



Security Imaging Systems (X-Ray): Design, Measurements Regulations, and Standards

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Topics

- Design
- Measurements
- U.S. Radiation Safety Regulation & History
- NCRP commentary no. 16 *Screening of Humans for Security Purposes Using Ionizing Radiation Scanning Systems* [December 2003]
- ISCORS Technical Report - *Guidance on Security Screening of Humans Using Ionizing Radiation* [August 2008]
- ANSI/HPS American National Standard N43.17-2009 *Radiation Safety for Personnel Security Screening Systems Using X-ray or Gamma Radiation* [Original 2002, Revision November 2009]
- ANSI/HPS N43.16-20XX *Radiation Safety for X and Gamma Ray Cargo and Vehicle Security Screening Systems, Energies Up To 10 MeV* [Draft nearly complete]
- Other Standards



Design: General-use Full-Body X-ray Security Screening Systems (1)

- X-ray source – moves vertically
- Slit collimator + Rotating chopper wheel with small slits
- Tiny beam area – ~ 0.7 to 1.5 millimeter (mm) length and width
- Beam scans horizontally
- Raster scan of individual ~ 3 to 8 seconds per scan
- Large sensitive detectors
- Image formed from backscatter



Design of General-use Full-Body X-ray Security Screening Systems (2)

- Exposure parameters can **not** be altered by operators (tube potential, tube current, speed of beam, etc.)
- Any parameter which can affect dose to subject required to be interlocked to remain within specification
- Deviation from specification with interlock failure would produce an obviously inadequate image - can not fail in undetectable manner
- Dose is low because exposure time at any one point approximately 70 microseconds
- Minimum of 1 mm aluminum equivalent filtration required

 **Measurements**

- Measure air kerma (or exposure)
- Instrument selection
 - Integrating mode
 - High sensitivity
 - Low energy dependence
 - Large non-pressurized ion chamber (1,500 cc or larger) preferred
 - Complex geometries require symmetrical (cylinder or sphere) chamber
 - Electrometer should have:
 - At least a 0.1 picocoulomb (pC) resolution
 - Capability to measure a pulse of charge of 5 pC magnitude and 10 ms duration within $\pm 10\%$ accuracy
 - Preferably does not perform automatic background subtraction
- Determine half-value layer of the beam
- See N43.17-2009 annex C for more information

 **Ion vs. OSL***

- Ion chamber: reference effective dose $\sim 0.033 \mu\text{Sv}$ (3.3 μrem)
- OSL dosimeters: average deep dose equivalent $0.038 \mu\text{Sv}$ (3.8 μrem)

* Results from *Potential Doses to Individuals Screened with Whole-Body Security Screening Systems: OSL Dosimeter Measurements*; Army Institute of Public Health; Craig R. Jones & Fran Szrom; 2011



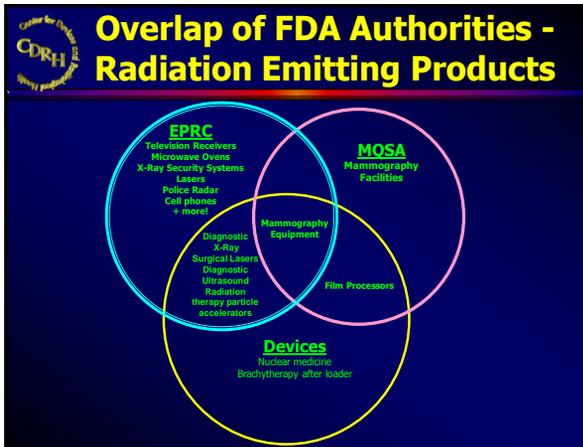
 **U.S. Regulation of Radiation Emitting Products**

- Radioactive material (ionizing)
 - Licensed by 
- Electronic products (ionizing & non-ionizing)
 -  = regulation of **manufacturers**
- State regulators &  = regulation of **use**

 **Law and Regulations**

- Electronic Product Radiation Control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act
 - United States Code (USC) Title 21, Chapter 9, Subchapter V, part C, sections 360hh – 360ss
- Title 21 Code of Federal Regulations (CFR) § 1000 – 1050





FDA Regulation of Electronic Products

- All manufacturers of electronic products
 - Report accidental radiation occurrence [Title 21 CFR § 1002.20]
 - Notify FDA of radiation safety defect or failure to comply with applicable mandatory performance standard [Title 21 CFR § 1003]
- All manufacturers of non-medical ionizing products
 - Radiation safety report, annual report, and required records [Title 21 CFR § 1002]

Performance Standards

- 21 CFR § 1020.10 Television Receivers
- 21 CFR § 1020.20 Cold-cathode Discharge Tubes
- 21 CFR § 1020.30 Diagnostic X-ray Systems & their major components
 - 21 CFR § 1020.31 Radiographic equipment
 - 21 CFR § 1020.32 Fluoroscopic equipment
 - 21 CFR § 1020.33 Computed tomography (CT) equipment
- 21 CFR § 1020.40 Cabinet X-Ray Systems
- 21 CFR § 1030.10 Microwave Ovens
- 21 CFR § 1040.10 Lasers and Laser Systems
 - 21 CFR § 1040.11 Specific Laser Products
- 21 CFR § 1040.20 Sunlamps and Sunlamp Products
- 21 CFR § 1050.10 Ultrasonic Therapy Products
- 21 CFR § 1040.30 High-intensity Mercury Vapor Discharge Lamps

Before Entry into Commerce

- Design & manufacture products which can be used **safely**
- Submit radiation safety report to FDA

And when a specific performance standard applies:

- Design & manufacture products to comply with all applicable performance standards
- Manufacturer certifies product meets requirements of all applicable performance standards
 - Certification must be based on mfr's quality control & testing program
 - Certification label or tag permanently affixed to product

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Defect Definition **DANGER!**

A radiation safety defect exists in products:

- Which rely on the radiation emission to accomplish their purpose when the product:
 - Fails to meet its design specifications for radiation emission
 - Emits radiation that is unnecessary which creates a risk of injury
 - Fails to accomplish its intended purpose
- Stating conformance to consensus standard = standard becomes product specification
- Defect applies to risks caused as a result of design, production, or assembly

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Pre-Standard People Screening X-ray Systems



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History – X-ray People Screening (1)

- May 14, 1984 – CDRH responded negatively to inquiry about x-ray security scanners used outside the U.S.
 - Not permitted: no direct benefit to screened individual
 - Must meet the medical diagnostic x-ray standard
- May 22, 1990 – First inquiry about extremely low dose product
- 1990, International Commission on Radiological Protection (ICRP) report 60 – concept of societal benefit

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History – X-ray People Screening (2)

- Aug. 17, 1992 CDRH acknowledged mfr. had complied with reporting requirements
 - Discussed within CDRH
 - Many questions asked and answered
 - Independent test results (Sandia National Laboratory)
- 1998 – 2003 Public meetings with FDA's Technical Electronic Product Radiation Safety Standards Committee
- April 1999 Accredited Standards Committee N43, *Equipment for Non-Medical Radiation Applications* working group convened
- July 2002 Consensus standard published, N43.17-2002



History – X-ray People Screening (3)

- Sept. 2002 FDA asked NCRP to comment
- 2003 NCRP Commentary No. 16, *Screening of Humans for Security Purposes Using Ionizing Radiation Scanning Systems*
- October 2003 Request for guidance on appropriate use to Interagency Steering Committee on Radiation Standards (ISCORS)
- May 2006 N43 working group starts revision of standard



History – X-ray People Screening (4)

- July 2006 CDRH Assessment of the *Rapiscan Secure 1000® Body Scanner for Conformance with Radiological Safety Standard for TSA*
- July 2008, ISCORS published *Guidance for Security Screening of Humans Utilizing Ionizing Radiation*
- November 2009, N43 publishes revised standard N43.17-2009
- August 2010 (original October 2009), Johns Hopkins University Applied Physics Laboratory *Radiation Safety Engineering Assessment Report for the Rapiscan Secure 1000 in Single Pose Configuration*



NCRP Commentary (2003)

- NCRP Commentary No. 16 - *Screening of Humans for Security Purposes Using Ionizing Radiation Scanning Systems*
- General-use:
 - Less than 0.10 μSv effective dose for a front scan (limit in N43.17-2002)
- Limited-use:
 - Users must limit any one individual to maximum of 250 μSv per year
 - Greater than 0.10 μSv and less than 10 $\mu\text{Sv}/\text{scan}$
 - Used with discretion



GSSHUIR (2008)

- ISCORS* Technical Report - *Guidance on Security Screening of Humans Using Ionizing Radiation* [Published July 2008]
 - How to evaluate the justification of a security practice
 - Considerations for optimization of radiation safety
 - Example radiation safety program
 - References to radiation safety publications and organizations

* U.S. Interagency Steering Committee on Radiation Standards

People Screening X-ray Systems

Stationary subject: general-use




Limited-use



Portals



Partial-body: casts & prostheses




Revised ANSI/HPS Standard N43.17-2009

- N43.17-2009 *Radiation Safety for Personnel Security Screening Systems Using X-ray or Gamma Radiation*
 - Published November 2009
- Expanded to address
 - General-use systems
 - Limited-use systems
 - Partial-body systems
 - Stationary, portal, and multi-mode configurations

ANSI/HPS N43.17-2009 Subject Dose Limit

- General-use full-body dose limits:
 - **0.25 μSv** (25 μrem) reference effective dose per screening
 - **250 μSv** (25 mrem) in one year
- Limited-use full-body dose limits:
 - **10 μSv** (1 mrem) reference effective dose per screening
 - **250 μSv** (25 mrem) in one year

Limited-Use

- General-use requires engineered safety features to assure dose limits
- Limited-use
 - Administrative controls critical to assuring safety
 - Burden on user to document annual dose or potential annual dose to subjects

 **Ambient Dose Equivalent Area Product (ADAP)**

$ADAP = H^*(10) \times \text{scanned area}$

- **General-use partial-body:**
 - Limit of $0.03 \mu\text{Sv m}^2$ ($3 \mu\text{rem m}^2$) per scan
 - Limit of N scans in any 12 month period
 - $N = 75 \mu\text{Sv m}^2/\text{ADAP}$ ($7,500 \mu\text{rem m}^2/\text{ADAP}$)
- **Limited-use partial-body**
 - Limit of $3 \mu\text{Sv m}^2$ ($300 \mu\text{rem m}^2$) per scan
 - Limit of N scans in any 12 month period
 - $N = 75 \mu\text{Sv m}^2/\text{ADAP}$ ($7,500 \mu\text{rem m}^2/\text{ADAP}$)

 **General-Use Subject Dose Limit**

2002 → **2009**

- **Subject dose limit: one configuration & imaging mode**
 - $250 \mu\text{Sv}$ (25 mrem) per year
 - Effective dose per front scan $0.1 \mu\text{Sv}$ ($10 \mu\text{rem}$)
- **Subject dose limit: consistent for all configurations & imaging modes**
 - $250 \mu\text{Sv}$ (25 mrem) per year
 - Reference Effective Dose of $0.25 \mu\text{Sv}$ ($25 \mu\text{rem}$) per screening
 - 4 scans for backscatter
 - 1 scan for transmission

 **Dose Measurement**

2002 → **2009**

- Measurement conversion based on peak tube potential
- Conversion tables included but not required
- Simple geometry = effective dose calculation practical
- Measurement conversion based on half-value layer
- HVL can be measured
- Complex geometries = effective dose calculation not practical
- Reference effective dose - required
 - $EREF = K_a \times C$
 - K_a is the measured air kerma in Gy
 - C in Sv/Gy is $0.125 \times \text{HVL}$ or 1.14 , whichever is smaller
 - Comparable

 **ANSI/HPS N43.17 Additional Dose Limits**

- Radiation emission (other than primary beam) $< 2.5 \mu\text{Sv}$ (0.25 mrem) in any hour
- Bystander protection:
 - Outside inspection zone $< 20 \mu\text{Sv}$ (2 mrem) in any one hour
 - Nearby work locations $< 1 \text{ mSv}$ (100 mrem) per year (based on occupancy and other factors)

 **Draft ANSI/HPS N43.16**

- ANSI/HPS N43.16 *Radiation Safety for X and Gamma Ray Cargo and Vehicle Security Screening Systems, Energies Up To 10 MeV*
- ANSI/HPS N43.16 establishes
 - Required engineered safety features
 - Requirements for installation
 - Dose limits
 - Required administrative controls for use

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 **Vehicles + People**

N43.16 & N43.17 apply – driver present & exposed to primary beam



N43.16 applies & N43.17 does not apply – primary beam prevented from directly exposing driver and passengers



 **Other Standards**

- **IEEE C95.1-2005** *Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz*
- **IEC 62463** Ed.1: Radiation protection instrumentation – *X-ray systems for the screening of persons for security and the carrying of illicit items*
- **ANSI / IEEE N42.47-2010** *American National Standard for Measuring the Imaging Performance of X-ray and Gamma-ray Systems for Security Screening of Humans*

 **Reports on Ionizing Radiation Health Effects**

- *Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2 (2006)*
- NCRP report no. 115 *Risk Estimates for Radiation Protection*
- NCRP report no. 116 *Limitation of Exposure to Ionizing Radiation (1993)* recommends annual limits on radiation dose for the general public.



More Information

- ANSI / HPS N43 Radiation Safety Standards: <http://hps.org/hpssc/>
- ISCORs - GSSHUIR: <http://www.iscorg.org/library.htm>
- NCRP Commentary No. 16 - *Screening of Humans for Security Purposes Using Ionizing Radiation Scanning Systems*:
<http://www.ncrppublications.org/index.cfm?fm=Product.AddToCart&pid=8182473315>
- FDA Electronic Product Radiation Control - Products for Security Screening of People:
<http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/SecuritySystems/ucm227201.htm>
- Potential Doses to Individuals Screened with Whole-Body Security Screening Systems: OSL Dosimeter Measurements – Army Institute of Public Health
http://s3.amazonaws.com/propublica/assets/docs/ArmyPHC_Dose_to_Screened_Individual_OSL_Measurements_with_Notes.ppt