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### FDA Guidance on transition from EPRC to IEC

#### Medical X-Ray Imaging Devices Conformance with IEC Standards

**Guidance for Industry and Food and Drug Administration Staff**


The draft of this document was issued on August 3, 2016.

**WHY?**

- “…to ensure consistent and efficient regulatory review”
- FDA determined conformance to IEC standards provides at least as much protection to public health and safety as conformance to existing standards
- Updating federal regulations is slow (Radiographic equipment standards last updated in 2005)
- IEC standards are considered “Consensus Standards” and have regular updates

- **Electronic Protection Radiation Control Regulations:**
  - Aimed “… at protecting the public from hazardous and unnecessary exposure to radiation from electronic products.”
  - Performance standards for X-ray imaging devices and their components
  - Major categories are:
    - 21 CFR 1020.30: Diagnostic x-ray systems and their major components
    - 21 CFR 1020.31: Radiographic equipment
    - 21 CFR 1020.32: Fluoroscopic equipment
    - 21 CFR 1020.33: Computed tomography (CT) equipment

- Applies to new equipment (not retroactive)
- Applies only to Medical X-Ray Imaging devices
- Manufacturers have option to claim conformance to certain IEC standards in lieu of The Electronic Product Radiation Control (EPRC) section performance standards in 21 CFR
- Does NOT apply to Radiation Therapy equipment as there are no EPRC regulations on these (covered by 510K process)
FDA Guidance on transition from EPRC to IEC

Table 3 – EPRC requirements deemed to be met based on conformity to applicable IEC standards:

|---------------------|---------------|--------------------------------------------------------------------------------|------------------------------------------------------------------|----------------|---------------------------------|---------------------------------|----------------|---------------------------------|

If manufacturer claims conformance to IEC standards should:
• Include in the instructions for Assembly, Installation, Adjustment and Testing (AIAT) a comparison document on radiation safety and testing between IEC and EPRC standards.
• The document should enable a physicist or state inspector to determine if system complies with IEC or EPRC standards.
• Documents will be publicly available through MITA website (medicalimaging.org).

FDA Guidance on transition from EPRC to IEC: WHAT IT MEANS FOR YOU

• At acceptance testing: confirm equipment meets applicable EPRC or IEC standards.
• Annual/QA: follow accrediting body and regulatory agency guidance (CMS, TJC, ACR, State, etc.).
• Some states reference FDA standards, so may need to test to EPRC or IEC standards as per state guidelines after acceptance.

Updates on IEC 62B Standards

• Further updates as guidance is implemented and used
• AAPM partnering with stakeholders (FDA, MITA, CRCPD) to work on smooth transition
Updates on IEC 628 Standards: Active Projects (7/12/19)

IEC 62853-2:2017 ED1: Medical electrical equipment - Medical image display systems - Acceptance and constancy tests (11/20 in CD stage).


Updates on IEC 628 Standards: Completed Recently


Updates on IEC 628 Standards: Significant Clinical Impact Standards

IEC 62841-1:2016 Ed 1.0 (2008-08-13) Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography

- Defined Exposure Index (EI) and Deviation Index (DI) in General Radiography
- Widely adopted across manufacturers
- DI calculated using EI (determined from pixel values of interest in the image) and Target EI for exam
- DI intended to provide universal value of over/under exposure - difficult to achieve
- If action limits are set on DI for repeats, the particular for each practice, piece of equipment and protocol need to be taken into account

Rush University, Systems for Health | 7/15/2019
Recent Standards with direct impact on practice of medical physics

**IEC 60801-2-44:2016:** Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

- Key element in standard is requirement of display and recording of reference point air kerma (K_{air}^p)
- Cumulative reference point air kerma identified by Society of Interventional Radiology as useful metric to identify if patient may need follow up for possible radiation burn (typically K_{air}^p ~ 5 Gy)
- A better metric for potential tissue reactions from radiation dose than fluoroscopy time as it incorporates dose from Cine/DSA/3D acquisitions.

Recent Standards with direct impact on practice of medical physics

**IEC 60601-2-44:2009-AMD2:2016:** Amendment 2 - Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography

- Amendment includes new approach to calculate CTDL_{air} large cone beam (> 40 mm) geometries
- Beam geometries (nT ~ 40mm) include scatter not captured in CTDL_{phantoms} and 100 mm chamber
- Correction factor to CTDL_{air} measured in a phantom requires measurement of dose in air using ion chamber
- Correction is ratio of dose in air using 100mm ion chamber at (nT)40 mm to (nT) < 40 mm
- Further updates to this correction factor may be coming

Updates on TC87 Standards

**TC 87 Ultrasound**

- **WG 3:** High power transducers
- **WG 6:** High intensity Therapeutic Ultrasound (HITU) and Focusing transducers
- **WG 7:** Surgical and therapeutic devices
- **WG 8:** Ultrasonic field measurement
- **WG 9:** Pulse-echo diagnostic equipment
- **WG 14:** Determination of ultrasound exposure parameters
- **WG 15:** Underwater Acoustics
- **JWG 38:** Ultrasound Therapeutic Equipment Managed by SC 69D

TC87 Work Program

**IEC 61835-20:** Ultrasound - Focusing transducers - Definitions and measurement methods for the transmitted fields (CDV 7/19)

- **IEC TR 61390-20:** Ultrasound - Real-time pulse-echo systems - Test procedures to determine performance specifications (CD 5/20)
- Upcoming standards work:
  - Upgrade IEC60601-2-44 ed 1.0 to 2.0 (2015-09) to 10 low-esd-sphere phantom and method for performance testing of gyn-scale medical ultrasound scanners applicable to a broad range of transducer types.
  - Revision of IEC60601-2-44 ed 1.0 (1998-07) to test procedure to determine performance specifications (action: revise Annex C)
  - IEC60601-2-44 ed 2.0 (2016-06) for basic methods for periodic testing to verify stability of an imaging system's elementary (action: extend the stability data for 3 years without changes and to advance to IS with inclusion of additional work on monitor display testing and Dicom-tag)

**TC 87 Standards of note**

**IEC 60826-1:2015:** Edition 1.0 (2019-09-06)

- Ultrasound - Pulse-echo scanners - Low-esd-sphere phantom and method for performance testing of front-scale medical ultrasound scanners applicable to a broad range of transducer types

**IEC 60826:2016:** Edition 1.0 (2016-07-12)

- Ultrasound - Pulse-echo scanners - Simple methods for periodic testing to verify stability of an imaging system's elementary performance

**IEC 61289:1999:** Edition 1.0 (1999-10-08)

- Ultrasound - Pulsed Doppler diagnostic systems - Test procedures to determine performance

**IEC 61289:1999:** Edition 1.0 (2003-04-30)

- Ultrasound - Continuous-wave Doppler systems - Test procedures


- Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment
AAPM involvement in IEC

- AAPM members join US Technical Advisory Group and are appointed as experts to relevant standards teams
- AAPM members provide unique insight to the standards teams (typically composed more of manufacturer engineers) on clinical impacts of standards
- Additional AAPM members interested in standards work are welcome to get in touch to discuss service opportunities
- AAPM members involved in MT39 on Dental Imaging Equipment recently recognized by the FDA CDRH with Special Citation Award for Collaborative Efforts

Thank you for your attention!