

IEC Standards vs. Performance Standards for Medical Devices

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Overview

- We propose accepting conformance with IEC standards in lieu of conformance to certain EPRC performance standards
- Questions:
 - Benefits and challenges with this approach
 - Voluntary vs mandatory
 - Extension to other electronic products/medical devices

International Electrotechnical Commission (IEC)



- Standards development organization (SDO)
 - Develops and publishes international standards on electrical, electronic, and related technologies
 - Voluntary consensus standards
 - Membership composed of National Committees
 - 61 Full Members, 23 Associate Members

International Electrotechnical Commission (IEC)



- Standards work is carried out through technical committees, each dealing with a particular subject, composed of experts from the Full Member National Committees.
- Representatives from industry, academia, consumers, and government
- National committees vote on approval of each standard
- IEC standards are published with stability dates to ensure regular review

Outline

- Scope
- Current Approach to Performance Standards
- IEC standards
- US Government Policy on Voluntary Consensus Standards
- Proposed Approach
- Benefits of Proposed Approach
- Impact on Stakeholders
- Questions



Scope: Electronic Products and Medical Devices

- X-Ray Imaging Medical Devices
- Electronic Product Radiation Control (EPRC) Program - to protect the public from hazardous and unnecessary exposure to radiation from electronic products
- Medical Devices – Risk based classification system that includes general controls, special controls, and/or premarket approval to ensure device safety and effectiveness

Current Approach to Performance Standards



- EPRC Performance Standards for diagnostic x-ray systems
 - Diagnostic x-ray systems and their major components (21 CFR 1020.30)
 - Radiographic Equipment (21 CFR 1020.31)
 - Fluoroscopic Equipment (21 CFR 1020.32)
 - Computed Tomography (CT) Equipment (21 CFR 1020.33)
- Certification of Compliance
- Initial Product Report
- Annual Reports
- Additional Requirements

Limitations of Current Approach

- EPRC performance standards are updated infrequently
 - Diagnostic x-ray systems and their major components: 2007
 - Radiographic Equipment: 2005
 - Fluoroscopy Equipment: 2005 with minor amendments in 2015
 - Computed Tomography Equipment: 1984
- EPRC performance standards are limited to radiation protection
- Duplication of information submitted to FDA

IEC Standards

- **IEC 60601-1-3:** Radiation protection in diagnostic X-ray equipment
- **IEC 60601-2-28:** X-ray tube assemblies for medical diagnosis
- **IEC 60601-2-43:** Interventional procedures
- **IEC 60601-2-44:** Computed tomography
- **IEC 60601-2-45:** Mammographic X-ray equipment
- **IEC 60601-2-54:** X-ray equipment for radiography and radioscopy
- **IEC 60601-2-63:** Dental extra-oral X-ray equipment
- **IEC 60601-2-65:** Dental intra-oral X-ray equipment

Standards Analysis

- EPRC regulations were compared to IEC standards
- For some requirements, EPRC is more restrictive, for some it is less restrictive
- We determined that IEC standards provide equivalent or better assurance of safety

FDA Involvement in IEC work

- IEC standards are updated on a regular basis
- FDA participates actively on IEC committees
- Existing FDA recognition program for consensus standards:
 - FDA can recognize these standards in whole or in part

OMB Circular A-119

- Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities (revised January 27, 2016)
- **“all Federal agencies must use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical.”** [Emphasis added]
- Basis in treaty obligations and Federal law

https://www.whitehouse.gov/omb/circulars_a119

OMB Circular A-119



- “...agencies should work closely with SDOs to determine appropriate access to the standards for stakeholders”
- “OMB encourages agencies to work closely with SDOs to ensure agencies are aware of, and thus able to consider, updates and alternatives to existing standards.”
- “OMB recognizes that agencies may have good reasons for not using the most recent version of a standard”

Proposal

- We propose accepting conformance with IEC standards in lieu of conformance to certain EPRC performance standards
- FDA would consider a manufacturer that submits a declaration of conformity to applicable IEC standards to have met certain EPRC performance standards and reporting requirements
- Meets requirements of OMC Circular A-119

Benefits

Conformance to applicable IEC standards would provide the same level of or improved protection of the public health and safety from electronic radiation as certain EPRC performance standards.

- Testing for radiation safety stays current
- IEC standards are more comprehensive
- Convergence of radiation safety regulatory frameworks with EU and China
- Reduce overlapping information in multiple submissions
- Fewer submissions for industry

Impact on Stakeholders

- Patients –
 - equipment is performance-tested according to comprehensive, modern safety standards
- Industry–
 - fewer submissions
 - consistent with regulations in EU and China

Impact on Stakeholders

- FDA
 - Review divisions – minimal impact on workflow
 - Field investigators – requires training on new, but similar performance standards
- States
 - Have included EPRC performance standards in state law, and inspect accordingly
 - Working with Conference of Radiation Control Program Directors

Summary

- Proposal to accept conformance with IEC standards in lieu of some EPRC performance standards
- Conformance to applicable IEC standards would provide the same level of or improved protection of the public health and safety from electronic radiation as certain EPRC performance standards.
 - Increase patient safety
 - Decrease regulatory burden on industry
- Federal law and policy point towards this

Questions

- What benefits and challenges do you see in the proposal to accept conformance and declaration of conformity to applicable recognized IEC standards in lieu of conformance to FDA performance standards and FDA product reporting requirements?

Questions

- How do these benefits and challenges change if the policy to accept conformance to IEC standards were implemented as a mandatory requirement instead of as an option for manufacturers?

Questions

- There are other electronic products that are also medical devices but lack EPRC performance standards (e.g., MRI systems). If there are IEC standards for safety and performance for these products, how should FDA approach the implementation of new performance standards?

