

PART H

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

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

Sec. H.2 - Scope.

- a. In addition to the requirements of this Part, all registrants are subject to the requirements of Parts A, B, D, and J of these regulations. This Part does not pertain to radiation safety requirements for x-ray equipment that is explicitly covered in other sections of these regulations (e.g., Diagnostic Machines [Part F], particle accelerators [Part I], industrial x-ray radiography [Part E], etc.).
- b. Radiography that meets the definition of "cabinet radiography" (H.4) and the requirements of H.6 (General Regulatory Provisions) and H.7 (closed beam provisions) should be regulated under this Part. This should include certified cabinet x-ray systems.
- c. Radiography that meets the definition of "shielded room" (H.4) and the requirements of H.6 (General Requirements) and H.10 (Shielded Room RGD) should be regulated under this Part.
- d. Radiography that meets the definition of "bomb detection radiation equipment" (H.4) should be regulated under this Part.
- e. Industrial radiography that is open-beam, and not in a shielded room and not otherwise listed here, should be regulated under Part E of these regulations (industrial radiography).

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

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

"Accessible surface" means the external or outside surface of the enclosure or housing provided by the manufacturer. This includes the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across any aperture or port.

"Active indication" means an engineered control and not an administrative control.

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

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

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

"Cabinet radiography " means industrial radiography using radiation machines not subject to FDA regulation in an enclosed, interlocked cabinet in which is contained at least that portion of a material being irradiated, and in which:

- i. The radiation machine will not operate unless all openings are closed with interlocks activated;
- ii. The cabinet is shielded such that every location on the exterior meets the conditions for an unrestricted area as defined in Part D of these regulations; and
- iii. The cabinet is constructed or arranged as to exclude the entrance of any part of the body of an individual during irradiation.

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

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

"Certified Cabinet X-ray System" means an RGD utilized in an enclosed, interlocked cabinet, such that the radiation machine will not operate unless all openings are securely closed, and which cabinet is shielded such that every location on the exterior meets conditions for an unrestricted area as specified in Part D of these regulations. These systems are certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of applicable federal radiation safety performance standards 21 CFR 1010 and 1020.40.

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

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

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

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

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

"Electron beam device" means any device using electrons below 1 MeV to heat, join or otherwise irradiate materials.

"Emergency procedure" means the written pre-planned steps to be taken in the event of actual or suspected exposure of individuals to excessive radiation. This procedure should include the names and telephone numbers of individuals to be contacted as well as directives for processing the film badge or other personnel monitoring devices.

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

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

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

"Hybrid gauge" means a gauging device utilizing both x-ray and radioactive sources.

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

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

"Ion implantation equipment, low-energy" means any closed device operating below 1 MeV used to accelerate elemental ions and implant them in other materials.

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

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

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

"Mobile equipment". See "Radiation Generating Device."

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

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

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

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

"Portable equipment". See "Radiation Generating Device."

"Primary beam" means ionizing radiation from an x-ray tube anode or secondary target which is allowed to pass through an aperture in the tube housing.

"Pulsed x-ray or flash system" means equipment used to investigate rapid processes in materials, machinery or explosive detonations where radiation pulses may be in the range of nanoseconds.

"Qualified individual" means an individual who has demonstrated to the satisfaction of the Agency that he possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs.

"Quality control" means a procedure or set of procedures intended to ensure that a manufactured product or performed service adheres to a defined set of quality criteria or meets the requirements of the user.

"Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (5 millirem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

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

- i. "Mobile RGD" means equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;
- ii. "Portable RGD " means equipment designed to be hand-carried;
- iii. "Stationary RGD" means equipment that is installed or placed in a fixed location; or
- iv. "Transportable RGD" means equipment to be installed in a vehicle or that may be readily disassembled for transport or use in a vehicle.

"Radiation Safety Officer (RSO)" means an individual who has been appointed by senior management and has training, knowledge, and responsibility to apply appropriate radiation protection regulations and guidance.

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

"Radiograph" means a permanent picture or image produced on a sensitive surface by a form of radiation other than visible light. "Radiography" is the process of radiographic images.

"Safety device" means a device or system that prevents the entry of any portion of an individual's body into the primary x-ray beam or that causes the beam to shut off upon entry into its path.

"Scattered radiation" means radiation that has been deviated in direction and / or energy bypassing through matter.

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

"Shielded room" means a room housing an RGD where, with the RGD at maximum techniques, the exterior room environs meets the unrestricted area limits of 0.02 mSv (2 mrem) in any one hour and 1 mSv (100 mrem) in a year.

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

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

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

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

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

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

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

Sec. H.5 - Exemptions.

- a. RGDs meeting the definition of "bomb detection radiation equipment", as defined under H.4e., are exempt from the requirements of H.6f. (posting), of the General Regulatory Provisions of this Rule.
- b. The following machines and equipment are exempt from these regulations:
 - i. Domestic television receivers, providing the exposure rate at 5 centimeters from any outer surface is less than 0.005 mSv (0.5 mrem) per hour
 - ii. Cold-cathode gas discharge tubes, providing the exposure rates shall not exceed 0.1 mSv (10 mrem) per hour at a distance of thirty (30) centimeters from any point on the external surface of the tube.
 - iii. Other electrical equipment that produces radiation incidental to its operation for other purposes, providing the dose rate to the whole body at the point of nearest approach to such equipment when any external shielding is removed does not exceed 0.25 mSv (25 mrem) per year. The production testing or factory servicing for such equipment shall not be exempt.
 - iv. Equipment described in this subsection shall not be exempt if it is used or handled in such a manner that any individual might receive a dose of radiation in excess of the limits specified in Part D of these regulations.

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

a. Warning Devices.

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

- b. Labeling.
- i. All RGD equipment shall be labeled with a readily visible and discernible sign or signs bearing the radiation symbol (defined in Part D.1901 of these regulations) and the words: "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube.
 - ii. For RGDs with designed openings (not ports) for object entries (such as baggage units), the following shall be posted at or near each opening: "CAUTION – X-RAY HAZARD: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED", or words having similar intent.
- c. Radiation Source Housing. Each x-ray tube housing shall be subject to the following requirements:
- i. Interlock. When the x-ray tube housing is the primary shielding for the x-ray tube, and is intended to be opened for normal use or maintenance, the housing shall be equipped with an interlock that shuts off the high voltage to the x-ray tube if the housing is opened; and
 - ii. Radiation Level Limit. Each x-ray tube housing shall be so constructed that, with all shutters closed, the leakage radiation measured at a distance of 5 centimeters from the x-ray tube housing surface does not exceed 0.025 mSv (2.5 mrem) per hour. This limit shall be met at the maximum tube rating. For closed beam systems, this requirement can be met by complying with Section H.7d. Radiation Level Limit. For an RGD in a shielded room, this limit can be met by measuring from any accessible surface outside the room housing the RGD. For hand-held, open-beam RGDs, this requirement can be met by complying with the limits in H.9c. Radiation Level Limit.
- d. Generator Cabinet or High Voltage Source Radiation Level Limits. Each x-ray generator or high voltage source shall be supplied with a protective cabinet which limits leakage radiation to 2.5 μ Sv (0.25 mrem) in one hour at a distance of 5 centimeters measured at the nearest accessible surface. For an RGD in a shielded room with the high-voltage generator also inside the shielded room, this limit can be met by measuring from any accessible surface outside the room housing the RGD. For hand-held, open-beam RGDs, this requirement can be met by complying with the limits in H.9c. Radiation Level Limit.
- e. Surveys.
- i. Radiation surveys of all RGDs shall be sufficient to show compliance with radiation level requirements of this Chapter, and as required by Part D.1201 (occupational exposure limits) and Part D.1301 (dose to member of the public) of these regulations. The radiation surveys should be reasonable under the circumstances to evaluate the magnitude and extent of radiation levels and the potential radiological hazards that could be present. These surveys shall include, but not limited to, surveys:

- (1) Upon installation of the equipment, and at least once every 12 months thereafter;
 - (2) Following any change in the initial arrangement, number, or type of local components in the system;
 - (3) Following any maintenance requiring the disassembly, removal, or repair of a local component in the system;
 - (4) During the performance of maintenance, calibration and other procedures if the procedures require the presence of a primary x-ray beam while any local component in the system is disassembled or removed;
 - (5) Any time a visual inspection of the local components in the system reveals an abnormal condition; and
 - (6) Whenever a personnel monitoring device shows a significant increase over previous monitoring period or readings are approaching the limits specified in Part D.1201 (occupational exposure limits) of these regulations.
- ii. The registrant shall have access to sufficiently calibrated, appropriate and operable radiation survey instruments to make physical radiation surveys as required by this Part. The instruments shall be capable of detecting and measuring the types and levels of radiation involved (including primary, scattered, and leakage radiation).
 - iii. Each radiation survey meter shall be calibrated at intervals not to exceed twelve months. Radiation survey meters shall also be calibrated after each servicing or repair, other than simple battery replacement. The calibration should have a minimum accuracy of plus or minus 20% and be traceable to instruments or radiation sources calibrated to a National Institute of Standard and Technology (NIST) standard.
 - iv. Radiation survey measurements shall not be required if a registrant can otherwise demonstrate compliance with the requirements of this Part to the satisfaction of the Agency.
- f. Posting. Each area or room containing an RGD where an individual may receive 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) per year shall be conspicuously posted with a sign or signs bearing the radiation symbol (as defined in Part D.1901 of these regulations) and the words "CAUTION - X-RAY EQUIPMENT," "CAUTION – RADIATION GENERATING DEVICE" or words having a similar intent.
 - g. Security. RGDs shall be secured in such a way as to be accessible to, or operable by, only authorized personnel when not in operation.
 - h. Operating Requirements.

- i. Procedures. Normal operating procedures shall be written and available to all RGD workers. No individual shall be permitted to operate an RGD in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.
- ii. Bypassing.
 - (1) No individual shall bypass a safety device, interlock or remove shielding unless such individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time.
 - (2) When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing and at the control switch.
 - (3) A record of any bypass of a safety device or interlock shall be maintained; the record should contain such information as the date the alteration was made, type of alteration, length of time the unit remained in the altered condition, and signed by the individual who made the alteration and the individual who restored the unit to original condition.
- iii. Control Panel.
 - (1) The RGD can only be activated from the control panel.
 - (2) All indicators and controls that control the primary beam shall be identifiable and discernible through the use of labels, symbols, software displays or the equivalent.
- iv. Interlocks.
 - (1) An interlock shall not be used to de-activate the x-ray tube or RGD, except in an emergency or during testing of the interlock system.
 - (2) After breaking any interlock, it shall be possible to restore the RGD to full operation only from the control panel.
 - (3) All interlocks shall be of a fail-safe design.
- v. Multiple Sources. If more than one x-ray tube assembly(s) or focal spot can be operated sequentially or simultaneously from a control panel, active, visual indicators located on the control panel shall indicate which tube assembly(s) or focal spot has been selected. The selectors shall be identified as to their function. If a letter or number is used, a reference card or table explaining the code shall be affixed to the control panel.

- i. Repair or Modification of X-Ray Tube or RGD Systems. Only trained personnel or registered service provider shall be permitted to install, repair, or make modifications to the RGD. No operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main power switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs. It is the responsibility of the registrant to assure that personnel who install, repair, or make modifications to the RGD are qualified.

- j. Testing of Safety Devices.
 - i. Tests of all safety devices, such as interlocks, shutters, warning lights, and required emergency shut-off switches shall be conducted at intervals not to exceed 6 months on all operable RGDs.
 - ii. If any safety device fails during testing, the RGD shall be removed from service until the safety device failure is corrected or proper temporary administrative controls established.
 - iii. Records of safety device tests, check dates, findings and corrective actions shall be available for inspection and maintained for 5 years.
 - iv. Records shall include the date of the test, the results of the test, the name of the person performing the tests and corrective actions taken for safety devices that fail the required test.
 - v. Testing of safety devices may be deferred if the unit and/or installation is clearly marked and kept out of service; units and/or installations brought back into service after exceeding the 6 month interval shall be tested prior to use.
 - vi. If testing of a safety device cannot be performed due to manufacturer design, the registrant shall document that the safety device will not be tested and specifically why the safety device cannot be tested.

- k. Instruction and Training. No individual shall be permitted to operate or maintain an RGD, or enter a shielded room unless such individual has received instruction in and demonstrated competence as to:
 - i. Types of radiation and identification of radiation hazards associated with the use of the RGD and associated equipment and precautions or measures to take to minimize radiation exposure;
 - ii. Significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;
 - iii. Commensurate with potential hazards of use, biological effects of radiation, radiation risks, and recognition of symptoms of an acute localized exposure;

- iv. Proper operating procedures for each type of RGD and associated equipment, supervised hands-on training and procedures to prevent unauthorized use;
- v. Emergency and proper procedures for reporting an actual or suspected accidental exposure or other radiation safety concerns, such as any unusual occurrence or malfunction that may involve exposure to radiation; and
- vi. Performing surveys where applicable.

Records shall be maintained of all required training and instruction, and made available for review by the Agency.

l. Radiation Protection Responsibility.

- i. Senior management shall make the ultimate decision to use any RGD and be ultimately responsible for radiation safety.
- ii. Senior management shall designate an individual responsible for radiation safety, or a radiation safety officer (RSO). This individual shall have direct access to senior management for radiation safety issues. This individual shall have training and experience commensurate with the scope of the radiation safety program to carry out the responsibilities as indicated below.
 - (1) Ensuring that all RGDs are operated within the limitations of the established radiation safety program and operating procedures.
 - (2) Instructing personnel with regard to safe working practices and ensuring all personnel are trained in radiation safety commensurate with the hazards of the job.
 - (3) Investigating any incident of abnormal operation or exposure or suspected overexposure of personnel to determine the cause and take remedial action and report the incident to the proper authority.
 - (4) Ensuring that interlocks, warning signals, and signs are functioning and located where required.
 - (5) Maintain all radiation safety records.

Sec. H.7 - Additional Requirements for Closed Beam RGDs. In addition to the requirements of H.6 above, the following additional requirements in this rule apply to all closed-beam x-ray RGDs.

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

- b. Interlocks. All doors and panels accessing the RGDs shall be interlocked. The interlocks required by this section shall be of a fail-safe design.
- c. Interlock Functions. The system enclosure, sample chamber, etc. closure shall be interlocked with the x-ray tube high voltage supply and/or a shutter in the primary beam so that no x-ray beam can enter the sample or object chamber while it is open unless the interlock has been conspicuously and deliberately defeated. The interlock required by this section shall be of fail-safe design or adequate administrative controls shall be exercised to ensure operations will not continue without a proper functioning interlock.
- d. Radiation Level Limit. The radiation level for all closed beam RGDs shall not exceed a dose rate of 0.005 mSv (0.5 mrem) in any one hour at five centimeters outside any accessible surface.
- e. Security Screening Units. Security screening units shall be provided with means to insure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-radiation.
 - i. During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.
 - ii. During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

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

- a. Safety Device.
 - i. Considerations should be made by the registrant for giving preference to the use of closed-beam systems over open-beam systems if possible.
 - ii. If the registrant needs to use an open-beam system, the registrant should consider a device which prevents the entry of any portion of the operator's body into the path of the primary beam or which causes the primary beam to be shut off upon entry into its path.
 - iii. If the registrant's use of the open-beam RGD does not permit the use of a safety device, the registrant shall maintain a written record of a description of the various safety devices that have been evaluated and reasons for why these devices cannot be used. These records shall be available for inspection.
 - iv. In lieu of the safety device, the registrant shall employ alternative methods (such as policies and procedures) to minimize the possibility of unnecessary exposure.

These policies and procedures will include information about the absence of safety devices.

- v. For portable open-beam RGDs that are manufactured to be used handheld, or potentially used as a hand-held, without such safety devices, this safety device requirement can be met by complying with all the requirements in H.9, Additional Requirements for Open-beam, Hand-held RGDs prior to use.
- b. X-ray On Status. For open beam equipment, RGDs shall be provided with a readily discernible and active indication of:
 - i. X-ray tube "on-off" status located near the radiation source housing. The warning lights as required by Part H.6a.ii. can meet this requirement if the warning lights are readily discernible and viewable by anyone near the primary beam;
 - ii. Shutter "open-closed" status located at the control panel and near each port on the radiation source housing, if the primary beam is controlled with a shutter. The shutter status device shall be clearly labeled as to the meaning of the status device (i.e., whether the shutter is open or closed). The status light at the control panel can meet the requirement for the status light at the port if the status light at the control panel is readily discernible and viewable by anyone near the primary beam; and
 - iii. The x-ray tube "on-off" status indicator and the shutter "open-closed" status indicators shall be of a fail-safe design.
- c. Labeling. Each unit will be labeled at or near the x-ray exit port to identify the location of the beam with the words, "CAUTION - X-RAY BEAM", or "CAUTION – HIGH INTENSITY X-RAY BEAM", or words having a similar intent.
- d. Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.
- e. Shutters. On open-beam RGD configurations that are designed to accommodate interchangeable components, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a component coupling has been connected to the port.
- f. Radiation Level Limits. The local components of an open beam RGD shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist (exclusive of the primary beam) in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits as outlined in Part D. 1301 (unrestricted area limits) of these regulations. These levels shall be met at any specified tube rating.
- g. Primary Beam Attenuation. In cases where the primary x-ray beam is not intercepted by the detector device under all conditions of operation, protective measures shall be provided, such as auxiliary shielding or administrative procedures, to avoid exposure to any individual from the transmitted primary x-ray beam.

- h. Operator Attendance. The operator shall be in immediate attendance at all times when the equipment is in operation except when the area is locked or the equipment is secured to protect against unauthorized or accidental entry.
- i. Control of Access. If the RGD is not in a restricted area (as defined in Part D), the operator shall be able to control access to the RGD at all times during operation. If the RGD is not in a restricted area (as defined in Part D) and the RGD is capable of creating a radiation area (See Part D), the operator shall be able to control access to the RGD at all times during operation, and:
 - i. Radiation areas in excess of 0.05 mSv (5 mrem) per hour shall be conspicuously identified. The radiation source shall be within a conspicuous perimeter (e.g., rope, tape, or other barrier) that identifies the area in which the dose equivalent exceeds 0.05 mSv (5 mrem) per hour. The area described by the temporary barricade shall be suitably posted with "CAUTION – RADIATION AREA" signs. The operator shall ensure that no one is inside or enters the radiation area during operation of the RGD;
 - ii. Radiation areas in excess of 1 mSv (100 mrem) per hour shall be conspicuously identified. The radiation source shall be within a conspicuous perimeter (e.g., rope, tape, or other barrier) that identifies the area in which the dose equivalent exceeds 1 mSv (100 mrem) per hour. The area described by the temporary barricade shall be suitably posted with "CAUTION – HIGH RADIATION AREA" area signs. The operator shall ensure that no one is inside or enters the radiation area during operation of the RGD;
 - iii. The operator shall perform a visual check of the controlled area to ensure it is free of all unauthorized personnel immediately prior to activating or exposing the radiation source;
 - iv. Surveillance of the exposure area shall be maintained during operation, either by visual or by other reliable means to ensure that no person enters the area;
 - v. With the exception of hand-held x-ray systems, when approaching the radiation source, following the conclusion of an exposure, the operator shall use a suitable calibrated and operable radiation detection instrument to verify that the source is in its fully shielded condition or that the x-ray tube has been de-energized;
 - vi. A personal alarming dose rate meter may be worn to approach the work area if the device is appropriately designed and calibrated for the type of x-ray emitted (i.e., pulse or continuous), set at an appropriate level to detect the presence of the source, for example 0.02 mSv (2 mrem) per hour, and has been source-checked prior to use. The radiation in the work area must be reasonably uniform so that the device responds to radiation exposure to any part of the body. It may not be used to measure radiation levels, nor may it be used to indicate the presence of the source for potential non-uniform exposure, such as may occur during machine maintenance or work in an RGD target area;

- vii. Measurement of radiation levels for a radiation survey must be performed using an appropriate calibrated radiation survey meter (see H.6e.i. and H.6e.ii.). A radiation survey meter must also be used when there is potential for non-uniform exposure to personnel, such as may occur during machine maintenance or work in an RGD target area;
 - viii. During the initial exposure, radiation levels should be measured around the perimeter of the controlled area and the perimeter adjusted as required to satisfy the requirement of not exceeding 0.05 mSv (5 mrem) in any one hour; and
 - ix. The survey around the perimeter should be made for each new operating condition and the perimeter adjusted accordingly. The area of operation should be monitored periodically if radiation levels are variable.
- j. Instruction and Training. In addition to the requirements in H.6k., no individual shall be permitted to operate or maintain an open beam RGD unless such individual has received more specific and detailed instruction in and demonstrated competence as to:
- i. Sources and magnitude of common radiation exposure;
 - ii. Units of radiation measurement;
 - iii. Radiation protection concepts of time, distance, shielding, and ALARA;
 - iv. Procedures and rights of a declared pregnancy;
 - v. Regulatory requirements and area postings;
 - vi. Worker, embryo/fetus, and public dose limits;
 - vii. Proper use of survey instruments and dosimetry; and
 - viii. The policies and procedures required by H.8a.
- k. Personnel Monitoring. In addition to the requirements of Part D 1201 of these regulations (occupational exposure limits), extremity dosimetry shall be provided and used by:
- i. Personnel working with or routinely working near and having potential for exposure to, the primary beam of an open beam RGD; and
 - ii. Personnel maintaining RGDs if the maintenance procedures require the presence of a primary radiation beam when any local component in the RGD is disassembled or removed.

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

- a. Procedures. All possessors of open-beam, hand-held RGDs shall have available for review to the Agency operating policies and procedures that contain measures to insure that:
 - i. Radiation protection is provided equivalent to that afforded in Part D. 1301 of these regulations (the unrestricted area requirements);
 - ii. Radiation protection is provided equivalent to that afforded in H.8g. (attenuation of primary beam);
 - iii. The operator will not hold the sample during operation of the RGD or that the operator's hands will not approach the primary beam; and
 - iv. The operator will not aim the primary beam at him/herself or at any individual during operation of the RGD.
- b. Training. In addition to the training requirements of H.6k. and H.8j. above, the registrant shall provide training for all users and operators on the above subjects of this Section. Records shall be maintained of all user and operator training.
- c. Radiation Level Limit. For hand-held RGDs, the limits of H.6c.ii. (Radiation Source Housing radiation level limits) and H.6d. (Generator Cabinet or High Voltage Source radiation level limits) shall be met if the radiation level at any accessible surface of the RGD does not exceed 0.025 mSv (2.5 mrem) per hour at 5 cm.
- d. Extremity Monitoring. For the purposes of the requirements in H.8k. (extremity monitoring), operators of hand-held RGDs shall be considered as working near the primary beam.

Sec. H.10 - Shielded Room RGD. For RGDs that are unable to meet the limits of Part D. 1301 (the unrestricted area limits), the RGD can be maintained inside a room in which the shielding in that room meets the limits of D 1301 of these regulations (unrestricted area limits) when the RGD is activated. The only requirements of this Part for RGDs in a shielded room are H.6 (General Requirements) and this Rule as follows:

- a. Posting. The door to the room containing the RGD shall be posted "CAUTION – RADIATION AREA", or "CAUTION – HIGH RADIATION AREA", or "GRAVE DANGER – VERY HIGH RADIATION AREA", as required by Part D of these regulations.
- b. Entrance Interlocks. All entrances into the shielded room shall be provided with interlocks. After an interlock has been interrupted, broken, or tripped, it shall be possible to cause x-rays to be produced again only from the control panel. Interlocks shall not be used to shut off the x-ray equipment except in an emergency or during testing.
- c. Entrance Warning Devices. All entrances into the shielded room shall be provided with a conspicuously visible warning device, which need not be flashing or rotating but which operates only when radiation is being produced.

- d. Room Warning Lights. The interior of the shielded room shall be provided with flashing or rotating warning lights that operate when, and only when, radiation is being produced. These lights shall be so positioned that they can be observed from any position or orientation within the room. The lights shall be posted indicating the meaning of the warning signal and instructions on what to do; the posting shall be legible, conspicuous, and accessible to view.
- e. Audible Room Warning Device. An audible warning signal within the room shall be actuated for at least ten (10) seconds immediately prior to the first initiation of radiation after the closing of any opening that can admit personnel. The registrant shall post the meaning of the warning signal and instructions on what to do; the posting shall be legible, conspicuous, and accessible to view.
- f. Emergency Shut-off. If dose rates exceed the High Radiation Area limits (as defined in Part D of these regulations - dose rate greater than 1 mSv (100 mrem) per hour at 30 cm from the source), emergency shut-off switches shall be located within the high radiation areas so as to be accessible to individuals therein. These switches and their mode of operation shall be identified by a conspicuously posted sign adjacent to the switch. The emergency shut-off switches shall include a manual reset that must be reset at the switch before x-rays can again be produced from the control panel. After an emergency shut-off switch has been activated, it shall be possible to produce x-rays again only from the control panel.
- g. Separate Electrical Systems. The interlock system and the emergency shut-off system shall be separate electrical and/or mechanical systems.
- h. Egress From Shielded Room. A person within the room housing an RGD shall be able to egress at all times.
- i. Entry into the Shielded Room.
 - i. After each exposure and before entry of any personnel, a survey shall be performed upon entry to the shielded room to determine that the RGD is no longer producing radiation.
 - ii. Personnel devices providing an audible signal when activated by radiation will be acceptable for the survey requirement of H.10i. above.
 - (1) Proper operation of the audible detection device shall be checked daily and a record maintained of this check.
 - (2) The audible device shall be designed so as to clearly indicate entry into a 0.02 mSv (2 mrem) per hour x-ray radiation field.
 - (3) All personnel working with the x-ray equipment shall be provided with such a device.
 - iii. Stationary area monitors providing an audible signal when activated by radiation will be acceptable for the survey requirement of H.10i. above.

- (1) Proper operation of the stationary detection device shall be checked daily and a record maintained of this check.
 - (2) The stationary device shall be designed so as to clearly indicate entry into a 0.02 mSv (2 mrem) per hour x-ray radiation field.
 - (3) Stationary area monitors shall be calibrated annually to determine that the audible signal operates at a 0.02 mSv (2 mrem) per hour radiation field.
- j. Personnel Monitoring. All personnel associated with the x-ray equipment shall be provided with personnel monitoring devices that shall be calibrated for the x-ray energies being utilized. Records of personnel exposure shall be maintained.
- k. Training. No registrant shall permit any individual to operate an RGD in a shielded room until such individual has received a copy of, instruction in, and demonstrated an understanding of, operating and emergency procedures for the unit and competence in its use. Records shall be maintained of all operator training.
- l. Control Panel Security. The x-ray equipment control panel shall be provided with a locking device to prevent unauthorized use. Such locking device shall, when locked, prevent the production of x-ray radiation by the equipment.
- m. Malfunctions. If a safety or warning device malfunctions, the x-ray control panel shall be locked in the “off” position. It shall not be used, except as may be necessary for repair or replacement of the malfunctioning safety or warning device, until the safety or warning device is functioning properly.

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

- a. Control Panel Security. When not in use, each bomb detection radiation machine shall be locked to prevent unauthorized use. This is in addition to the requirements of H.6g. (Security).
- b. Utilization Log. The registrant shall maintain for each bomb detection radiation machine a utilization log. This log shall record the description of the unit, the date removed from storage, the date returned to storage, the identity and signature of the person to whom the device is assigned, the dates of use and the site of use.
- c. Area Control. The registrant shall provide security to prevent entry by individuals from any point when the machine is energized during training.

Sec H.12 - RGDs Used in Personnel Security Screening or Vehicle Screening for Public Protection. In addition to the General Requirements in H.6., the following requirements in this section apply.

A person requesting Agency approval for a RGD to be used in Personnel Security Screening or Vehicle Screening with intended exposure of human occupants to the primary beam for public

protection shall submit in writing the following information for evaluation and show how the dose limits noted below will be met.

- a. Efficacy Evaluation. An evaluation of all known alternate methods that could achieve the goals of the security screening program, and why these methods are not used in preference to the proposed approach utilizing ionizing radiation.
- b. Equipment Evaluation. RGDs used for non-healing arts personnel security screening of humans shall be evaluated every 12 months by a qualified expert for optimization of image quality and radiation dose.
- c. Dose Limits For "General Use" Equipment. For "general-use" screening systems, where equipment is used without regard to the number of individuals scanned or number of scans per individual in a year, an effective dose for a single complete screening shall be limited to 0.25 μSv (25 μrem).
- d. Dose Limits For "Limited Use" Equipment. For "limited-use" screening systems, where equipment is capable of operation greater than 0.25 μSv (25 μrem) per screening, and is used with discretion, the effective dose per screening shall be less than or equal to 0.01 mSv (1 mrem).
- e. Dose Limits For Repeat Security Screenings. For individuals subject to repeat security screening at a single venue, no individual shall exceed an effective dose of 0.25 mSv (25 mrem) in any one year at the registrant or licensee's facility.
- f. Vehicle Limitations.
 - i. When the procedures for operation of a mobile or fixed RGD used for security screening of vehicles includes knowingly exposing human occupants to the primary beam when screening vehicles or structures, the system shall be subject to the same requirements as general-use or limited-use equipment as provided in H.12a. through H.12f.
 - ii. If the requirements in H.12c. through H.12e. cannot be met if vehicle occupants are knowingly exposed to the primary beam of a security screening system, then there shall be means to assure the occupied portion of the vehicle is outside of the scan area while the primary beam is emitted or procedures shall be established and implemented to assure all occupants are not present in the vehicle during screening.
 - iii. The effective dose to an individual for a single inadvertent exposure to the primary beam shall not exceed 5 mSv (500 mrem) and should not exceed 1 mSv (100 mrem). The reliability of the procedure used to assure that there are no occupants of a vehicle to be scanned shall be commensurate with the potential severity of an inadvertent exposure. If the 5 mSv (500 mrem) limit cannot be assured, a pre-screening with a mode or system which can meet the limits in H.12c. through H.12f. should be used to verify there are no occupants in the vehicle being examined.

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

- a. That the use of the RGD will not result in undue hazard to public health and safety or property;
- b. That compliance would require replacement or substantial modification of the RGD;
- c. That the registrant will achieve, through other means, radiation protection equivalent to that required by the regulation; and
- d. Why the regulatory standard or requirement could not be met.