The New IEC/FDA Regulatory Paradigm for X-ray Devices: FDA Perspective

AAPM Spring Clinical Meeting
March 30, 2019
Robert Sauer
U.S. Food and Drug Administration
CDRH’s Mission

The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

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CDRH Director
Two sets of FDA regulations apply to X-ray systems

**Medical Devices**
- Quality Systems
- Adverse Event Reporting
- Recalls
- 510(k) Premarket Submission

**Electronic Products**
- Certification & Testing Program
- Accidental Radiation Occurrence Reports
- Notification of Defects
- Reporting Requirements*

X-ray System Radiation Safety

[Links](https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm)
[Links](https://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/default.htm)
FDA hasn’t significantly updated the CT performance standard since 1984
Consensus standards organizations like IEC publish updates regularly

1984
FDA Establishes CT Performance Standard

1999
IEC publishes 60601-2-44 Version 1.0

IEC 60601-2-44: Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
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- **2001**
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- **Today**

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- **2009**
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- **2016**
  - IEC publishes 60601-2-44 Version 3.2

IEC 60601-2-44: Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography.
IEC standards have many advantages

• Broad membership

• Standards stay current

• Harmonized with other countries
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To improve safety, FDA is encouraging the use of IEC standards

- Voluntary program for manufacturers of diagnostic x-ray equipment to choose IEC over EPRC Standard
- Leverages existing FDA standards program
- Maintain strong enforcement capabilities
- Keeps comprehensive medical device premarket review
To improve safety, FDA is encouraging the use of IEC standards

- Manufacturers opt-in with a declaration of conformity to a recognized standard
- FDA will enforce the radiation safety specifications in the standard to which they declare conformity
- Scope:
  - Radiographic Equipment
  - Fluoroscopic Equipment
  - Computed Tomography Equipment
  - Components
Guidance comments highlighted practical issues

• Implementation and enforcement by FDA

• Ensuring users have appropriate information to test these systems
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• Implementation and enforcement by FDA
  Outreach around FDA standards program and EPRC enforcement
• Ensuring users have appropriate information to test these systems
  Providing more information to end users
CDRH has over 20 years of experience with our standards program

- Started in 1997
- Frequently used to meet premarket requirements for many types of devices
- Many x-ray systems already conform to these standards
FDA’s standards program is robust and flexible

- Active participation in standards development
- Flexible recognition process
- Transparency
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• Active participation in standards development

• **Flexible recognition process**

• Transparency

- Full Recognition
- Partial Recognition
- Non-recognition
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Federal Register Notice
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Online Standards Database

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm
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FDA is maintaining strong enforcement capabilities

- Continue to receive premarket submissions
- Monitoring adverse events & safety signals
- Collaborating with investigators in the Office of Regulatory Affairs
- Declaring conformity to an IEC standard sets radiation safety specifications for an electronic product
- FDA has authority to enforce compliance with radiation safety specifications that the manufacturer sets
Guidance comments highlighted practical issues

• Implementation and enforcement by FDA
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• Ensuring users have appropriate information to test these systems
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FDA asked for help coming up with a solution

• Met with state regulators and medical physicists to better understand their needs
• Discussed with manufacturers and end users what was practical
• Proposed solutions went through many iterations
Manufacturers will fill in the gaps

Manufacturers will provide a radiation safety specification and testing document that includes:

• The radiation safety specifications that apply to the device, where those specifications would not otherwise meet the comparable EPRC performance standards;
• The IEC document number, version, and specific clause(s) under which each such specification may be found;
• The EPRC performance standard requirement being replaced by the IEC standard; and
• The test method and acceptance criterion.
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- Leverages existing FDA standards program
- Maintain strong enforcement capabilities
- Ensure end users have the information they need
Thank You