Radiography and Fluoroscopy
X-ray Systems

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Diagnostic X-ray: Product Overview

- Radiography/Dental
- Fluoroscopy/Interventional
- Hand-held radiographic units
- Third party components
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Diagnostic X-ray: Product Overview

• Radiography/Dental
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Radiation Safety Concerns

• Tissue reactions
  – Acute radiation injuries from interventional procedures

• Stochastic
  – Patient dose
  – Operator dose

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?