21 CFR and IEC X-Ray Standard Comparison Project

Comparison Tables for 21 CFR Sub J and IEC 60601

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Project Summary

- FDA issues draft guidance (Aug 2016)
- RSNA meeting – FDA comparison table proposal (Nov 2017)
- CRCPD, AAPM, RSNA – vetting tables with user groups (2018)

Section 1

The Structure

What's Being Developed?

- MITA is creating two documents:
  - 3 template tables comparing 21 CFR 1020.30-33 to IEC 60601-1 standard series for x-ray imaging modalities (Fluoro/Rad, CT, Mammo)
  - An extract of IEC 60601-1 particular/collateral reference document
- Manufacturer Tailored Tables
  - Manufacturers can utilize the MITA template tables to develop manufacturer-specific product or product family tables
- Benefits
  - Field inspectors quickly understand the IEC requirements and test methods for applicable equipment
  - Continuous harmonization with state-of-the-art international safety standards
  - Improved operator/patient safety and quality control

The Comparison Table

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	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

- Clearly indicates corresponding 21 CFR and IEC standards containing overlapping requirements
- Clearly describes the differences

21CFR to IEC Reference Text

Topic: SID Indication

1020.31(e)(1)

Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to ***indicate the SID to within 2 percent****;*

60601-1-3:2008 Clause 8.5.2

The FOCAL SPOT TO IMAGE RECEPTOR DISTANCE shall be indicated as follows:

- the ACCOMPANYING DOCUMENTS shall contain particulars of the values or ranges of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE specified for NORMAL USE;
- if the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE is adjustable and the specified applications require its value to be known to the OPERATOR prior to LOADING, the currently selected value shall be indicated on the EQUIPMENT;S
- the accuracy of indication shall be such that the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE does not differ by more than 5 % from any corresponding value indicated on the EQUIPMENT or from any corresponding value stated in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection and functional tests, by examination of the ACCOMPANYING DOCUMENTS and, where applicable, by measurement of the FOCAL SPOT TO IMAGE RECEPTOR DISTANCE in selected configurations and settings of the EQUIPMENT.

- IEC text is free to use in accordance with prior authorization (reuse must be < 10% of standard)
- IEC text selected by MITA and submitted to Central Office of the IEC for authorization
- IEC glossary of defined terms (ALL-CAPITAL LETTERS) is publically available on the web
- Describes requirements and test methods for indicated comparisons

Section 2

Examples

Example 1: "Fluoroscopic Irradiation Time Display", 1020.32(h)(2)(i)

1. Visit mfg specific site via mfg provided link on MITA website
2. Use mfg specific site to find table of applicable IEC comparison to be utilized in a particular model or family of devices
3. Utilize table to identify requirements where the IEC limits/ test methods are used rather than 21 CFR
4. Update test plan accordingly

21 CFR Subchapter J Reference	IEC Reference	Topic	IEC/EPRC Comparison	Specifications/testing information specific to this device
1020.32(h)(2)(i)	60601-2-54: 203.6.4.3.101	Fluoroscopic irradiation time display	CFR requires minutes and tenths of minutes, while IEC allows for minutes and seconds as well as minutes and tenths of minutes	This device displays fluoroscopic irradiation time in minutes and seconds in lieu of minutes and tenths of minutes.

Example 1: “Fluoroscopic Irradiation Time Display”, 1020.32(h)(2)(i)

Topic: Radiation Time Display

1020.32(h)(2)(ii)(A)

When the x-ray tube is activated, the fluoroscopic irradiation time in ***minutes and tenths of minutes*** *shall be continuously displayed and updated at least once every 6 seconds.*

60601-2-54:2009 Clause 203.6.4.3.101

The units of indication shall be as follows:

- for X-RAY TUBE VOLTAGE, kilovolts;
- for X-RAY TUBE CURRENT, milliamperes;
- for LOADING TIME, seconds and/or milliseconds;
- for CURRENT TIME PRODUCT, milliampereseconds;
- in RADIOSCOPY, the LOADING TIME may be indicated in minutes and seconds or decimally in minutes.

Compliance is checked by inspection.

Example 2: “Illuminance of Light Localizer”, 1020.31(d)(2)(ii)

21 CFR Subchapter J Reference	IEC Reference	Topic	IEC/EPRC Comparison	Specifications/testing information specific to this device
1020.31(d)(2)(ii)	60601-2-54: 203.8.102.5	Light localizer	CFR requiers min. 160 lux @ 1m SID, IEC requiers min. 100 lux @ 1m SID.	CFR allows measurement in 1m or max. SID, IEC only at 1m distance

Example 2 "Illuminance of Light Localizer", 1020.31(d)(2)(ii)

Topic: Light Localizer

1020.31(d)(2)(ii)

When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement

60601-2-54:2009 Clause 203.8.102.5

If a LIGHT FIELD-INDICATOR is provided, it shall delineate the edges of the X-RAY FIELD and it **shall provide an average illumination of not less than 100 lx in a plane normal to the X-RAY BEAM AXIS at a distance of 1 m from the FOCAL SPOT**.

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Compliance is checked by examination of the ACCOMPANYING DOCUMENTS and by the following test:

- *check that light-attenuating components as specified by the MANUFACTURER, e.g. the IONIZATION CHAMBER of a DOSE AREA PRODUCT meter, are in place.*
- *if the whole area of the indicated field is illuminated, determine the average illumination as the mean value from measurements in the approximate centre of each quarter of the LIGHT FIELD;*
- *in all other cases, determine the average illumination from at least four measurements at different points in the centres of the illuminated areas;*
- *measure the contrast, using a measuring aperture not larger than 1 mm. Take the contrast as I_1/I_2, where I_1 is the illumination 3 mm from the edge of the LIGHT FIELD towards the centre of the field and I_2 is the illumination 3 mm from the edge of the LIGHT FIELD away from the centre of the field;*
- *correct the MEASURED VALUES for ambient illumination.*

Note: IEC provides more prescriptive test methods than 21 CFR in many cases

Section 3

Next Steps

Distribution & Availability

- Reference documents shared today to be made available as a Medical Imaging & Technology Alliance document
- Manufacturers will be able to use these template documents to create tailored product and product family tables
- Manufacturers will be able to provide links to tables from a central MITA location
- Dependent on final FDA guidance and product adoption

MITA Websites URLs:
https://www.medicalimaging.org/cfr-iec-comparison/

https://www.medicalimaging.org/cfr-iec-manufacturer-portal/