Radiography and Fluoroscopy X-ray Systems

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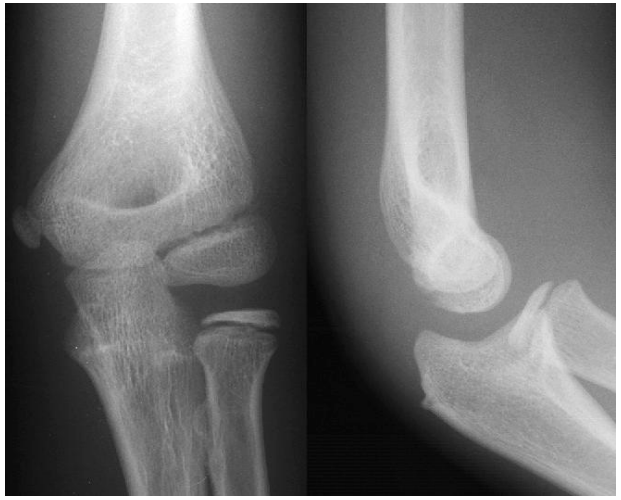
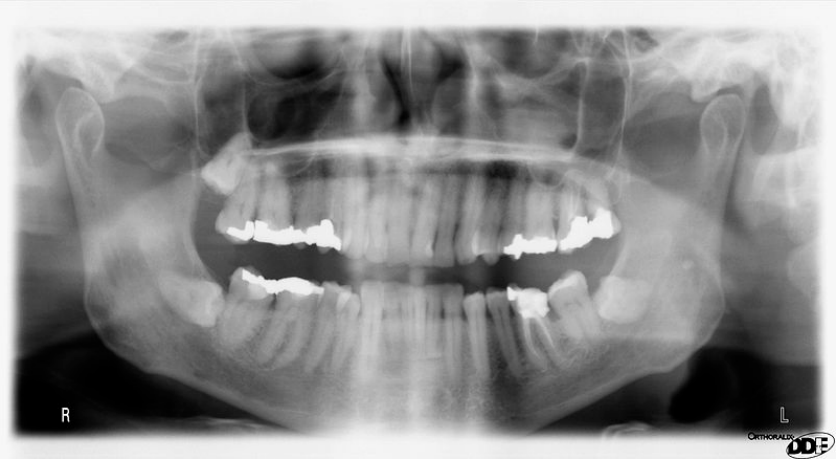
Technical Electronic Product Radiation Safety Standards Committee Meeting, October 25-26, 2016

Diagnostic X-ray: Product Overview

- **Radiography/Dental**
- Fluoroscopy/Interventional
- Hand-held radiographic units
- Third party components





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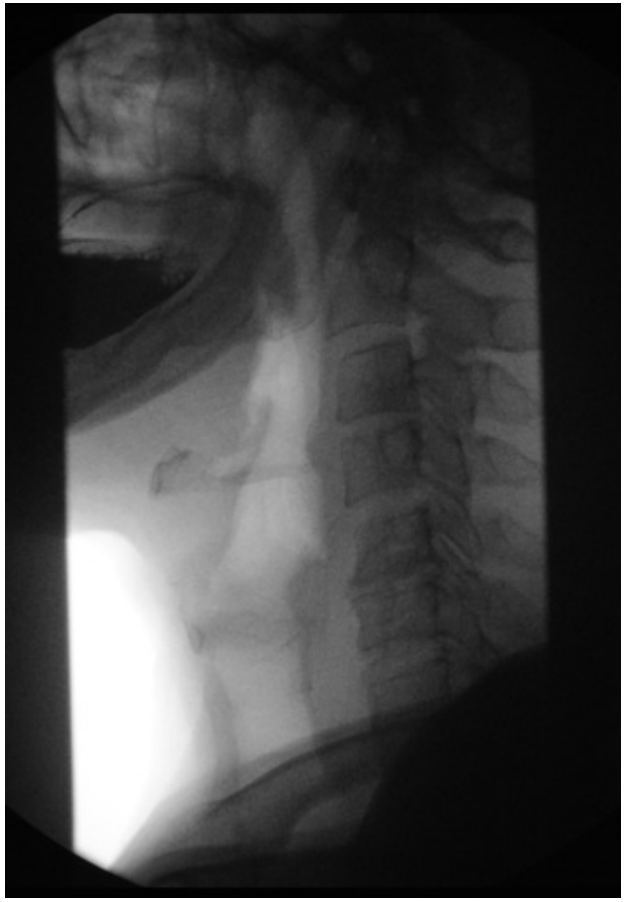

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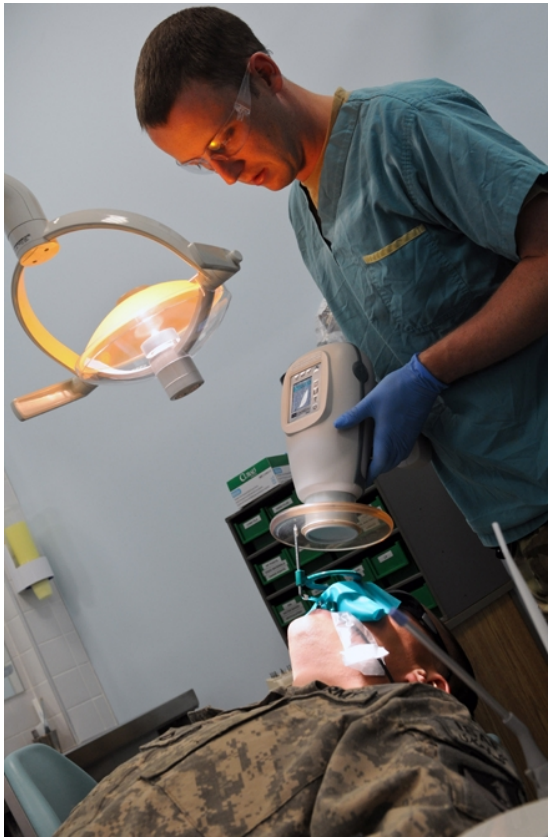
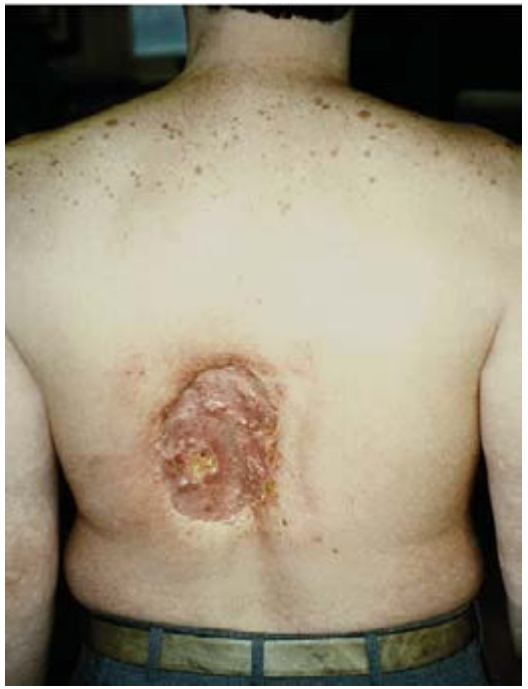


Radiation Safety Concerns

- Tissue reactions
  - Acute radiation injuries from interventional procedures
- Stochastic
  - Patient dose
  - Operator dose



Shope TB. "Radiation-induced skin injuries from fluoroscopy," RadioGraphics. 16: 1195-1199, 1996.

Performance Standards

- 21 CFR 1020.30 Diagnostic x-ray system and their major components
- 21 CFR 1020.31 Radiographic equipment
- 21 CFR 1020.32 Fluoroscopic equipment
- 2005 Amendment
  - Mode of operation description and user instructions
  - Display of fluoroscopy time
  - Air Kerma (dose) meters
  - Schedule of maintenance

What are FDA's Current Concerns

- Inadequate quality control information for end user
- Availability of protocols and descriptions for imaging different-sized patients
- Insufficient shielding for hand-held x-ray systems
- Inadequate integration information for third party certified components
- Reporting of radiation dose

International Consensus Standards

- IEC 60601-2-54 Radiography and Radioscopy
- IEC 60601-2-43 Interventional X-ray Equipment
- IEC 60601-2-63 Extra-Oral Dental Equipment
- IEC 60601-2-65 Intra-Oral Dental Equipment

What would FDA like to do?

- Require certain features (already in existing or proposed IEC standards)
  - Manufacturer defined quality control procedures in the user manual
  - Requirement for Physics Mode
  - Easily removable anti-scatter grid
  - Size-specific presets (unless AEC present)
  - Radiation Dose Structured Report

What would FDA like to do?

- Require additional features (not in IEC standards)
  - Standardized quality control tests
  - User access control
  - Descriptions of parameters affecting dose/image
  - Skin dose mapping for interventional fluoroscopy equipment

What would FDA like to do?

- Consider a performance standard for hand-held x-ray radiography units
- Ensure hand-held devices include safety features
  - Shield the unit housing and identify necessary safety precautions
  - Provide shielding or a means to increase distance between the operator and unit

What would FDA like to do?

- Address integration issues with third-party certified components
  - Third-party certified components (x-ray detector with software to control the generator) may affect quantity, quality, or direction of radiation
  - Clarify how connections are made
  - Provide a list of compatible systems in labeling

Questions for Committee

- What is your opinion on the value of requiring manufacturers to include a QC phantom with radiographic and/or fluoroscopic x-ray systems free of charge similar to CT?

Questions for Committee

- What is the committee's opinion on including the proposed features above for radiography and fluoroscopic systems in a performance standard?

Questions for Committee

- Are there additional safety improvements that should be pursued for radiography and fluoroscopy?

Questions for Committee

- What information is necessary to ensure adequate integration of third-party certified components?
- Should third-party component integration issues be addressed in a performance standard?

Questions for Committee

- What is the committee's opinion on the importance of regulating hand-held x-ray systems through a specific performance standard?
- Does the committee have any additional concerns with the use of hand-held devices?

Questions for Committee

- Should FDA include requirements for Radiation Dose Structured Reports (RDSRs) for all imaging equipment that generates ionizing radiation (radiography, fluoroscopy, CT, and dental cone-beam CT (CBCT) in the performance standards?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