2013 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.f. *As historically defined under 21 CFR 1020.40*

Section H.4.g. *From 21 CFR 1020.40(b)(3)).*

Section H.4.k. *IEC 62495*

Section H.4.l. *21 CFR 1020.20(b) Definitions*

Section H.4.m. *IEC 62495*

Section H.4.n. *ANSI 43.5 Definitions*

Section H.4.q. *ANSI 43.2 Definitions*

Section H.4.r. *ANSI 43.17 Definitions*

Section H.4.s. *IEC 62495*

Section H.4.t. *Oregon Administrative Rules, Division 115:* Radiation Safety Requirements for X-ray & Hybrid Gauges, *333-111-0005(4) (definitions).*

Section H.4.v. *IEC 62495*

Section H.4.x. *IEC 62495*

Section H.4.y. *ANSI 43.17 Definitions*

Section H.4.z. *From Part H of the Suggested State Regulations, 1991 revision*

Section H.4.bb. *From Part H of the Suggested State Regulations, 1991 revision*

Section H.4.cc. *IEC 62495*

Section H.4.gg. *IEC 62495*

Section H.4.mm. *ANSI N43.2 3 Definitions*

Section H.4.nn. *ANSI N43.2 3 Definitions*

Section H.4.qq. *IEC 62495*

Section H.4.tt. *ANSI N43.5 2. Definitions*

Section H.4.ww. *IEC 62495*

Section H.4.xx. *IEC 62495*

Section H.4.yy. *ANSI N43.2 3 Definitions*

Section H.4.zz. *ANSI N43.2 3 Definitions*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section H.7.e. *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.8.a *See ANSI N43.2 6.2.2.2.3*

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

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

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

Section H.8.k. *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.9.a. *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

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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.