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Updates to IEC 62B and 87 Standards On Diagnostic Imaging Equipment and the FDA Transition to the Use of Some IEC Standards

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1. FDA Guidance on transition from EPRC to IEC
2. Updates on IEC 62B Standards
3. Updates on IEC TC87 Standards
4. AAPM involvement in IEC standards

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

Document issued on: May 8, 2019.

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

FDA Guidance on transition from EPRC to IEC

- 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*

FDA Guidance on transition from EPRC to IEC

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

FDA Guidance on transition from EPRC to IEC

- 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 standard(s)

21 CFR 1002 Subpart B	Required Manufacturers' Reports for Listed Electronic Products
21 CFR 1020.30(c), (h), (k), (l), (m), (n), (o)	Diagnostic x-ray systems and their major components
21 CFR 1020.31	Radiographic equipment
21 CFR 1020.32(a), (b), (c), (d)(1), (d)(2), (d)(3)(i) – (iv), (d)(4), (f), (h), (i), (j), (k)	Fluoroscopic equipment
21 CFR 1020.33(a), (b), (c), (f), (g), (h), (i), (j)	Computed tomography (CT) equipment

FDA Guidance on transition from EPRC to IEC

- 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

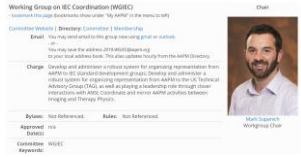
21 CFR Subchapter J Reference	IEC Reference	Topic	IEC/EPRC Comparison	Specifications/testing information specific to this device
1020.31(e)(1)	60601-2-54: 203.8.104(a)	Center-to-center	CFR requires 2% of SID, whereas IEC does not specify any tolerance.	This system does not specify a tolerance for center-to-center measurement.
1020.31(e)(1)	60601-1-3: 8.5.2	SID Indication	CFR requires 2% accuracy, while IEC requires 5% SID indication accuracy.	This system has an SID indication accuracy of 5%.
1020.31(e)(2)	60601-2-54: 203.8.102.2	Limitation of X-Ray Field to Image Receptor	CFR requires that the beam-limiting device numerically indicate the field size in the plane of the image receptor, while IEC allows exemptions for field size indication.	Display of the field size is not provided in the following circumstances (exemptions): a) Field size is preset for distances of interest and are not selectable by the operator b) System contains an interlock that does not allow an exposure if the x-ray field exceeds the image receptor c) During fluoroscopy, the boundaries of the x-ray field can be displayed visually.

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

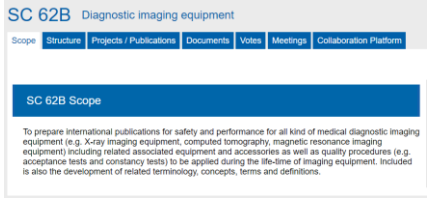
- At acceptance testing: confirm equipment meets applicable EPRC or IEC standards
- Annual/QA: follow accrediting body and regulatory agency guidance (CMS, TJC, ACR, State, etc.)
- Some states reference FDA standards, so may need to test to EPRC or IEC standards as per state guidelines after acceptance

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

- Further updates as guidance is implemented and used
- AAPM partnering with stakeholders (FDA, MITA, CRCPD) to work on smooth transition



Updates on IEC 62B Standards



Group	Description
WG 31	Mammographic X-ray equipment
WG 37	Diagnostic X-ray equipment - general requirements for radiation protection and particular requirements for radiography and radioscopy, including acceptance and constancy tests
WG 39	Standards for Dental Imaging Equipment
WG 45	Items within the controlled access area of Magnetic resonance equipment for human application
WG 51	Medical image display systems
WG 53	Refurbishment of Medical Imaging Equipment
PT 62985	Methods for calculating Size Specific Dose Estimate (SSDE) on Computed Tomography
MT 30	Computed tomography
MT 32	Requirements for X-ray source assemblies
MT 34	Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
MT 40	Magnetic resonance equipment for medical diagnosis
MT 41	Revision of IEC 60601-2-43
MT 44	Characteristics of digital X-ray imaging devices
MT 47	Protective devices against diagnostic medical X-radiation
MT 50	Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids
MT 52	Maintenance of the IEC 62464 series, Magnetic resonance equipment for medical imaging
JWG 1	Requirements for the safety and compatibility of MRI for patients with an active implantable medical device

Updates on IEC 62B Standards: Active Projects (7/12/19)

IEC 62985 ED1: Methods for calculating size specific dose estimates (SSDE) on computed tomography (9/19 FDIS)

IEC 61223-3-5 ED2: Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests and and constancy tests - Imaging performance of computed tomography X-ray equipment (9/19 FDIS)

IEC 60601-2-43/AMD2 ED2: Amendment 2 - Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures (10/19 FDIS)

IEC 63077 ED1: Good refurbishment practices for medical imaging equipment (2/20 CDV)

IEC 61223-3-6 ED1: Evaluation and routine testing in medical imaging departments – Part 3-6 Acceptance and Constancy tests – Imaging performance of mammographic tomosynthesis mode of operation of mammographic X-Ray equipment (8/20 CDV)

- Date following the description is the expected date of publication
- NP: New Work Item Proposal – description of changes/new standard sent out for vote
- CD: Committee Draft – circulated to National Committees for comment
- CDV: Committee Draft for Vote – technical comments still accepted
- FDIS: Final Draft International Standard – no comments allowed with supporting vote

Updates on IEC 62B Standards: Active Projects (7/12/19)

IEC 62563-2 ED1: Medical electrical equipment - Medical image display systems - Acceptance and constancy tests (11/20 in CD stage)

IEC 61223-3-7 ED1: Evaluation and routine testing in medical imaging departments – Acceptance testing and quality control of dental extra-oral X-ray equipment used with dental cone beam computed tomograph

(8/21 CD)

IEC 61223-3-8 ED1: Evaluation and routine testing in medical imaging departments – Acceptance and constancy tests - Radiography and radioscopy (7/22 New Project)

IEC 62563-1/AMD2 ED1: Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods (12/22 CD)

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Updates on IEC 62B Standards: Completed Recently

IEC 60601-2-54:2009+AMD1:2015+AMD2:2018 CSV: Edition 1.2 (2018-06-29)

Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

IEC 60601-2-54:2009/AMD2:2018: Edition 1.0 (2018-06-29)

Amendment 2 - Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

IEC 62464-1:2018: Edition 2.0 (2018-12-13)

Magnetic resonance equipment for medical imaging - Part 1: Determination of essential image quality parameters

Updates on IEC 62B Standards: Completed Recently

IEC 60601-2-28:2017: Edition 3.0 (2017-06-16)

Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

IEC 60601-2-43:2010/AMD1:2017: Edition 2.0 (2017-05-31)

Amendment 1 - Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

IEC 60601-2-63:2012/AMD1:2017: Edition 1.0 (2017-07-07)

Amendment 1 - Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment

IEC 60601-2-65:2012/AMD1:2017: Edition 1.0 (2017-05-17)

Amendment 1 - Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment

Updates on IEC 62B Standards: Significant Clinical Impact Standards

IEC 62494-1:2008 Edition 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 particulars for each practice, piece of equipment and protocol need to be taken into account

Selected references related to 62494-1

Dave, J.K. et al. "Report of AAPM Imaging Physics Committee Task Group 232." Med. Phys., 45: e1146-e1160.

Butler, M. L., et al. "Are exposure index values consistent in clinical practice? A multi-manufacturer investigation." *Radiation protection dosimetry* 139.1-3 (2010): 371-374.

Seibert, J. Anthony, and Richard L. Morin. "The standardized exposure index for digital radiography: an opportunity for optimization of radiation dose to the pediatric population." *Pediatric radiology* 41.5 (2011): 573-581.

Don, Steven, et al. "New exposure indicators for digital radiography simplified for radiologists and technologists." *American Journal of Roentgenology* 199.6 (2012): 1337-1341.

Recent Standards with direct impact on practice of medical physics

IEC 60601-2-43:2010 Edition 2.0 (2010-03-25)

Medical electrical equipment - Part 2-43: 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 ($K_{a,r}$)
- 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 $K_{a,r}$ ~ 5 Gy)
- $K_{a,r}$ is a better metric for potential tissue reactions from radiation dose than fluoroscopy time as it incorporates dose form Cine/DSA/3D acquisitions

Selected references related to 60601-2-43

B. C. Perry, C. R. Ingraham, B. K. Stewart, K. Valji and K. M. Kanal, Academic radiology 26 (2), 163-169 (2019).

Balter, Stephen. "Methods for measuring fluoroscopic skin dose." *Pediatric radiology* 36.2 (2006): 136.

Miller, Donald L., et al. "Quality improvement guidelines for recording patient radiation dose in the medical record." *Journal of vascular and interventional radiology* 15.5 (2004): 423-429.

Neil, S., C. Padgham, and C. J. Martin. "A study of the relationship between peak skin dose and cumulative air kerma in interventional neuroradiology and cardiology." *Journal of Radiological Protection* 30.4 (2010): 659.

Recent Standards with direct impact on practice of medical physics

IEC 60601-2-44:2009/AMD2:2016 Edition 3.0 (2016-03-31)

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 $CTDI_{100}$ large cone beam (> 40 mm) geometries
- Beam geometries (nT) > 40mm include scatter not captured in $CTDI_{vol}$ phantoms and 100 mm chamber
- Correction factor to $CTDI_{100}$ 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

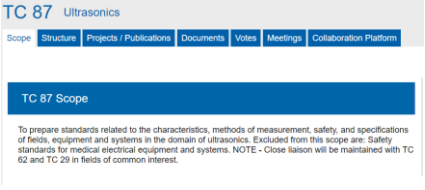
Selected references related to 60601-2-44

Bujila, R. , Kull, L. , Danielsson, M. and Andersson, J. (2018), Applying three different methods of measuring $CTDI_{vol}$ to the extended CTDI formalism for wide-beam scanners (IEC 60601-2-44): A comparative study. J Appl Clin Med Phys, 19: 281-289

Dixon, Robert L. *The Physics of CT Dosimetry: CTDI and Beyond*. CRC Press, 2019.

Fukuda, Atsushi, et al. "Estimation of primary radiation output for wide-beam computed tomography scanner." *Journal of applied clinical medical physics* 20.6 (2019): 152-159.

Updates on TC87 Standards



Group	Description
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 62D

TC87 Work Program

IEC 61828 ED2: Ultrasonics - Focusing transducers - Definitions and measurement methods for the transmitted fields **(**CDV 7/20**)**

IEC TR 61390 ED1: Ultrasonics - Real-time pulse-echo systems - Test procedures to determine performance specifications (CD 5/20)

Upcoming standards work:

- Upgrade IEC/TS62791 ed 1.0 (2015-09) to IS on low-echo sphere phantoms and method for performance testing of gray-scale medical ultrasound scanners applicable to a broad range of transducer types.
- Revision of IEC/TD61390 ed 1.0 (1996-07) on test procedures to determine performance specifications (action: revise Annex C)
- IEC/TS62736 ed 1.0 (2016-09) on simple methods for periodic testing to verify stability of an imaging system's elementary (action: extend the stability date for 3 years without changes and to advance to IS with inclusion of additional work on monitor display testing and DICOM tags)

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- **FDIS: Final Draft International Standard – no comments allowed with supporting vote**

TC 87 Standards of note

IEC TS 62791:2015: Edition 1.0 (2015-09-08)

Ultrasonics - Pulse-echo scanners - Low-echo sphere phantoms and method for performance testing of gray-scale medical ultrasound scanners applicable to a broad range of transducer types

IEC TS 62736:2016: Edition 1.0 (2016-07-12)

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

IEC TS 61895:1999: Edition 1.0 (1999-10-08)

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

IEC TS 61206:1993: Edition 1.0 (1993-04-30)

Ultrasonics - Continuous-wave Doppler systems - Test procedures

IEC TR 60854:1986: Edition 1.0 (1986-10-30)

Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment

AAPM Involvement in IEC Standards

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!

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