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PROPOSED RULEMAKING

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.**

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Industrial radiography—[An examination of the structure of materials by nondestructive methods, including fluoroscopy, which utilizes radiation producing machines to make radiographic images.] A method of non-destructive testing where many types of manufactured components are examined to verify the internal structure and integrity of the specimen.

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 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 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 during use of the machine, 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 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.]

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§ 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:

(1) The inability to terminate irradiation from a radiation producing machine.

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

(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, 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.

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(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 $\mu\text{C}/\text{kg}$) [(**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.

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§ 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.

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**RADIATION SURVEY INSTRUMENT AND PERSONNEL MONITORING
REQUIREMENTS**

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§ 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 $\mu\text{C}/\text{kg}$) [(**2 mR**)] per hour through **1 R** (258 $\mu\text{C}/\text{kg}$) [(**1 R**)] per hour can be measured.

(b) Each radiation instrument shall be calibrated:

(1) At energies appropriate for use.

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- (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 $\mu\text{C}/\text{kg}$) [(**2 mR**)] and **1000 mR** (258 $\mu\text{C}/\text{kg}$) [(**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 $\mu\text{C}/\text{kg}$) [(**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.

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(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 REQUIREMENTS

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

[(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.]

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.

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(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.

[(d)] **(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 [3] **5** years:

(i) Upon [installation] **acceptance** of the equipment.

(ii) Following [a change in the initial arrangement, relocation of the unit, or following any] maintenance requiring the disassembly or removal of any shielding component.

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

[(e)] **(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 [3] **5** years.

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

§ 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

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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.

(b) 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.

(c) 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.

(d) 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 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 machine maintenance or work in a radiation-producing device target area.

(e) 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 machine maintenance or work in a radiation-producing device target area.

(f) 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.

(g)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)](h) Mobile or portable radiation producing machines 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 $\mu\text{c}/\text{kg}$ (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).

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(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 $\mu\text{C}/\text{kg}$ (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.

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(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.]

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

[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).

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[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.

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- (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:

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- (1) The unit shall be designed so that when the unit is operating at the maximum kilovoltage and current ratings, the leakage radiation will not be in excess of 0.5 milliroentgens (.129 $\mu\text{C}/\text{kg}$) per hour at a distance of 4 centimeters from any external surface.
- (2) Radiation surveys using appropriate radiation survey equipment shall be performed on the analytical X-ray unit upon installation, after moving the unit to a new location, and after maintenance or repair requiring the disassembly or removal of a local component or radiation shielding.
- (3) Safety and warning devices shall be tested for proper operation at least annually. If the test reveals that a safety or warning device is not working properly, the unit may not be operated until the warning device is repaired or replaced.
- (4) Records of all tests and surveys sufficient to show compliance with subsection (h) shall be maintained and kept available for inspection by the Department for 4 years.
- (5) A sign bearing the radiation symbol and the words “CAUTION RADIATION—THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED,” or words of similar intent shall be placed next to any switch or device that activates the X-ray tube.
- (6) A sign bearing the radiation symbol and the words “CAUTION—RADIATION,” or words of similar intent shall be placed next to the opening of the sample chamber.
- (i) Analytical X-ray equipment operating at less than or equal to 50 kV tube voltage and designed to be held by an operator during use are exempt from the requirements of this section and § 227.12a(b), but shall meet the requirements of subsection (f)(2) and §§ 227.13a(a) and 227.14(a).]

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

- [(a) The source housing construction shall be of a type that when all the shutters are closed and the source is in any possible operating mode, the leakage radiation will not be in excess of 2.5 milliroentgens (.645 $\mu\text{C}/\text{kg}$) per hour at a distance of 5 centimeters from the housing surface.
- (b) The X-ray generator shall have a protective cabinet constructed so that the leakage radiation will not be in excess of 0.5 milliroentgen (.129 $\mu\text{C}/\text{kg}$) per hour at a distance of 5 centimeters from the housing surface.
- (c) The local components of an analytical X-ray system shall be located and arranged and shall include sufficient shielding or access control so that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the limits given in 10 CFR 20.1301 (relating to dose limits for individual members of the public). For systems utilizing X-ray tubes, these requirements shall be met at any specified tube rating.

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(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.

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

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

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

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

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

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

§ 227.14. [Personnel requirements] (Reserved).

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

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

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

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

(4) Symptoms of an acute localized radiation exposure.

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

(6) Use of survey and personnel monitoring equipment.

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

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(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]

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§ 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 (RPD)**

Subch.

- A. GENERAL PROVISION...227a.1**
- B. GENERAL TECHNICAL REQUIREMENTS...227a.10**
- C. CLOSED-BEAM RADIATION-PRODUCING DEVICES...227a.30**
- D. OPEN-BEAM RADIATION-PRODUCING DEVICES...227a.40**

Subchapter A. GENERAL PROVISIONS

Sec.

- 227a.1. Purpose and scope.
- 227a.2. Definitions.
- 227a.3. Exemptions.
- 227a.4. Application for Exemptions.

§ 227a.1. Purpose and scope.

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

(b) In addition to this chapter, all registrants are subject to Chapters 215, 216, 219 and 220. This chapter does not pertain to radiation safety requirements for X-ray equipment covered under Chapters 221, 225, and 228 (relating to X-ray 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” as defined under § 227a.2 (relating to definitions) is regulated under this chapter.

(e) Radiography equipment that meets the definition of “bomb detection radiation equipment” under section 227a.2 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 unit.

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

Cabinet radiography—Industrial radiography using radiation machines 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 machine 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

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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 X-ray equipment—A system 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 X-ray system—A portable instrument designed to operate when held in the hand, such as a hand-held XRF analytical device.

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Individual security screening system—X-ray equipment used on humans for security evaluation.

Industrial Radiography—An examination of the structure of materials by nondestructive methods using 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

μrem —Microrem.

μSv —Micro Sievert.

mrem—Millirem.

mSv—Milli Sievert.

Mobile equipment—Radiation-producing device equipment 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, table top and handheld X-ray devices and electron beam welders.

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

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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 machine where the apparatus, device, electronic product, system, subsystem or component 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 equipment, portable equipment, stationary equipment or transportable equipment.

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.

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 unit—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.

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

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.

§ 227a.3. Exemptions.

- (a) A radiation-producing device meeting the definition of “bomb detection radiation equipment” under § 227a.2 is exempt from § 227a.16 (related to posting).
- (b) Unless used in a dedicated location, a handheld radiation-producing device is exempt from § 227a.16.
- (c) The following machines 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 a distance of 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 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 or manufacturer that cannot meet the applicable requirements of sections 227a.1—227a.3 (relating to purpose and scope; definitions; and exemptions) shall submit to the Department a written request for an exemption to the provision it cannot meet. The exemption request must explain why the provision cannot be met and must demonstrate all of the following to the Department’s satisfaction:

- (1) That the use of the radiation-producing device will not result in undue hazard to public health and safety or to property.
- (2) That compliance with the provision from which the registrant is seeking exemption would require replacement or substantial modification of the radiation-producing device.
- (3) That the registrant will achieve, through other means, radiation protection equivalent to that required by the provision from which the registrant is seeking exemption.

Subchapter B. GENERAL TECHNICAL REQUIREMENTS

Sec.

- 227a.10. Radiation safety program.
- 227a.11. Warning devices.
- 227a.12. Labeling.
- 227a.13. Radiation source housing.
- 227a.14. Generating cabinet or high voltage source radiation emission limits.
- 227a.15. Surveys.
- 227a.16. Posting.
- 227a.17. Security.
- 227a.18. Operating requirements.
- 227a.19. Repair or modification of X-ray tube or radiation-producing device.
- 227a.20. Testing of safety devices.
- 227a.21. Instruction and training.
- 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 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 radiographic operations 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.

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(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) Radiation-producing device equipment 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 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 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 μ Sv) per hour at a distance of 5 centimeters measured at the nearest accessible surface. For closed-beam systems, 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.51(c) (relating to radiation emission limit).

§ 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

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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 inspection by the Department for 5 years. At a minimum, surveys must be performed in all of 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 X-ray 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 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 survey measurements 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 as defined in § 219.159 (relating to posting of radiation-producing machines) or words having a similar intent.

§ 227a.17. Security.

Radiation-producing devices must be secured to be accessible to, or operable by, only authorized personnel when not in operation.

§ 227a.18. Operating requirements.

(a) *Procedures.* Normal operating procedures must 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 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 must be limited to 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, must be placed on the radiation source housing and at the control switch.

(3) A record of a bypass of a safety device or interlock must be maintained. The record must contain the following information:

- (i) The date the alteration was made.
- (ii) The type of alteration.
- (iii) The length of time the unit remained in the altered condition.
- (iv) The post bypass survey.
- (v) Other similar and useful information.

(4) A record of a bypass must be signed by the radiation safety officer, the individual who made the alteration and the individual who restored the unit to 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.

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(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, must be used for routine shutdown in preparation for repairs. The registrant shall assure 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, must 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 must 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 must 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) must be tested prior to use.

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(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 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 must receive instruction in, and shall demonstrate competence as to, all of 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) 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 senior management shall make the ultimate decision to use a radiation-producing device. The registrant's senior management shall be ultimately responsible for radiation safety.
- (b) The registrant's senior management shall designate an individual responsible for radiation safety or 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:

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- (1) Ensuring that all radiation-producing devices are operated within the limitations of the established radiation safety program and 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.
- 227a.31. Interlocks.
- 227a.32. Interlock functions.
- 227a.33. Radiation emission limit.
- 227a.34. Security screening devices.
- 227a.35. Electron microscope devices.

§ 227a.30. System enclosure.

The radiation source, sample or object, detector and analyzing crystal (if used) 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 radiation-producing devices must be interlocked. The interlocks required by this section must be of a fail-safe design.

§ 227a.32. Interlock functions.

The system 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 all closed-beam radiation-producing devices 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.

Security screening devices must be provided with a means to ensure operator presence at the control area in a position that permits surveillance of the openings and doors of the control area during generation of radiation.

(1) During an exposure or preset succession of exposures of one-half second or greater duration, the device must be provided with a means 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 one-half second duration, the devices must be provided with a means to allow completion of the exposure in progress but must enable the operator to prevent additional exposures.

§ 227a.35. Electron microscope devices.

(a) An electron microscope device must be labeled with a readily discernable 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 an 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 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.

Subchapter D. OPEN-BEAM RADIATION-PRODUCING DEVICES

Sec.

- 227a.40. Safety device.
- 227a.41. X-ray on status.
- 227a.42. Labeling.
- 227a.43. Beam ports.
- 227a.44. Shutters.
- 227a.45. Radiation emission limits.
- 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 devices.

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

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

227a.54. Shielded room configuration.

§ 227a.40. Safety device.

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

(b) If the registrant needs to use an open-beam system, 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 must 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 alternative methods must be documented. The documentation must include information about the absence of safety devices. This documentation must 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) may be met by complying with § 227a.51 (relating to handheld radiation-producing devices) prior to use.

§ 227a.41. X-ray on status.

For open-beam equipment, radiation-producing devices must be provided with a readily discernible and active indication of the following, as applicable:

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

(2) 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 must be clearly labeled as to the meaning of the status device (in other words, 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.

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(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 must 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 (exclusive of the primary beam) must be met at any specified tube rating. 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 20.1201 (relating to occupational dose limits for adults), or
- (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 X-ray beam is not intercepted by the detector device 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 X-ray 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 under Chapter 219 (relating to standards for protection against radiation), the operator shall be able to 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 under Chapter 219, the operator shall be able to control access to the radiation-producing device at all times during operation. All of 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 by the temporary barricade 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 by the temporary barricade 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 § 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:

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- (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 Subchapters B and D (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 himself or at any individual 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 must be maintained of all user and operator training and be made available for review by the Department for 5 years.

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(3) *Radiation emission limit.* For hand-held radiation-producing devices, the limits of §§ 227a.13(b) and 227a.14 (relating to radiation source housing; 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 Subchapter B (relating to general technical requirements), except § 227a.16 (relating to posting), the following requirements apply to bomb detection radiation devices:

(1) *Control panel security.* A bomb detection radiation device must 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 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, and the dates of use and the site(s) of use.

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

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

In addition to Subchapter B (relating to general technical requirements), the following requirements apply to radiation-producing devices used in individual security screening. Any 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 in writing the following information to the Department for evaluation and approval. The applicant shall show how the dose limits noted below will be met. Department approval must be given prior to use.

(1) *Efficacy evaluation.* An evaluation of all known alternate methods that could achieve the goals of the 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 security screening of humans must be evaluated by a qualified expert at the following times for optimization of image quality and radiation dose:

(i) Upon installation of the device.

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

(iii) Upon unintended damage to the system.

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(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 security screening at a single venue may not receive an effective dose greater than 25 μrem (0.25 μSv) in a 12-month period at the registrant 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 all of the following:

(i) The RSO 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, the operators must receive at least 2 hours of radiation safety training.

(iii) All operators and the RSO must receive annual radiation safety refresher training. Training must include the topics under Chapter 221 Appendix A (relating to (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 age 18 and an individual known or declared pregnant is prohibited.

(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 program must be developed, documented, and implemented. The radiation protection program must be reviewed by the RSO 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 fixed 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 shall be 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 the requirements in § 227a.52(3)—(5) 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.

(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) must be used to verify that the vehicle being examined is unoccupied if the 500 mrem (5 mSv) limit cannot be assured.

§ 227a.54. 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 10 CFR 20.1601 (relating to control of access to high radiation areas).

(b) The operator must 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

§ 228.1. Purpose and scope.

This chapter establishes radiation safety requirements for persons utilizing particle accelerators for industrial, research or medical purposes. Persons who use particle accelerators shall comply with this chapter. The requirements in this chapter are in addition to and not in substitution for other applicable requirements of this article.

§ 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.

Beam-limiting device—A device providing a means to restrict the dimensions of the X-ray field.

Beam scattering filter—A filter used to scatter a beam of electrons.

Central axis of the beam—A line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.

Dose monitoring system—A system of devices for the detection, measurement and display of quantities of radiation.

Dose monitor unit—A unit response from the dose monitoring system from which the absorbed

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dose can be calculated.

Existing equipment—Systems manufactured on or before October 3, 1998.

Field flattening filter—A filter used to provide dose uniformity over the area of a useful beam of X-rays at a specified depth.

Field size—The configuration of the radiation field along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance and defined by the intersection of the major axes and the 50% isodose line.

Filter—Material placed in the useful beam to modify the spectral energy distribution and flux of the transmitted radiation and remove radiation that does not contribute to the efficacy of the useful beam.

Isocenter—A fixed point in space located at the center of the smallest sphere through which the central axes of the beams pass.

Leakage radiation—Radiation emanating from the source assembly except for the following:

- (i) The useful beam.
- (ii) Radiation produced when the exposure switch or timer is not activated.

Moving beam therapy—Radiation therapy with relative displacement of the useful beam and the patient during irradiation.

New equipment—Systems manufactured after January 1, 1985.

Normal treatment distance—

- (i) For isocentric equipment, the isocenter.
- (ii) For nonisocentric equipment, the target to patient skin distance along the central axis as specified by the manufacturer.

Particle accelerator—See the definition of “accelerator.”

Phantom—A volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Primary dose monitoring system—A system which will monitor the useful beam during irradiation and which will terminate irradiation when a preselected number of dose monitor units have been attained.

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Radiation detector—A device which provides a signal or other indication suitable for measuring one or more quantities of incident radiation.

Radiation head—The structure from which the useful beam emerges.

Secondary dose monitoring system—A system which will terminate irradiation in the event of failure of the primary dose monitoring system.

Shadow tray—A device attached to the radiation head to support auxiliary beam limiting material.

Spot check—A procedure to assure that a previous calibration continues to be valid.

Stationary beam therapy—Radiation therapy without relative displacement of the useful beam and the patient during irradiation.

Subsystem—A combination of two or more components of an accelerator.

Target—The part of a radiation source which intercepts a beam of accelerated particles with subsequent emission of other radiation.

Tube housing assembly—The term includes high-voltage or filament transformers, or both, and other appropriate elements when contained within the tube housing.

Useful beam—The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Virtual source—The nominal location of either the first scattering foil (for equipment providing electrons only) or the photon focal spot (for equipment capable of delivering both photons and electrons).

Wedge filter—An added filter effecting continuous progressive attenuation on all or part of the useful beam.