in an emergency or during testing of the interlock system.

(2) After triggering any interlock, it shall be possible to reset the RGD to full operation only from a control panel.

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

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

i. Repair or Modification of X-Ray Tube or RGD Systems. Only trained personnel or registered service provider shall be permitted to install, repair, or make modifications to the RGD. No operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without 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. It is the responsibility of the registrant to assure that qualified personnel install, repair, or make modifications to the RGD.

j. Testing of Safety Devices.

i. Tests of all safety devices, such as interlocks, shutters, warning lights, and required emergency shut-off switches shall be conducted at intervals not to exceed 6 months on all operable RGDs.

ii. If any safety device fails during testing, the RGD shall be removed from service until the safety device failure is corrected or proper temporary administrative controls established and approved in writing by the RSO.

iii. Records of safety device tests, check dates, findings and corrective actions shall be available for inspection and maintained for 5 years.

iv. Records shall include the date of the test, a list of the safety devices tested, survey instrument information, calibration date, the results of the test, the name of the person performing the tests and corrective actions taken for safety devices that fail the required test.

v. Testing of safety devices may be deferred if the unit and/or installation is clearly marked and kept out of service; units and/or installations brought back into service after exceeding the 6 month interval shall be tested prior to use.

vi. If testing of a safety device cannot be performed due to manufacturer design, the registrant shall document that the safety device will not be tested and specifically why the safety device cannot be tested.

k. Instruction and Training. The registrant shall document the scope of training required for the RGD they possess in accordance with this section. No individual shall be permitted to operate or maintain an RGD, or enter a shielded room without appropriate instruction and training. Records shall be maintained onsite of all required training and instruction, and made available for review by the Agency. Each such individual shall receive instruction in and demonstrated competence as to:

i. Types of radiation and identification of radiation hazards associated with the use of the RGD and associated equipment and precautions or measures to take to minimize radiation exposure;

ii. Significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

iii. Commensurate with potential hazards of use, biological effects of radiation, radiation risks, and recognition of symptoms of an acute localized exposure;

iv. Normal operating procedures for each type of RGD and associated equipment, including having received hands-on training, and procedures to prevent unauthorized use;

v. Procedures for reporting an actual or suspected accidental exposure or other radiation safety concerns, such as any unusual occurrence or malfunction that may involve exposure to radiation; and

vi. Performing surveys where applicable.

l. Radiation Protection Responsibility.

i. The registrant's senior management shall make the ultimate decision to use any RGD and be ultimately responsible for radiation safety.

ii. The registrant's senior management shall designate an individual responsible for radiation safety, or a RSO. This individual shall have direct access to senior management for radiation safety issues. This individual shall have training and experience commensurate with the scope of the radiation safety program to carry out the responsibilities as indicated below.

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

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

(3) Investigating any incident of abnormal operation or exposure or suspected overexposure of personnel to determine the cause, take remedial action, and 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) Maintain all radiation safety records.

Sec. H.7 - Additional Requirements for Closed-Beam RGDs. In addition to the requirements of Section H.6, the following applies to all closed-beam x-ray RGDs:

a. System Enclosure. The radiation source, sample or object, detector, and analyzing crystal (if used) shall be enclosed in a chamber or coupled chambers that cannot be entered by any part of the body during normal operation.

b. Interlocks. All doors and panels accessing the RGDs shall be interlocked. The interlocks required by this section shall be of a fail-safe design.

c. Interlock Functions. The system enclosure, sample chamber, etc. closure shall be interlocked with the x–ray tube high voltage supply and/or a shutter in the primary beam so that no x-ray beam can enter the sample or object chamber while it is open unless the interlock has been conspicuously and deliberately defeated. The interlock required by this section shall be of fail–safe design or adequate administrative controls shall be exercised to ensure operations will not continue without a proper functioning interlock.

d. Radiation Emission Limit. The radiation emission for all closed beam RGDs shall not exceed a dose rate of 0.005 mSv (0.5 mrem) in one hour at five centimeters outside any accessible surface.

e. Security Screening Units. Security screening units shall be provided with means to ensure operator presence at the control area in a position which permits surveillance of the openings and doors during generation of x-radiation.

i. During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.

ii. During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

Sec. H.8 - Additional Requirements for Open Beam RGDs. In addition to the requirements in Section H.6, the following requirements apply to all open beam RGDs not otherwise addressed in this Part.

a. Safety Device.

i. The registrant shall document their justification of the use of open-beam instead of closed-beam systems.

ii. If the registrant needs to use an open-beam system, the registrant shall consider a safety device which prevents the 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.

iii. If the registrant's use of the open-beam RGD does not permit the use of a safety device to prevent direct body exposure, the registrant shall maintain a written record of a description of the various safety devices that have been evaluated and reasons for why these devices cannot be used. These records shall be available onsite for inspection.

iv. In lieu of the safety device described in section H.8a.ii. above, the registrant shall employ alternative methods (such as policies and procedures) to minimize the possibility of unnecessary exposure. These alternative methods shall be documented. The documentation shall include information about the absence of safety devices. This documentation shall be available for inspection as long as these methods are employed, plus an additional 5 years.

v. For portable open-beam RGDs that are manufactured to be used hand-held, or potentially used as a hand-held, without such safety devices, this safety device requirement may be met by complying with all the requirements in H.9, Additional Requirements for Open-beam, Hand-held RGDs prior to use.

b. X-ray On Status. For open beam equipment, RGDs shall be provided with a readily discernible and active indication of:

i. X-ray tube "on-off" status located near the radiation source housing. The warning lights as required by H.6a.ii. can meet this requirement if the warning lights are readily discernible and viewable by anyone near the primary beam;

ii. Shutter "open-closed" status 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 shall be clearly labeled as to the meaning of the status device (i.e., whether the shutter is open or closed). The status light at the control panel can meet the requirement for the status light at the beam port if the status light at the control panel is readily discernible and viewable by anyone near the primary beam; and

iii. The x-ray tube "on-off" status indicator and the shutter "open-closed" status indicators shall be of a fail-safe design.

c. Labeling. Each unit will 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.

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

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

f. Radiation Emission Limits. The local components of an open-beam RGD shall be located and arranged and shall include sufficient shielding or access control such that no radiation emissions exist (exclusive of the primary beam) in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits as outlined in Part D. 1301 (Dose Limits for Individual Members of the Public) of these regulations. These emissions shall be met at any specified tube rating.

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

h. Operator Attendance. The operator shall be in immediate attendance 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.

i. Control of Access. If the RGD is not in a restricted area (as defined in Part A of these regulations), the operator shall be able to control access to the RGD at all times during operation. If the RGD is not in a restricted area (as defined in Part A) and the RGD is capable of creating a radiation area or a high radiation area (as defined Part A), the operator shall be able to control access to the RGD at all times during operation, and:

i. Radiation areas shall be conspicuously identified. The radiation source shall be within a conspicuous perimeter (e.g., rope, tape, or other barrier) that identifies the area in which the dose equivalent rate exceeds 0.05 mSv (5 mrem) per hour. The area described by the temporary barricade shall be suitably posted with "CAUTION - RADIATION AREA" signs. The operator shall ensure that no one is inside or enters the radiation area during operation of the RGD;

ii. High radiation areas shall be conspicuously identified. The radiation source shall be within a conspicuous perimeter (e.g., rope, tape, or other barrier) that identifies the area in which the dose equivalent rate exceeds 1 mSv (100 mrem) per hour. The area described by the temporary barricade shall be suitably posted with "CAUTION -

HIGH RADIATION AREA" signs. The operator shall ensure that no one is inside or enters the high radiation area during operation of the RGD;

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

iv. 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;

v. 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;

vi. A personal alarming dose rate meter may be worn to approach the work area if the device is appropriately designed and calibrated for the type of x-ray emitted (i.e., pulse or continuous), set at an appropriate level to detect the presence of the source, for example 0.02 mSv (2 mrem) 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 machine maintenance or work in a RGD target area;

vii. Measurement of radiation levels for a radiation survey shall be performed using an appropriate calibrated radiation survey meter (see H.6e.i. and H.6e.ii.). A radiation survey meter shall also be used when there is potential for non-uniform exposure to personnel, such as may occur during machine maintenance or work in a RGD target area;

viii. 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; and;

ix. 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.

j. Instruction and Training. In addition to the requirements in H.6k., no individual shall be permitted to operate or maintain an open-beam RGD unless such individual has received more specific and detailed instruction in and demonstrated competence as to:

i. Sources and magnitude of common radiation exposure;

ii. Units of radiation measurement;

iii. Radiation protection concepts of time, distance, shielding, and ALARA;

iv. Procedures and rights of a declared pregnancy;

v. Regulatory requirements and area postings;

vi. Worker, embryo/fetus, and public dose limits;

vii. Proper use of survey instruments and dosimetry; and

viii. The policies and procedures required by H.8a.

k. Personnel Monitoring. In addition to the requirements of Part D 1201 of these regulations (Occupational Dose Limits for Adults), extremity dosimetry shall be provided and used by:

i. Personnel working with or routinely working near and having potential for exposure to, the primary beam of an open-beam RGD; and

ii. Personnel maintaining RGDs if the maintenance procedures require the presence of a primary radiation beam when any local component in the RGD is disassembled or removed.

Sec H.9 - Additional Requirements for Open-beam, Hand-held RGDs. In addition to the requirements in Sections H.6 and H.8, the following requirements in this Section apply to open-beam, hand-held RGDs.

a. Procedures. All registrants possessing open-beam, hand-held RGDs shall have available for review to the Agency operating policies and procedures that contain measures to insure that:

i. Radiation protection is provided equivalent to that afforded in Part D. 1301 of these regulations (Dose Limits for Individual Members of the Public);

ii. Radiation protection is provided equivalent to that afforded in H.8g. (Primary Beam Attenuation);

iii. The operator will not hold the sample during operation of the RGD and that the operator's hands will not approach the primary beam;

iv. The operator will not aim the primary beam at him/herself or at any individual during operation of the RGD; and

v. Operator radiation exposure is as low as reasonably achievable (ALARA), for example, by use of ancillary equipment that will reduce exposure.

b. Training. In addition to the training requirements of H.6k. and H.8j. above, the registrant shall provide training for all users and operators on the subjects in section H.9a. Records shall be maintained of all user and operator training.

c. Radiation Emission Limit. For hand-held RGDs, the limits of H.6c.ii. (Radiation Source Housing Radiation Emission Limits) and H.6d. (Generator Cabinet or High Voltage Source Radiation Emission Limits), excluding the primary beam, shall be met if the radiation emission at any accessible surface of the RGD does not exceed 0.025 mSv (2.5 mrem) per hour at 5 cm.

d. Extremity Monitoring. For the purposes of the requirements in H.8k. (extremity monitoring), operators of hand-held RGDs shall be considered as working near the primary beam.

Sec. H.10 - Shielded Room RGDs. For RGDs that do not meet the limits of Part D. 1301 (Dose Limits to Individual Members of the Public), the RGD can be maintained inside a shielded room such that the exterior of the room meets the limits of Part D.1301 of these regulations (Dose Limits to Individual Members of the Public) when the RGD is activated. RGDs in a shielded room shall be required to meet only the requirements of H.6 (General Requirements) and the following:

a. Posting. The door to the room containing the RGD shall be posted "CAUTION – RADIATION AREA", or "CAUTION – HIGH RADIATION AREA", or "GRAVE DANGER – VERY HIGH RADIATION AREA", as required by Part D of these regulations.

b. Entrance Interlocks. All entrances into the shielded room shall be provided with interlocks. After an interlock has been interrupted, broken, or tripped, it shall be possible to cause x-rays to be produced again only from the control panel. Interlocks shall not be used to shut off the x-ray equipment except in an emergency or during testing.

c. Entrance Warning Devices. All entrances into the shielded room shall be provided with a conspicuously visible warning device, which need not be flashing or rotating but which operates only when radiation is being produced. The warning device shall be labeled in accordance with H.6a.

d. Room Warning Lights. The interior of the shielded room shall be provided with flashing or rotating warning lights that operate when, and only when, radiation is being produced. These lights shall be positioned so that they can be observed from any position or orientation within the room. The lights shall be posted indicating the meaning of the warning signal and instructions on what to do; the posting shall be legible, conspicuous, and accessible to view.

e. Audible Room Warning Device. An audible warning signal within the room shall be actuated for at least ten (10) seconds immediately prior to the first initiation of radiation after the closing of any opening that can admit personnel. The registrant shall post the meaning of the warning signal and instructions on what to do; the posting shall be legible, conspicuous, and accessible to view.

f. Emergency Shut-off. If dose rates exceed the High Radiation Area limits (as defined in Part A of these regulations), emergency shut-off switches shall be located within the high radiation areas so as to be accessible to individuals therein within 10 seconds. These switches and their mode of operation shall be identified by a conspicuously posted sign adjacent to the switch. The emergency shut-off switches shall include a manual reset that must be reset at the switch before x-rays can again be produced from the control panel. After

an emergency shut-off switch has been activated, it shall be possible to produce x-rays again only from the control panel.

g. Separate Electrical Systems. The interlock system and the emergency shut-off system shall be separate electrical and/or mechanical systems.

h. Egress from Shielded Room. A person within the room housing a RGD shall be able to egress at all times.

i. Entry into the Shielded Room.

i. After each exposure and before entry of any personnel, a survey shall be performed upon entry to the shielded room to determine that the RGD is no longer producing radiation.

ii. Personnel devices providing an audible signal when activated by radiation will be acceptable for the survey requirement of H.10i.i.

(1) Proper operation of the audible detection device shall be checked daily and a record maintained of this check.

(2) The audible device shall be designed so as to clearly indicate entry into a 0.02 mSv (2 mrem) per hour or greater radiation field.

(3) All personnel working with the RGD shall be provided with such a device.

iii. Stationary area monitors providing an audible signal when activated by radiation will be acceptable for the survey requirement of H.10i.i.

(1) Proper operation of the stationary detection device shall be checked daily and a record maintained of this check.

(2) The stationary device shall be designed so as to clearly indicate entry into a 0.02 mSv (2 mrem) per hour or greater radiation field.

(3) Stationary area monitors shall be calibrated annually to determine that the audible signal operates at a 0.02 mSv (2 mrem) per hour radiation field.

j. Personnel Monitoring. All personnel associated with the x-ray equipment shall be provided with personnel monitoring devices that shall be calibrated for the x-ray energies being utilized. Records of personnel exposure shall be maintained.

k. Training. No registrant shall permit any individual to operate a RGD in a shielded room until such individual has received a copy of, instruction in, and demonstrated an understanding of, operating and emergency procedures for the unit and competence in its use. Records shall be maintained of all operator training.

l. Control Panel Security. The equipment control panel shall be provided with a locking device to prevent unauthorized use. Such locking device shall, when locked, prevent the production of radiation by the equipment.

m. Malfunctions. If a safety or warning device malfunctions, the control panel shall be locked in the "off" position. The control panel shall not be used, except as may be necessary for repair or replacement of the malfunctioning safety or warning device, until the safety or warning device is functioning properly.

Sec H.11 - Bomb Detection RGDs. In addition to the General Requirements in H.6 (not otherwise exempted under H.5a.), the following requirements in this section apply to bomb detection radiation equipment.

a. Control Panel Security. When not in use, each bomb detection radiation machine shall be locked to prevent unauthorized use. This is in addition to the requirements of H.6g. (Security).

b. Utilization Log. The registrant shall maintain for each bomb detection radiation machine a utilization log. This log shall 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(s) of use.

c. Area Control. The registrant shall provide security to prevent entry by individuals from any point when the machine is energized during training.

Sec H.12 - RGDs Used in Personnel Security Screening or Vehicle Screening for Public Protection. In addition to the General Requirements in H.6., the following requirements in this section apply. A person requesting Agency approval for a RGD to be used in Personnel Security Screening or Vehicle Screening with intended exposure of human occupants to the primary beam for public protection shall submit in writing the following information to the Agency for evaluation and approval, and show how the dose limits noted below will be met.

a. Efficacy Evaluation. An evaluation of all known alternate methods that could achieve the goals of the security screening program, and why these methods will not be used in preference to the proposed approach utilizing ionizing radiation.

b. Equipment Evaluation. RGDs used for non-healing arts personnel security screening of humans shall be evaluated every 12 months by a qualified expert for optimization of image quality and radiation dose.

c. Dose Limits for General-Use Systems. For general-use screening systems, where system is used without regard to the number of individuals scanned or number of scans per individual in a year, an effective dose for a single complete screening shall be limited to 0.25 μSv (25 μrem).

d. Dose Limits for Limited-Use Systems. For limited-use screening systems, where equipment is capable of operation greater than 0.25 μSv (25 μrem) per screening, and is used with discretion, the effective dose per screening shall be less than or equal to 0.01 mSv (1 mrem).

e. Dose Limits for Repeat Security Screenings. Individuals subject to repeat security screening at a single venue shall not receive an effective does greater than 0.25 mSv (25 mrem) in any one year at the registrant or licensee's facility.

f. Vehicle Limitations.

i. When the procedures for operation of a mobile or fixed RGD used for security screening of vehicles includes knowingly exposing human occupants to the primary beam when screening vehicles, structures or containers, the system shall be subject to the same requirements as general-use or limited-use systems as provided in H.12a. through H.12e.

ii. If the requirements in H.12c. through H.12e. cannot be met if vehicle occupants are knowingly exposed to the primary beam of a security screening system, then there shall be means to assure 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.

iii. The effective dose to an individual for a single inadvertent exposure to the primary beam shall not exceed 5 mSv (500 mrem) and should not exceed 1 mSv (100 mrem). The reliability of the procedure used to assure that there are no occupants of a vehicle to be scanned shall be commensurate with the potential severity of an inadvertent exposure. If the 5 mSv (500 mrem) limit cannot be assured, a pre-screening with a mode or system which can meet the limits in H.12c. through H.12f. shall be used to verify there are no occupants in the vehicle being examined.

Sec. H.13 - Application for Exemptions. Any RGD user or manufacturer that cannot meet the applicable requirements of the above sections in this Part shall submit to the Agency a request for an exemption to the specific regulation in question. The exemption request shall demonstrate to the Agency's satisfaction:

a. That the use of the RGD will not result in undue hazard to public health and safety or property;

b. That compliance would require replacement or substantial modification of the RGD;

c. That the registrant will achieve, through other means, radiation protection equivalent to that required by the regulation; and

d. Why the regulatory standard or requirement could not be met.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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

By: Amy M. Elliott (Deputy Attorney General)

7/6/2021
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 May 19, 2021

BY

TITLE PATRICK MCDONNELL
CHAIRPERSON

EXECUTIVE OFFICER CHAIRPERSON OR SECRETARY

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

BY Marisa H. Z. Lehr

June 7, 2021
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 PROPOSED 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

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

Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices

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

This proposed rulemaking was adopted by the Board at its meeting on May 19, 2021.

A. *Effective Date*

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

B. *Contact Persons*

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

C. *Statutory Authority*

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

D. *Background and Purpose*

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

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

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

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

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

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

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

E. *Summary of Regulatory Requirements*

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

§ 225.71. Definitions

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

§ 225.72. Duties of personnel

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

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

§ 225.74. Training and testing

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

§ 225.76. Reporting requirements

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

§ 225.81. Permanent radiographic installations

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

§ 225.82. Operating requirements

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

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

§ 225.84. Operating and emergency procedures

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

§ 225.85. Surveys and survey records

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

§ 225.86. Utilization logs

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

§ 225.92. Radiation survey meter calibration requirements

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

§ 225.93. Personnel monitoring control

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

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

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

§ 225.101a. Radiographic X-ray systems

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

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

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

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

§ 225.102. Shielded room X-ray radiography

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

§ 225.103. Field site radiography.

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

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

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

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

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

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

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

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

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

Subchapter A. GENERAL PROVISIONS

§ 227a.1. Purpose and scope

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

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

§ 227a.2. Definitions

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

§ 227a.3. Exemptions

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

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

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

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

§ 227a.4. Application for exemptions

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

Subchapter B. GENERAL TECHNICAL REQUIREMENTS

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

§ 227a.10. Radiation safety program

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

§ 227a.11. Warning devices

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

§ 227a.12. Labeling

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

§ 227a.13. Radiation source housing

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

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

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

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

§ 227a.15. Surveys

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

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

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

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

§ 227a.16. Posting

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

§ 227a.17. Security

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

§ 227a.18. Operating requirements

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

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

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

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

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

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

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

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

§ 227a.20. Testing of safety devices

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

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

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

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

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

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

§ 227a.21. Instruction and training

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

§ 227a.22. Radiation protection responsibility

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

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

Subchapter C. CLOSED-BEAM RADIATION-PRODUCING DEVICES

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

§ 227a.30. System enclosure

Proposed § 227a.30 provides that a radiation source, sample or object, detector and analyzing crystal of a closed-beam radiation-producing device must be enclosed in a chamber or coupled chambers that cannot be entered by any part of the human body during normal operation in order to protect the user from unnecessary radiation exposure.

§ 227a.31. Interlocks

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

§ 227a.32. Interlock functions

Proposed § 227a.32 provides that a closed-beam radiation-producing device enclosure, sample chamber or similar enclosure must be interlocked with the X-ray tube high voltage supply or a shutter in the primary beam, or both, so that no X-ray beam can enter the sample or object chamber while it is open unless the interlock has been deliberately defeated. An interlock would be deliberately defeated if a bypass was performed as described in § 227a.18. It also provides that the interlock must be of a fail-safe design or have adequate administrative controls to ensure operations can only continue with a proper functioning interlock.

§ 227a.33. Radiation emission limit

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

§ 227a.34. Security screening devices

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

§ 227a.35. Electron microscope devices

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

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

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

Subchapter D. OPEN-BEAM RADIATION-PRODUCING DEVICES

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

§ 227a.40. Safety devices

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

Proposed subsection (b) provides that if a registrant uses an open-beam radiation-producing device, the registrant must consider the use of a safety device to minimize the chance of entry of any portion of the operator's body into the path of the primary beam or which causes the primary beam to shut off upon entry into its path.

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

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

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

§ 227a.41. X-ray on status

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

§ 227a.42. Labeling

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

§ 227a.43. Beam ports

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

§ 227a.44. Shutters

Proposed § 227a.44 provides that for open-beam radiation-producing device configurations that are designed to accommodate interchangeable components, each beam port on the radiation source housing must be equipped with a shutter that cannot be opened unless a collimator or a component coupling has been connected to the beam port. This has been incorporated from SSR Part H and prevents unnecessary radiation being emitted from a port that is not being used.

§ 227a.45. Radiation emission limits

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

§ 227a.46. Primary beam attenuation

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

§ 227a.47. Operator attendance

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

§ 227a.48. Control of access

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

§ 227a.49. Instruction and training

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

§ 227a.50. Handheld radiation-producing devices

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 227a.54. Permanent radiographic installations

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

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

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

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

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

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

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

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

CHAPTER 228. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

§ 228.2. Definitions

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

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

F. *Benefits, Costs and Compliance*

Benefits

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

Compliance costs

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

Compliance assistance plan

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

Paperwork requirements

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

G. *Pollution Prevention*

Pollution prevention is not applicable to this proposed rulemaking.

H. *Sunset Review*

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

I. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on July 14, 2021, the Department submitted a copy of this proposed rulemaking and a copy of the Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Environmental Resources and Energy Committees. A copy of this material is available to the public upon request.

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

J. *Public Comments*

Interested persons are invited to submit written comments, suggestions, support or objections regarding the proposed rulemaking to the Board. Comments, suggestions or objections must be received by the Board by September 13, 2021.

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

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

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

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

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

K. *Public Hearings*

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

PATRICK McDONNELL,
Chairperson

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]** **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]** **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]** **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 non-destructive 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]** **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 **200 milliroentgen** (51.6 μC/kg) **[(200 milliroentgen)]** 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 **2 mR** **(**0.516 μC/kg**)** **[(2 mR)]** 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)]** and **1000 mR** (258 μC/kg) **[(1000 mR)]** 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)]** 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.

(e) 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.]

§ 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 (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 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.

(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 (i.e., 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 appropriate 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]** 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 μC/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] <u>(Reserved).</u>

[(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.]

§ 227.14a. [Personnel requirements] <u>(Reserved).</u>

[(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 (relating to general provisions; registration of radiation-producing machines and radiation producing machine service providers; standards for protection against radiation; and notices, instructions and reports to workers; inspections and investigations). This chapter does not pertain to radiation safety requirements for X-ray equipment covered under Chapters 221, 225, and 228 (relating to X-rays in the healing arts; radiation safety requirements for industrial radiographic operations; and radiation safety requirements for particle accelerators).

(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 (relating to radiation safety requirements for industrial field radiographic operations).

§ 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 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 U.S. 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. This procedure must include the names and telephone numbers of individuals to be contacted as well as directives for processing the film badge or other personnel monitoring devices.

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

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

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

kV—Kilovolt.

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

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

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

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 tube—The term has the meaning given to it under § 221.2.

§ 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 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 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 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 such 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 labelling; and instruction and training).

§ 227a.4. Application for exemptions.

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.22. Radiation protection responsibility.

§ 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) Warning devices must be labeled so that their purpose is easily identified.

(b) 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) 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) 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) 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 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).

(b) 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) The registrant shall assure the maintenance and calibration of all monitoring and survey instruments under 10 CFR 20.1501 (relating to general).

(d) 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 one 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. The record must contain 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 of all 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) 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) Records of safety device tests, check dates, findings and corrective actions shall be available for inspection and maintained for 5 years.

(d) 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) 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) 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 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) 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) 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 responsibilities described below:

(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 all radiation safety records, including annual audits of the radiation protection program and documentation of its findings, 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.

All 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 one 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.

(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) 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) 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) 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.46. Primary beam attenuation.
227a.47. Operator attendance.
227a.48. Control of access.
227a.49. Instruction and training.
227a.50. Handheld radiation-producing devices.
227a.51. Bomb detection radiation-producing devices.
227a.52. Radiation-producing devices used in individual security screening.
227a.53. Radiation-producing devices used in vehicle security screening.
227a.54. Permanent radiographic installations.
227a.55. Shielded room radiation-producing devices.

§ 227a.40. Safety device.

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

(b) 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) 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 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) 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) 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 of 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 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 also apply:

(1) Radiation areas must be conspicuously identified.

(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 (1)(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.

(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 (1)(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 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; and 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.* A bomb detection radiation-producing device shall be locked to prevent unauthorized use when not in use. This is in addition to § 227a.17 (relating to security).

(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.

(3) *Area control.* The registrant shall provide security to prevent entry by individuals from any point when the device is energized during training.

§ 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.

(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 X-rays in the healing arts; and 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 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) 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) 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 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) 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 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.

§ 227a.54. Permanent radiographic installations.

(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) 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 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 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) 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) 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) 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:]** **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).**

[(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.]

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

* * * * *

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

July 14, 2021

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

Re: Proposed Rulemaking: Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices (#7-555)

Dear Mr. Sumner:

Pursuant to Section 5(a) of the Regulatory Review Act, please find enclosed a copy of the Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices (#7-555) proposed rulemaking for review by the Independent Regulatory Review Commission (Commission). This proposal is scheduled for publication in the *Pennsylvania Bulletin* on August 14, 2021, with a 30-day public comment period. The Environmental Quality Board adopted this proposal on May 19, 2021.

This proposed rulemaking will update the radiological health regulations related to non-medical X-ray equipment, which have not been amended since 2009. The proposed amendments address non-medical X-ray operations and emerging technologies in the industrial field to ensure that exposure to radiation from non-medical radiation-producing devices is as low as reasonably possible.

As set forth in the Regulatory Review Act, the Department will consider any comments and recommendations made by the Commission, as well as the House and Senate Environmental Resources and Energy Committees and the public, prior to final adoption of the enclosed rulemaking.

Please contact me by e-mail at laurgriffi@pa.gov or by telephone at 717.783.8727 if you have any questions or need additional information.

Sincerely,

Laura Griffin
Regulatory Coordinator

Enclosures

0120-FM-PO0011 6/2015

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
POLICY OFFICE

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 7-555

SUBJECT: Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices

AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION, Environmental Quality Board

TYPE OF REGULATION

- [x] Proposed Regulation
- [ ] 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

RECEIVED
JUL 14 2021
Independent Regulatory Review Commission

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
7/14/21	Pam Newyard	Majority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Representative Daryl Metcalfe
7/14/21		Minority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Representative Greg Vitali
7/14/21	electronic submittal	Majority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator Gene Yaw
7/14/21	electronic submittal	Minority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator Carolyn Comitta
		INDEPENDENT REGULATORY REVIEW COMMISSION David Sumner
		ATTORNEY GENERAL (for Final Omitted only)
7/14/21	electronic submittal	LEGISLATIVE REFERENCE BUREAU (for Proposed only) Leah Brown

Stephen Hoffman

From: Troutman, Nick <ntroutman@pasen.gov>
Sent: Wednesday, July 14, 2021 10:55 AM
To: Griffin, Laura
Cc: Shirley, Jessica; Reiley, Robert A.; Kauffman, Gregory
Subject: RE: Delivery of Proposed Rulemaking - Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices (7-555)

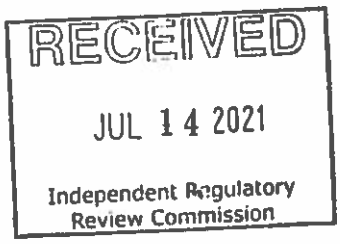
Received. Thanks Laura

From: Griffin, Laura <laurgriffi@pa.gov>
Sent: Wednesday, July 14, 2021 10:15 AM
To: Troutman, Nick <ntroutman@pasen.gov>
Cc: Shirley, Jessica <jesshirley@pa.gov>; Reiley, Robert A. <rreiley@pa.gov>; Kauffman, Gregory <grekauffma@pa.gov>
Subject: Delivery of Proposed Rulemaking - Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices (7-555)
Importance: High

Good morning,

Pursuant to Section 5(a) of the Regulatory Review Act, please find attached the Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices (#7-555) proposed rulemaking for review by the Senate Environmental Resources and Energy Committee. 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
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

Stephen Hoffman

From: Eyster, Emily <Emily.Eyster@pasenate.com>
Sent: Wednesday, July 14, 2021 10:20 AM
To: Griffin, Laura; Fuller, Lisa
Cc: Shirley, Jessica; Reiley, Robert A.; Kauffman, Gregory; Hartman, Michael
Subject: Re: Delivery of Proposed Rulemaking - Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices (7-555)

Received. Thank you!

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

From: Griffin, Laura <laurgriffi@pa.gov>
Sent: Wednesday, July 14, 2021 10:14 AM
To: Eyster, Emily <Emily.Eyster@pasenate.com>; Fuller, Lisa <Lisa.Fuller@pasenate.com>
Cc: Shirley, Jessica <jesshirley@pa.gov>; Reiley, Robert A. <rreiley@pa.gov>; Kauffman, Gregory <grekauffma@pa.gov>; Hartman, Michael <Michael.Hartman@pasenate.com>
Subject: Delivery of Proposed Rulemaking - Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices (7-555)

■ EXTERNAL EMAIL ■

Good morning,

Pursuant to Section 5(a) of the Regulatory Review Act, please find attached the Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices (#7-555) proposed rulemaking for review by the Senate Environmental Resources and Energy Committee. 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
Phone: 717.772.3277| Fax: 717.783.8926
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www.dep.pa.gov

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Stephen Hoffman

From: Leah Brown <lbrown@palrb.us>
Sent: Wednesday, July 14, 2021 3:11 PM
To: Griffin, Laura
Subject: [External] RE: Delivery of Proposed Rulemaking - Radiation Safety Reqs. Non-Healing Arts Radiation Generating Devices (7-555)

ATTENTION: This email message is from an external sender. Do not open links or attachments from unknown sources. To report suspicious email, forward the message as an attachment to CWOPA_SPAM@pa.gov.

Hello Laura!
Thank you for submitting proposed #7-555 for publication in the Bulletin. The Code and Bulletin office has received your documents and will publish this according to the previously stated date.
Please let me know if you need anything further!
Have a great week!
Leah

From: Griffin, Laura <laurgriffi@pa.gov>
Sent: Wednesday, July 14, 2021 11:50 AM
To: Code&Bulletin <codeandbulletin@palrb.us>; Bulletin <bulletin@palrb.us>
Cc: Leah Brown <lbrown@palrb.us>; Adeline E. Gaydosh <agaydosh@palrb.us>
Subject: Delivery of Proposed Rulemaking - Radiation Safety Reqs. Non-Healing Arts Radiation Generating Devices (7-555)
Importance: High

Good morning,

Please see the attached documents, including Word versions of the Preamble and Annex A, for Proposed Rulemaking – Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices (7-555), for publication on August 14, 2021.

The transmittal sheet confirming receipt of the rulemaking by the House ERE Committee and email confirmation of receipt by both the Senate ERE Committee chairs is attached.

Please confirm that you received the rulemaking documents for publication.

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
Phone: 717.772.3277| Fax: 717.783.8926
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