PART H

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

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

Sec. H.2 - Scope.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Radiography" is the process of creating radiographic images.

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

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

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

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

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

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

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

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

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

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

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

Sec. H.5 - Exemptions.

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

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

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

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

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

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

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

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

a. Warning Devices.

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

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

b. Labeling.

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

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

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

i. Interlock. When the x-ray tube housing is the primary shielding for the x-ray tube, and is intended to be opened for normal use or maintenance, the housing shall be equipped with an interlock that shuts off the high voltage to the x-ray tube if the housing is opened; and

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

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

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

e. Surveys.

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

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

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

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

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

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

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

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

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

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

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

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

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

h. Operating Requirements.

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

ii. Bypassing.

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

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

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

iii. Control Panel.

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

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

iv. Interlocks.

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

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

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

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

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

j. Testing of Safety Devices.

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

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

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

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

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

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

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

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

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

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

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

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

vi. Performing surveys where applicable.

l. Radiation Protection Responsibility.

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

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

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

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

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

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

(5) Maintain all radiation safety records.

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

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

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

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

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

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

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

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

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

a. Safety Device.

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

ii. If the registrant needs to use an open-beam system, the registrant shall consider a safety device which prevents the entry of any portion of the operator's body into the path of the primary beam or which causes the primary beam to be shut off upon entry into its path.

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

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

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

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

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

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

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

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

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

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

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

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

h. Operator Attendance. The operator shall be in immediate attendance at all times when the equipment is in operation except when the area is locked or the equipment is secured to protect against unauthorized or accidental entry.

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

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

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

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

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

iv. Surveillance of the exposure area shall be maintained during operation, either by visual or by other reliable means to ensure that no person enters the area;

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

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

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

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

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

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

i. Sources and magnitude of common radiation exposure;

ii. Units of radiation measurement;

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

iv. Procedures and rights of a declared pregnancy;

v. Regulatory requirements and area postings;

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

vii. Proper use of survey instruments and dosimetry; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

i. Entry into the Shielded Room.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

b. Utilization Log. The registrant shall maintain for each bomb detection radiation machine a utilization log. This log shall record the description of the unit, the date removed from storage, the date returned to storage, the identity and signature of the person to whom the device is assigned, the dates of use and the site(s) of use.

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

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

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

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

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

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

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

f. Vehicle Limitations.

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

ii. If the requirements in H.12c. through H.12e. cannot be met if vehicle occupants are knowingly exposed to the primary beam of a security screening system, then there shall be means to assure the occupied portion of the vehicle is outside of the scan area while the primary beam is emitted or procedures shall be established and implemented to assure that no occupants are present in the vehicle during screening.

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

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

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

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

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

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

2016 Rationale

Part H
Radiation Safety Requirements for
Non-Healing Arts Radiation Generating Devices

Introduction

The SSR Part H Working Group has performed a major revision to this Part. The former Part H was primarily focused on 'Analytical X-ray Equipment.' Many of these devices, such as x-ray diffraction units, had historically been of great concern due to poorly interlocked components allowing operator access to high dose rate beams. Much improvement has been made to interlock these critical components and beam ports by the equipment manufacturers, thereby preventing the acute injuries observed in the past. Over the years there has also been an evolution of [characteristic] x-ray analyzers, from primarily bench-top lab units, to now the more common hand-held type unit. In fact, given the numerous uses of non-medical x-ray systems for analytical chemical and physical analysis, material thickness gauging, ion implantation, electron beam welding, cabinet or open beam inspection (e.g., radiography, fluoroscopy or scanning beam), as well as irradiation of materials for sterilization or processing – it was felt Part H should be renamed from Analytical X-ray Equipment to 'Radiation Generating Devices' (RGD). To differentiate from non-healing arts accelerators, covered by SSR Part I, where neutron exposures and activation of components may be of concern, Part H will only apply to devices capable of generating particles or photons above 5 kiloelectron volts (keV) and below 1 million electron volts (MeV). With the advent and utilization of non-medical x-ray body scanners for security purposes, these RGDs are now covered in Part H. Lastly, with the exception of field industrial radiography, the intent is to remove the x-ray requirements in SSR Part E (Industrial Radiography) and capture them in SSR part H.

Specific Provisions

In that SSR Part H has had a significant re-write, it is recommended that reviewers read the old Part H, then review the revised Part H for completeness in its expanded scope. The Work Group believes the revised Part H is comprehensive in scope, but welcomes input from federal, state and industry peer reviewers.

Numerous federal regulations (e.g., FDA and NRC), technical articles, reports and voluntary standards were reviewed and considered in preparing this revision. Below is a listing of Part H sections and annotations of reference materials utilized.

Acronyms Used in this Rationale

ANSI	American National Standards Institute
CFR	Code of Federal Regulations
DOE	Department of Energy
FDA	Food and Drug Administration
HPS	Health Physics Society

IAEA	International Atomic Energy Agency
IEC	International Electrotechnical Commission
ISCORS	Interagency Steering Committee on Radiation Standards
NCRP	National Council on Radiation Protection and Measurements
NRC	Nuclear Regulatory Commission
RGD	Radiation Generating Device
SSR	Suggested State Regulations

Rationale

Section H.3 *The statement* "If applicable, all RGDs shall comply with applicable FDA manufacturing regulations as defined in Title 21 Code of Federal Regulations" *is specifically referring to 21 CFR 1020.40, Cabinet x-ray systems.*

Note: If a unit is totally enclosed and meets the rules under Part H.5 and H.6, then the type of work it does should not matter; this includes industrial radiography.

Section H.4

Cabinet radiography	*As historically defined under 21 CFR 1020.40*
Cabinet x-ray system	*From 21 CFR 1020.40(b)(3)).*
Closed-beam x-ray equipment	*IEC 62495*
Cold-cathode gas discharge tube	*21 CFR 1020.20(b) Definitions*
Collimator	*IEC 62495*
Control panel	*ANSI 43.5 Definitions*
Fail-safe design	*ANSI 43.2 Definitions*
General use system	*ANSI 43.17 Definitions*
Hand-held x-ray system	*IEC 62495*
Interlock	*IEC 62495*
Leakage radiation	*IEC 62495*
Limited use system	*ANSI 43.17 Definitions*
Local components	*From Part H of the Suggested State Regulations, 1991 revision*
Normal operating procedures	*From Part H of the Suggested State Regulations, 1991 revision*

Open-beam x-ray equipment	*IEC 62495*
Radiation source (or x-ray tube) housing	*ANSI N43.2 3 Definitions*
Scattered radiation	IEC 62495
Warning device	*IEC 62495*
X-ray generator	*IEC 62495*

Section H.5c.i. *21 CFR 1020.10(c), revised April 1, 2012.*

Section H.5c.ii. *21 CFR 1020.20(c), revised April 1, 2012.*

Section H.5c.iii. *NCRP Report No. 116 (1993), chapter 15* Non-occupational Dose Limits: Exposure of Individual Members of the Public.

Section H.6a.ii. *Annotation: "… when the tube is energized" means when there is a potential across the anode or current applied to the filament in the tube. It does not only mean when x-rays are being emitted from the port of the tube. This regulation applies to all RGDs, open and closed beam alike.*

Section H.6c.ii. *The dose limit of 2.5 mrem is from ANSI/HPS N43.2 – 6.2.2.2.1 (2001)*

2.5 mrem/hour x 2000 working hours per year equals 5,000 mrem.

Section H.6d. *See ANSI N43.2 - 6.2.2.1.1 (2001)*

0.25 mrem/hour x 2000 working hours per year equals 500 mrem.

Section H.6e.i. *From Part H of the Suggested State Regulations, 1991 revision*

Section H.6e.ii. *See ANSI/HPS N43.3 – 9.6.2 (2008)*

Section H.6h.i. *From Part H of the Suggested State Regulations, 1991 revision*

Section H.6h.ii.(1) *From Part H of the Suggested State Regulations, 1991 revision*

Section H.6h.ii.(2) *From Part H of the Suggested State Regulations, 1991 revision*

Section H.6h.v. *See ANSI N43.5-5.4 (2005)*

Section H.6j.i. - vi. *See ANSI N43.3 - 8.7 (2008)*

Section H.6j.vi. *Annotation: It is not always practical for the registrant to test some safety features, such as a warning light inside the device that, if removed, might void a warranty, or a computerized programmable logic controller (PLC). The purpose of vi. is to assure that the registrant is aware of the safety device, why*

it is not being tested regularly and that the manufacturer is in concordance with the safety device not being tested. However, there are ways to test and document the functionality of an LED light. For example, if a warning light is known not to be of a fail-safe design, you could routinely use the device with a detector (weekly, monthly, quarterly) demonstrating the production of x-rays and document that the light is functioning during this testing. This would be an administrative control (procedure for testing) in lieu of an engineering control (fail-safe design). Ultimately, the inspector or the Agency will have to determine what is acceptable. The point of this regulation is that if the registrant is not going to test a particular safety device and the Agency accepts that there will be no testing of the safety device, then the registrant does need to document that.

Section H.6k. *From Part H of the Suggested State Regulations, 1991 revision*

Section H.6l. *See ANSI N43.17 – 8.2.1 (2009)*

Section H.7c. *See ANSI N43.2 6.2.2.3.3.*

Section H.7d. *See 21 CFR 1020.40* Cabinet x-ray systems *[Revised as of April 1, 2011]*

Section H.7e. *From 21 CFR 1020.40(c)(10)* Additional requirements for x-ray baggage inspection systems.

Annotation: Guidance from the FDA, Guidance for Industry and FDA Staff – Compliance Guide for Cabinet X-ray Systems *(issued September 19, 2007) further states:*

> "X-ray baggage systems must have a means to ensure that the operator is present at the controls so that the operator can clearly view the ports and doors at all times during x-ray generation."

Additionally, the guidance document states:

> "Cabinet x-ray systems that are in controlled access areas and are always loaded and unloaded by trained operators are not subject to this section."

It is the intent here to follow those concepts.

Section H.8a. *See ANSI N43.2 6.2.2.2.3*

Section H.8b. *See ANSI N43.2 6.2.2.1.3 and 6.2.2.1.4.*

Section H.8b.i. *Annotation: The intent here is to have an indication near the operator if the operator is not at the control panel per se, e.g., putting samples in and out of the sample chamber. In other words, anybody that needs to know whether the tube is energized (anyone close to the primary beam) should be able to readily tell.*

Section H.8b.ii. *Annotation: The intent here is to have an indication near the operator if the operator is not at the control panel per se, e.g., putting samples in and out of the sample chamber. In other words, anybody that needs to know whether the shutter is open (someone close to the primary beam) should be able to readily tell.*

Annotation: Not all open beam units have a shutter; they may not be used in such a manner that there is a need for one. It is ***not*** *a requirement for open beam units to have a shutter. Again, the intent is for anyone who needs to know (who is near the primary beam) if the primary beam is being emitted, there should be an indicator readily available to tell them that.*

Section H.8c. *Annotation: The intent here is for anyone to be able to readily identify where the primary x-ray beam is located.*

Section H.8d. *Annotation: The intent here is to not have any unused, open ports that are not blocked and locked, and unable to be inadvertently opened.*

Section H.8i. *See ANSI/HPS N43.3 – 9.3.3.2 and 9.3.3.3 (2008)*

Section H.8k. *Annotation: Extremity monitoring is appropriate when individuals are working near the primary beam. Not all open beam RGD units should require extremity monitoring; for example, a non-hand-held bomb squad RGD, where the operator is distant from the RGD or the primary beam. Note that this Paragraph addresses the concern of extremity exposures*; *Part D (occupational exposure limits) still applies if whole body monitoring is needed. It is the intent of this committee to include hand-held RGDs in this requirement. States will need to determine whether this should be a permanent requirement or if the registrant will be able to provide a determination over time (show that occupational exposures will not exceed 10% of the limits of Part D).*

Section H.9a. *Annotation: The intent is to assure that the lack of the engineering control of a beam trap or the inherent shielding in a closed beam RGD is adequately addressed in an administrative control, such as a procedure, to ensure that the primary beam is accounted for by the operator.*

Section H.12 *Annotation: The following documents were used for this section:*

Guidance for Security Screening of Humans Utilizing Ionizing Radiation (GSSHUIR), ISCORS Technical Report 2008-1, July 2008.

Screening of Humans for Security Purposes Using Ionizing Radiation Scanning Systems, NCRP Commentary No. 16, 2003.

Radiation Safety For Personnel Security Screening Systems Using X-rays, ANSI/HPS N43.17-2002.

It is the understanding of this committee that the guidelines under Part H herein refer only to backscatter type security screening systems and not transmission security systems. The need for transmission type security systems in the future will demand further development of this Part to include such RGDs.

Section H.13 *Annotation: The intent here is that any exemption should show at least the same level of radiation protection as the intent of the initial regulation. This may mean taking an engineering control and replacing it with an administrative control (procedure). Paragraph c. would therefore include assurances of ample training for users and operators of the RGD on such administrative controls.*

References

ANSI/HPS N13.36-2001 Ionizing Radiation Safety Training for Workers

ANSI/HPS N13.49-2001 Performance and Documentation of Radiological Surveys

ANSI/HPS N43.2-2001 Radiation Safety for X-ray Diffraction and Fluorescence Analysis Equipment

ANSI/HPS N43.3 – 2008 For General Radiation Safety – Installations Using Non-Medical X-Ray and Sealed Gamma-Ray Sources, Energies Up to 10 MeV

ANSI/HPS N43.5-2001 Radiation Safety for the Design of Radiographic and Radioscopic Non-Medical X-ray Equipment Below 1 MeV

ANSI/HPS N43.8-2008 Classification of Industrial Ionizing Radiation Gauging Devices

ANSI/HPS N43.17-2009 Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation

Billy Freeman, State of Tennessee, Department of Environment and Conservation, Division of Radiological Health, Inspections and Enforcement Manager, Grammar and Style Consultant

Code of Federal Regulations, FDA 21 CFR Parts 1000-1005, 1010 and 1020

Code of Federal Regulations, DOE 10 CFR Part 835

Code of Federal Regulations, NRC 10 CFR Part 19, 20, 21

DOE – Radiological Control Manual, DOE-STD-1098-2008, Change Notice 1, May 2009

DOE – Radiation Generating Devices, DOE G 441.1-5, April 15, 1999

FDA – Guidance for Industry and Staff, Radiation Safety Considerations for X-ray Equipment Designed for Hand-Held Use

IAEA (draft) Safety Guide DS401, Application and Justification to Practices, Including Non-Medical Human Imaging

IAEA (draft) Safety Guide DS409, Radiation Safety of Gamma, Electron and X-ray Irradiation Facilities

IAEA (draft) Safety Guide DS471, Radiation Safety of X-ray Generators Used for Inspection Purposes and Non-Medical Imaging

International Electrotechnical Commission (IEC) 62495, Nuclear Instrumentation – Portable X-ray Fluorescence Analysis Equipment Utilizing a Miniature X-ray Tube, Edition 1.0 2011-04

ISCORS TECHNICAL REPORT 2008-1 Guidance for Security Screening of Humans Utilizing Ionizing Radiation (GSSHUIR) – July 2008

NCRP Commentary No. 16, Screening of Humans for Security Purposes Using Ionizing Radiation Scanning Systems, December 15, 2003

Matters for Future Consideration

With the advent of newer technology and RGDs that require special regulatory framework, SR-H should be revisited.

1988
Rationale for Revisions

Part H
Radiation Safety Requirements for Analytical X-Ray Equipment

Introduction

The Suggested State Regulations for Control of Radiation (SSRCR) Part H Working Group has carefully considered the items in the Matters for Future Consideration (MFC) of the last edition of Volume I (Ionizing Radiation) of the SSRCR. MFC No. 1 suggested that "chirper" type personal dosimeters be used by users of analytical x-ray units as warning devices. Tests of one such device and a review of the operating specifications of others suggests that these units are not suitable for this purpose. Item 1.b. suggested the use of leaded glasses be required. Although visual alignment techniques are sometimes used with analytical x-ray units, our knowledge of accident history indicates that most accidental exposures affect primarily the extremities, especially the fingers and hands. Item 1.c. regarding the use of leaded gloves was also considered. The Working Group does not know of any leaded gloves which would not interfere with the safe operation and/or adjustment of analytical x-ray units. In review of MFC No. 2, the Part H Working Group felt that the phrase "or words having similar intent" in Subparagraph H.3(f)(1) of the last SSRCR edition allows an appropriate substitute for "X-RAY ON" when radioactive materials are used. The Part H Working Group members are not aware of any situation where the words "X-RAY ON" were used inappropriately. The other suggestions in MFC No. 2 were either incorporated in Part H as indicated below, or were retained as a MFC.

Specific Changes

1. Paragraphs H.3(b) and H.3(f) were combined as they address the same matter.

2. Some paragraphs and a subparagraph of Section H.3 were redesignated for continuity.

Specific Provisions

H.3(b) Warning Devices was amended to include specific warning lights under warning devices. The new provision combines requirements for warning devices into the same paragraph.

H.3(f) Warning Lights (previous edition). The provisions of Paragraph H.3(f) were incorporated into Paragraph H.3(b) as stated above.

H.3(g) Radiation Source Housing (previous edition) was redesignated as Paragraph H.3(f) for continuity.

H.3(h) Generator Cabinet (previous edition) was redesignated as Paragraph H.3(g) for continuity.

Matter for Future Consideration

1. The SSRCR Technical Review Committee recommends that the Part H Working Group consider removal of all references to radioactive material so that Part H relates to machine-produced radiation only.

1982
Rationale for Revisions

Part H
Radiation Safety Requirements for Analytical X-Ray Equipment

Introduction

An intensive series of meetings during October 1979 was held at Rockville, Maryland, to discuss indicated changes as a result of comments by Part H Working Group members and others. An outcome of that session and further discussion has resulted in several changes detailed below; editorial changes have not been listed.

Specific Changes

1. Where "[licensee]*" has appeared following reference to a registrant in the past versions, a change to "[or licensee]" has been made. Rationale: Such a change makes the language universally adaptable to either machine or radioactive material sources and eliminates the use of any footnotes.

2. The word "interlock" appears for the first time in Part A of the 1982 Edition of the Suggested State Regulations for Control of Radiation (SSRCR) and denotes a specific type of safety device. Interlocks are applicable to other Parts of these regulations and the definition, therefore, was included in Part A.

Specific Provisions

H.3(g) Radiation Source Housing was reworded to specify an interlock to shut off an x-ray tube when removed from its housing or the housing disassembled (Subparagraph H.3(g)(1)). The dose rate allowable at 5 cm from the surface of any radiation source housing was kept the same as for x-ray tube housings, 2.5 mrem in one hour (Subparagraph H.3(g)(2)). Rationale: There have been reports of individuals removing x-ray tubes from their housings, when energized, and holding them in their naked hands. Virtually, the new language is the same language that was included as one of the only two changes in the April 1978 revision of NBS Handbook 111 (American National Standard "Radiation Safety for X-Ray Diffraction and Fluorescence Analysis Equipment"). Additionally, the same dose rate at 5 cm from the housing of both x-ray tubes and radioactive material sources was considered to be valid as the tubes are energized for protracted periods of time, simulating radioactive source conditions and presenting virtually identical dose potential.

H.5(c) Repair or Modification of X-Ray Tube Systems. This is a new paragraph to emphasize the importance of using the main instrument switch to prevent accidental exposure during repair or modification operations. Rationale: The new paragraph is almost

identical in wording to the language contained in one of only two changes in the April 1978 revision of NBS Handbook 111.

H.5(d) Radioactive Source Replacement, Testing, or Repair. This new paragraph requires that such operations be conducted only under a license from the NRC, an Agreement State, or a Licensing State. Rationale: This paragraph was added to provide specific safety considerations for radioactive material source apparatus maintenance operations comparable to what Paragraph H.5(c) does for x-ray tube apparatus.

Matters for Future Consideration

1. A suggestion recommended that an area monitor having an audio readout be provided in rooms where analytical x-ray equipment is used. Such an audible warning should alert a person entering the room to an exposed beam condition and could be added to Paragraph H.6(b). The testing of this suggestion has not been completed. In addition, the following allied matters have been conceived and should also be tested for applicability:

    a. The use of a suitable chirper device to be worn by personnel in lieu of the area monitor recommended.

    b. The wearing of protective glasses or goggles having leaded glass lenses.

    c. The wearing of protective gloves supple enough so as not to hinder operation of the analytical equipment.

2. The Technical Review Committee (TRC) felt the provisions of Paragraphs H.3(b) and (f) should be combined as they are addressing the same matters. Additionally, Subdivision H.3(f)(1)(ii) addresses radioactive material, and the TRC questions the applicability of the warning lights labeled "X-RAY ON" without other qualifications.

1978
Rationale for Revisions

Part H
Radiation Safety Requirements for Analytical X-Ray Equipment

Introduction

Part H was first made a part of the Suggested State Regulations for Control of Radiation (SSRCR) in the October 1974 Edition. On November 15, 1976, the Part H Working Group met with the Technical Review Committee (TRC) of the SSRCR to present the Working Group's recommendations for this revision. The rationale for changes which were adopted are presented below. It should be noted that there were many proposals presented to the Working Group which were excellent in nature, but which were not adopted because it was felt that they were either unenforceable or involved a concept which could not be written in precise legal terminology.

Specific Changes

H.2 Definitions

"Local components" has been defined due to concern that reference to "local components" in Section H.4 may not be accurately interpreted and could result in the lack of intended safety precautions.

"Analytical x-ray system" was modified to reflect the addition of the definition of "local components".

"Normal operating procedures" was altered to reflect the intent that all day-to-day procedures used by the operator should be included in the definition. The routine removal and replacement of shielding and barriers by the operator is meant to be included but not disassembly which would normally be performed by a maintenance person. Emergency radiation considerations were eliminated from this definition because it was not intended that bypassing interlocks should be considered to be a normal operating procedure. The revised definition includes "routine maintenance by the registrant" with the intent that normal troubleshooting which is performed by the operator should be a consideration. Thus, written normal operating procedures which are required in Paragraph H.5(a) are intended to include such actions as simple alignment and elimination of vacuum loss if these are performed by the operator.

H.4(b)(1)(i) Surveys. Requirements for radiation surveys were expanded to provide for a minimum frequency of at least one survey every 12 months. This provision was added to guard against changes in radiation levels which result from unauthorized equipment alterations.

H.(5)(b) Bypassing. Bypassing of safety devices may create a serious potential for injury, thus bypassing should never become a routine operating procedure. It is required that the safety device may not be bypassed

without the approval of the radiation safety officer. A further restriction has been added which will require that the approval be for a designated time period. This requirement is intended to discourage leaving a safety device in the bypass mode for unreasonable periods of time. For example, in certain situations it may not be reasonable to leave the safety device bypassed overnight.

Matter for Future Consideration

1. With reference to the bracketed material in Paragraph H.3(g) on Radiation Source Housing (i.e., [If radioactive sources are used, corresponding dose limits shall not exceed ____ per hour.]), it was suggested by the TRC of the SSRCR that the Part H Working Group for the next revision develop a dose rate limit value related to leakage radiation from the source housing when radioactive sources are used for inclusion in this paragraph.

1974
Rationale

Part H
Radiation Safety Requirements for Analytical X-Ray Equipment

Introduction and General Approach

X-ray diffraction and fluorescence analysis equipment are major tools in research, teaching, and quality control programs. It is estimated that there may be on the order of 5000 such units now in use. During the past few years the hazards associated with the use of this type equipment have been well documented. The high levels of radiation produced within this equipment and the lack of built-in safety features, particularly in older units, have frequently resulted in serious radiation injuries.

In 1972, the American National Standards Institute (ANSI) published the American National Standard "Radiation Safety for X-Ray Diffraction and Fluorescence Analysis Equipment" under the sponsorship of the National Bureau of Standards. The document establishes voluntary standard practices for this equipment. This ANSI Standard has been followed, where practical, in the preparation of Part H. In particular, the radiation levels established by the ANSI document and in Part H are essentially the same. However, the approach to determining the applicability of these radiation levels to a certain situation is quite different in this draft of Part H from that taken by ANSI. This deviation was deemed necessary in order to produce a regulation which is legally enforceable, whereas the ANSI document was intended as a voluntary guide of good practice. Part H is intended to be applicable to existing installations as well as to new installations.

It is intended that the operator of analytical x-ray equipment be considered to be an occupationally exposed individual and subject to the radiation dose limits specified in Section D.101. Other individuals in the vicinity of the analytical x-ray equipment shall not be considered to be occupationally exposed individuals and are, therefore, subject to the provisions of Section D.105, as indicated in Paragraph H.4(a).

Due to the great complexity of this equipment and variety of operational modes, it is difficult to write specific safety engineering requirements which do not overly restrict the use for which the equipment is intended. For this reason, provision is given in Paragraph H.3(a) to allow the registrant or licensee to apply to the regulatory Agency for an exemption from the safety device requirements in Part H. It is intended that such exemptions be granted only after all reasonable alternatives have been eliminated.

There are other types of analytical x-ray equipment (e.g., equipment employing absorption phenomenon) that could be included in this Part along with x-ray diffraction and fluorescence analysis equipment; however, the potential radiation exposure and radiation protection problems associated with the use of this equipment need further study. Therefore, the present provisions of this Part are limited to x-ray equipment used in x-ray diffraction and fluorescence analysis.

Specific Provisions

H.2(d) Definitions. Emergency radiation safety considerations have been included in the definition of "normal operating procedures". This is to avoid confusion in interpreting the difference between "routine" and "emergency". Such confusion could arise when an emergency procedure, such as bypassing of interlocks, must be undertaken on a frequent basis.

H.3(a) Safety Device. It is recognized that conditions may exist in which it may be extremely difficult to contain the primary beam without submitting the user to impractical limitations. This paragraph of Part H allows the registrant or licensee to apply for relief from this requirement provided he can show that all reasonable alternative engineering approaches have been considered and that the alternatives suggested seem feasible to the regulatory Agency.

H.3(b)(2) Warning Devices. Current analytical x-ray equipment normally utilizes warning devices provided with fail-safe characteristics. It is desirable to encourage this feature through purchase of modern equipment or retrofit safety devices; however, the effective requirement date is left to the discretion of the regulatory Agency.

H.3(e) Shutters and (f) Warning Lights. The rationale for requirements on shutters and warning lights is the same as that for warning devices Subparagrpah H.3(b)(2).

H.3(g) Radiation Source Housing and (h) Generator Cabinet. Leakage radiation limits for the x-ray tube housing and the x-ray generator cabinet are consistent with those of the ANSI standard. Corresponding dose limits for leakage radiation from equipment using radioactive sources are left to the option of the regulatory Agency.

H.4(a) Radiation Levels. The approach taken for limiting area radiation levels is different from that used in the ANSI Standard; but upon careful analysis, it may be seen that the limits using either approach are similar. The ANSI limits which are specified for various classes of x-ray systems are all traceable to the same values established by the National Council on Radiation Protection and Measurements and published in their NCRP Report No. 39 on Basic Radiation Protection Criteria. These values have not been adopted as yet by the Federal Radiation Council for use by all Federal agencies, and the radiation dose limits in Part D are based upon applicable Federal regulations. Therefore, rather than using the Maximum Permissible Dose Equivalent Values (Table 1), and other radiation dose limits as specified in area requirements of the ANSI standard, reference is made in Paragraph H.4(a) to the appropriate section in Part D. An approach different from that taken by ANSI was used because the ANSI approach seemed more applicable to new equipment and installations, whereas Part H is written to be applicable to new as well as existing equipment and installations.

H.4(c) Posting. Provisions in Section D.203 regarding radiation areas and high radiation areas may also be applicable in lieu of the posting requirement ("Caution - X-Ray Equipment") in Paragraph H.4(c).

There is no requirement in Part H for routine medical examinations because such a requirement seems impractical when considering types of injuries which have been caused by analytical x-ray equipment. In

addition to the possibility of genetic damage, there is the possibility of exposure of the lens of the eye to large radiation doses resulting in cataracts and other opacities. Although the damage from these types of injuries are not apparent or may not become apparent until years later, the majority of injuries from use of analytical x-ray equipment are apparent within a short time subsequent to the exposure, and would be followed up by a special medical examination, as compared to a periodic (routine) medical examination. An opthalmological examination, with particular reference to the lens of the eye would be useful. However, the majority of injuries resulting through use of analytical x-ray equipment are superficial and local in nature, and would not be detected by the usual tests included in a medical examination for ionizing radiation workers (e.g., blood cell examination)