Medical X-Ray Imaging Devices Conformance with IEC Standards

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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For questions regarding this document, contact the Division of Radiological Health at 301-796-2121 and Robert Sauer at Robert.A.Sauer@fda.hhs.gov or (301) 796-3580.

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Food and Drug Administration
Center for Devices and Radiological Health

Office of In Vitro Diagnostics and Radiological Health (OIR)
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Office of Science and Engineering Laboratories (OSEL)
Division of Imaging, Diagnostics, and Software Reliability

Preface

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Medical X-Ray Imaging Devices Conformance with IEC Standards

Draft Guidance for Industry and Food and Drug Administration Staff

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1. Introduction

This draft guidance describes FDA's policy regarding the regulation of medical x-ray imaging equipment that are subject to requirements in the Federal Food, Drug & Cosmetic Act (FD&C Act) and FDA's regulations that apply to medical devices and electronic products. In this draft guidance, FDA is seeking to harmonize performance standards prescribed pursuant to section 534 of Subchapter C (Electronic Product Radiation Control (EPRC)) of the FD&C Act with International Electrotechnical Commission (IEC) standards, where appropriate, to help to ensure streamlined regulatory review of submissions for these products. The draft guidance also provides recommendations to industry on how to comply with the applicable requirements. FDA believes industry conformance to certain IEC standards would provide the same level of or improved protection of the public health and safety from electronic radiation as certain EPRC regulatory standards. FDA also believes conformance to certain IEC standards would be sufficient to meet the 510(k) premarket notification requirement for certain devices. FDA review of related radiological health and safety data in premarket submissions, as opposed to EPRC product reports, would maintain or improve device safety while consolidating the information manufacturers submit to FDA.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

2. Background

Medical x-ray imaging equipment may fall under the definition of both a medical device, under section 201(h) of the FD&C Act, and an electronic product, under section 531(2) of the FD&C Act. As such, these devices may be subject to the provisions of the FD&C Act and FDA's regulations[1] that apply to medical devices (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm) and electronic products (http://www.fda.gov/ohrms/dockets/ac/03/briefing/3987b1_Summary-EPRC.htm).

While the legal authorities relating to medical devices and electronic products focus primarily on safety/effectiveness and radiation safety, respectively, there is some overlap in the requirements established by these authorities. FDA is issuing this draft guidance to clarify the relevant, applicable standards and to help to ensure a streamlined regulatory review of submissions for these devices. This draft guidance describes current Agency thinking in the following areas:

1) Product conformance to IEC standards;

2) Compliance with EPRC performance standards and reporting requirements; and

3) Compliance with 510(k) premarket notification requirements.

a. Device Regulations

FDA categorizes medical devices into one of three classes – Class I, II, or III – based on their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. Class I devices generally pose the lowest risk to the patient and/or user and Class III devices pose the highest risk.

- For Class I devices, manufacturers generally must comply with general controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the FD&C Act (see 21 CFR 860.3(c)(1)). The following regulations set forth requirements related to these general controls:

    - 21 CFR 801: Labeling,
    - 21 CFR 807: Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices,
    - 21 CFR 803: Medical Device Reporting, and
    - 21 CFR 820: Quality System Regulation.

[1] The regulations specific to medical devices and electronic products are found in 21 CFR Chapter I Subchapter H on Medical Devices and Subchapter J on Radiological Health, respectively.

Most Class I devices can be legally marketed without FDA premarket clearance of a 510(k) submission.

- For Class II devices, manufacturers must comply with general controls and applicable special controls, and are required to have 510(k) clearance unless otherwise exempted. (21 CFR 860.3(c)(2))

- For Class III devices, manufacturers must comply with general controls and generally must receive FDA approval of a premarket approval application (PMA) that demonstrates the safety and effectiveness of the device. (21 CFR 860.3(c)(3))

b. EPRC Regulations

The EPRC regulations are aimed at protecting the public from hazardous and unnecessary exposure to radiation from electronic products. FDA identified nine types of electronic products, including diagnostic x-ray systems and their major components, and established product performance standards for those products to control radiation.

Manufacturers and importers of x-ray imaging devices must comply with applicable requirements set forth in the following regulations:

- 21 CFR 1002.10: Product reports
- 21 CFR 1002.11: Supplemental reports
- 21 CFR 1002.12: Abbreviated reports
- 21 CFR 1002.13: Annual reports
- 21 CFR 1002.20: Reporting of accidental radiation occurrences
- 21 CFR 1002.30: Records to be maintained by manufacturers
- 21 CFR 1002.40: Records to be obtained by dealers and distributors
- 21 CFR Part 1003: Notification of defects or failure to comply
- 21 CFR Part 1004: Repurchase, repairs, or replacement of electronic products
- 21 CFR 1010.2: Certification
- 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

c. Avoidance of Duplication

Industry has previously raised concerns about overlapping information required to be submitted to FDA by the medical device and EPRC regulations for products that are both medical devices and electronic products. The Agency has addressed this overlap regarding:

1. Ultrasound devices (a letter from the director of CDRH to the ultrasound device industry exempted manufacturers and importers from submitting initial and annual product

reports under the EPRC regulation on February 24, 1986 [http://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/UCM509874.pdf]);

2. Laser Products (see "Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22; (Laser Notice No. 50)" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094361.htm -- see also "Laser Products; Amendment to Performance Standard (proposed rule)" at https://www.federalregister.gov/articles/2013/06/24/2013-14846/laser-products-proposed-amendment-to-performance-standard); and

3. CT with respect to CTDI (see "Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094379.htm).

To avoid duplication and streamline the regulatory review of submissions relating to medical x-ray imaging devices, this draft guidance clarifies the relevant, applicable standards for these products and provides alternative submission options.

3. Scope

a. Products Addressed in the Draft Guidance

This draft guidance addresses diagnostic x-ray imaging systems and their major components (see 21 CFR 1002.1 and 21 CFR 1020.30(a)(1)). Most diagnostic x-ray imaging systems and their major components are classified as Class I or II devices. Tables 1 and 2 include the regulations and product codes for these devices.

Table 1 – Class II devices that are covered by this draft guidance

Regulation Number	Regulation Description	Associated Product Codes
21 CFR 872.1800	Extraoral source x-ray system	EHD, MUH
21 CFR 872.1810	Intraoral source x-ray system	EAP
21 CFR 892.1600	Angiographic x-ray system	IZI
21 CFR 892.1610	Diagnostic x-ray beam limiting-device	KPW, IZW, IZX
21 CFR 892.1630	Electrostatic x-ray imaging system	IXK
21 CFR 892.1650	Image-intensified fluoroscopic x-ray system	JAA, OWB, OXO
21 CFR 892.1660	Non-image-intensified fluoroscopic x-ray system	JAB
21 CFR 892.1670	Spot-Film Device	IXL
21 CFR 892.1680	Stationary x-ray system	KPR, MQB, MWP
21 CFR 892.1710	Mammographic x-ray system	IZH
21 CFR 892.1715	Full-field digital mammography system	MUE
21 CFR 892.1720	Mobile x-ray system	IZL
21 CFR 892.1730	Photofluorographic x-ray system	IZG
21 CFR 892.1740	Tomographic x-ray system	IZF
21 CFR 892.1750	Computed tomography x-ray system	JAK, OAS
21 CFR 892.1860	Radiographic Film/Cassette Changer	KPX
21 CFR 892.1980	Radiologic table	KXJ, IXQ, IXR, IZZ

Table 2 – Class I devices that are covered by this draft guidance

Regulation Number	Regulation Description	Associated Product Codes
21 CFR 892.1700	Diagnostic X-Ray High Voltage Generator	IZO
21 CFR 892.1760	Diagnostic X-Ray Tube Housing Assembly	ITY
21 CFR 892.1880	Wall-mounted Radiographic Cassette Holder	IXY
21 CFR 892.1830	Radiologic Patient Cradle	KXH

b. Standards Addressed in the Draft Guidance

Under section 514(c)(1)(A) of the FD&C Act, FDA must, by publication in the Federal Register, recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement under the FD&C Act to which such standard is applicable. FDA has recognized the following IEC standards that apply to one or more of the devices covered by this draft guidance (see Appendix A):

- IEC 60601-1-3: Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment;

- IEC 60601-2-28: 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: Medical electrical equipment – Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures;

- 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 60601-2-45: Medical electrical equipment – Part -2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices;

- IEC 60601-2-54: Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy;

- IEC 60601-2-63: Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment; and

- IEC 60601-2-65: Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment.

4. Policy

As discussed further below, FDA believes conformance[2] to certain 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, and that submitting a declaration of conformity to the applicable standard(s) would be sufficient to meet the EPRC reporting requirements. FDA also believes conformance with certain IEC standards would be sufficient to meet the 510(k) premarket notification requirement for certain devices. Thus, a manufacturer or importer that conforms to the IEC standards identified in section 3b of this draft guidance (see Appendix A), and otherwise complies with section 514(c) of the FD&C Act, would be deemed to have met certain EPRC requirements as described in section 4a of this draft guidance, and 510(k)

[2] Conformance shall be to the current version, including corrigenda and amendments of the applicable IEC standards as recognized by FDA at the time of device manufacture.

premarket notification requirements for certain devices as described in section 4b of this draft guidance.

a. Electronic Products - Performance Standards and Reporting Requirements

The IEC standards described in section 3b of this draft guidance (see Appendix A for additional details) are applicable to many parts of the performance standards for diagnostic x-ray systems (see Table 3) established under section 534 of the FD&C Act.

FDA believes conformance to the identified IEC standards would provide the same level of or improved protection of the public health and safety from electronic product radiation as the requirements in 21 CFR 1020.30 (in part), 1020.31, 1020.32 (in part), 1020.33 (in part) (see Table 3). Therefore, a manufacturer or importer that has submitted a declaration of conformity to the applicable IEC standards, see process discussed in sections 5 and 6 of this draft guidance, would be deemed to have met certain performance standard requirements in 21 CFR 1020.30, 1020.31, 1020.32, and 1020.33, assuming the criteria in section 514(c) of the FD&C Act are satisfied.

Furthermore, if a device conforms to the applicable standards in section 3b of this draft guidance (see Appendix A), FDA believes that the reports in 21 CFR 1002 Subpart B (1002.10, 1002.11, and 1002.13) would be duplicative because the manufacturer would have already submitted applicable radiation safety information in a declaration of conformity. Therefore, a manufacturer that has submitted a declaration of conformity to the applicable standards, see process discussed in section 5 of this draft guidance, would be deemed to have met the reporting requirements in 21 CFR 1002 Subpart B (1002.10, 1002.11, and 1002.13), assuming the criteria in section 514(c) of the FD&C Act are satisfied.

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[3]
21 CFR 1020.33(a), (b). (c), (f), (g), (h), (i), (j), (k)	Computed tomography (CT) equipment

Some sections of the electronic product regulations are not adequately addressed or are outside the scope of the IEC standards identified in section 3b of this draft guidance (see Appendix A). For these parts of the electronic product regulations, FDA has determined there is no applicable portion of the IEC standards that can be used to meet the requirements. Consequently, manufacturers, importers, and their devices would not be deemed to have met the requirements identified in Table 4 below solely based on conformance with the identified IEC standards.

Table 4 – EPRC requirements that would not be deemed to be met based solely on conformity to IEC standards

21 CFR 1002 Subparts A, C, D, E, F	Records and Reports
21 CFR 1010.3	Identification
21 CFR 1010.4	Variances (from EPRC requirements only)
21 CFR 1020.30(a)	Applicability
21 CFR 1020.30(b)	Definitions (see note)
21 CFR 1020.30(d)	Assemblers Responsibility
21 CFR 1020.30(e)	Identification of x-ray components
21 CFR 1020.30(g)	Information Provided to Assemblers
21 CFR 1020.30(j)	Warning Label
21 CFR 1020.30(q)	Modification of Certified Components
21 CFR 1020.32(d)(3)(v)	Lateral Plane patient entrance point
21 CFR 1020.32(g)	Source-skin distance
21 CFR 1020.33(d)	Quality assurance

[3] FDA is considering whether to issue separate guidance to address the termination of exposure for fluoroscopic equipment and operation of emergency fluoroscopic mode.

b. Medical Devices – 510(k) Clearance

To obtain 510(k) clearance, manufacturers must establish the substantial equivalence of their new device to a legally marketed predicate that does not require premarket approval. This is done by showing their new device has the same intended use, and technological characteristics that are either the same or different but the differences do not raise different questions of safety and effectiveness than the predicate (see section 513(i) of the FD&C Act). Conformance with recognized consensus standards may in some situations support a substantial equivalence determination (see guidance entitled "Use of Standards in Substantial Equivalence Determinations" (March 2000) found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm). Moreover, declaration(s) of conformity to recognized consensus standard(s) could be sufficient to eliminate the need for manufacturers to submit in their 510(k) (and for FDA to review) the actual test data for those aspects of the device addressed by the standards. There are few mandatory FDA standards that apply to medical devices, but there are numerous national and international voluntary consensus standards that the Agency has reviewed and recognized (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm). A discussion of the substantial equivalence review process is found in the guidance entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications" (March 1998) found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm.

FDA also believes that conformance to the applicable standards in section 3b of this draft guidance (see Appendix A) would be sufficient to meet the premarket notification requirements for the Class II devices listed in Table 5, assuming the criteria in section 514(c) of the FD&C Act are satisfied.

Table 5 – Devices for which conformity to applicable IEC standards is sufficient to meet 510(k) premarket notification requirements

Regulation Number	Regulation Description	Associated Product Codes
21 CFR 892.1610	Diagnostic x-ray beam limiting device	KPW, IZW, IZX
21 CFR 892.1670	Spot-Film Device	IXL
21 CFR 892.1860	Radiographic Film/Cassette Changer	KPX

This means that manufacturers and importers of devices in Table 5 would be deemed to have met the 510(k) premarket notification requirement if they submit a declaration of conformity to the applicable standard(s) identified in section 3b of this draft guidance (see Appendix A) and satisfy the criteria in section 514(c) of the FD&C Act, see process discussed in sections 5 and 6 of this draft guidance.

5. Submission of Declarations of Conformity

If manufacturers and importers elect to conform to a recognized and applicable IEC standard to meet one of the requirements discussed above (*i.e.*, premarket notification, performance standard, or reporting requirement), they must submit a declaration of conformity that certifies that the device is in conformity with the standard (see section 514(c)(1)(B) of the FD&C Act). Information on such declarations is available in guidance entitled "Recognition and Use of Consensus Standards" found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm.

Further guidance on the manner in which and the substance that should be included in declarations of conformity submitted by manufacturers and importers is included below.

a. Devices for which a 510(k) is submitted

For devices for which a 510(k) is submitted, manufacturers or importers should submit their declaration of conformity to the applicable IEC standards as part of their 510(k) submission. Manufacturers of devices subject to 21 CFR 1020.30(c) also should state in the device description of the 510(k) that adequate assembly instructions have been developed, are available, and will be provided to assemblers.

b. Devices for which no 510(k) is submitted

For devices for which no 510(k) is submitted, including investigational devices, manufacturers and importers should submit a declaration of conformity in an Abbreviated Report submitted under 21 CFR 1002.12(e). An Abbreviated Report for devices subject to 21 CFR 1020.30(c) should include a statement that adequate assembly instructions have been developed, are available, and will be provided to assemblers.

6. Certification

Manufacturers of diagnostic x-ray systems and their major components for which an applicable EPRC performance standard is in effect, including those that conform to applicable IEC standards to meet EPRC performance standards, must provide certifications for their products (see 21 CFR 1010.2(a)). To properly certify their product, manufacturers must furnish product certifications to dealers or distributors, at the time of delivery, that the product conforms to the IEC standards that are declared in the associated declaration of conformity and any other standards in Chapter J (Radiological Health) of Title 21 of the CFR (such as parts of 21 CFR 1020.30) (see 21 CFR 1010.2(a)).

The certification must be provided on a label or tag permanently affixed to or inscribed on the product so as to be legible, readily accessible to view when the product is fully assembled for use, and the label or tag must be in the English language (see 21 CFR 1010.2(b)).

The certification label or tag should use the following modified statement of compliance:

> Complies with 21 CFR Subchapter J and, in lieu of [insert FDA performance standard CFR number(s)], with IEC [insert IEC Standard number and edition number], dated [Insert publication date of the FDA-recognized IEC standard], [add, as appropriate] including corrigenda dated [insert publication dates of the FDA-recognized corrigenda] and amendments dated [insert publication dates of the FDA-recognized amendments], as permitted by "Medical X-Ray Imaging Devices: Conformance with IEC Standards;" dated [Insert date of final guidance issuance]."

For example:

> Complies with 21 CFR Subchapter J and, in lieu of 21 CFR 1020.33, with IEC 60601-2-44 ed1.0 (2009), including Amendment 1 (2012), as permitted by "Medical X-Ray Imaging Devices: Conformance with IEC Standards;" dated [date of issuance of final guidance].

Under 21 CFR 1010.2(c), this certification must be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practice. The manufacturer's quality system should address various aspects of radiation safety and conformity to standards through design controls. Testing results should be documented and placed in the firm's records.

7. Compliance and Enforcement

This draft guidance does not limit the Agency's ability to pursue an enforcement action if manufacturers do not comply with the applicable regulations.

As discussed previously, FDA's intention of considering manufacturers compliant with regard to certain requirements as discussed in this draft guidance is contingent on a manufacturer or importer declaring conformance to certain IEC standards, with that conformance being based on a testing program. The manufacturer's quality system should address various aspects of radiation safety and conformity to standards through design controls. Testing results should be documented and placed in the firm's records. The policy described in this draft guidance would not apply if FDA finds that a manufacturer's testing program does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the appropriate standards (*see* 21 CFR 1010.2(c)).

By declaring conformance with the IEC standards, corrigenda, and amendments identified in this draft guidance, manufacturers declare that they have established design specifications that relate to radiation emission. As stated in 21 CFR 1003.2(b), one of the definitions of an electronic

product defect is failure to conform to design specifications relating to the emission of electronic product radiation. Thus, failure to meet any of the requirements of an IEC standard, corrigenda, or amendment to which a manufacturer declares conformance is an electronic product defect and is cause for notification and repurchase, repair or replacement as defined in 21 CFR parts 1003 and 1004.

This draft guidance does not change FDA's policy towards enforcement of correction of such defects. Manufacturers and importers must notify FDA upon discovery of a radiation safety defect, as required by 21 CFR 1003.10. Also, as required by 21 CFR 1003.11, FDA will notify industry when the Agency makes such discoveries. As required by 21 CFR part 1004, the manufacturer must repurchase, repair or replace defective products without charge, under a plan approved by FDA. FDA will review and approve or reject all corrective action plans, as required by 21 CFR 1004.6.

8. Imports

In order to import medical x-ray imaging equipment, importers are required to affirm compliance with applicable EPRC performance standards, either by using the Customs Automated Forms Entry System or by filing Form FDA 2877, *Declaration for Imported Electronic Products Subject to Radiation Control Standards* (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM080778.pdf). This affirmation consists of declaring that a product either (1) complies with applicable standards, as evidenced by provision of an accession number for the radiation safety report or most recent annual report filed by the manufacturer for the product or (2) is excluded by the applicability clause or definition in the standard or by FDA written guidance and specification of the reason for exclusion. Firms would be issued an accession number when they submit a declaration of conformity, see process discussed in section 5 of this draft guidance. Devices for which a 510(k) is submitted would be issued an accession number upon clearance of the 510(k) containing appropriate declarations of conformity. Devices for which no 510(k) is submitted would be issued an accession number upon receipt of an abbreviated report containing a declaration of conformity to the appropriate standards. Importers that follow this draft guidance should declare that their product complies with the applicable standards (Option 1) and provide the accession number received in response to the 510(k) or abbreviated report.

Appendix A: Applicability of IEC Standards to Specific Device Types

The IEC uses a tiered structure for its standards: general standards, collateral standards and particular standards. The base standard (e.g., IEC 60601-1 for medical electrical equipment) is called the general standard. Collateral standards (e.g., IEC 60601-1-3 for radiation protection in diagnostic x-ray equipment) provide general specifications for safety that are applicable to a subgroup of devices covered by the general standard, or a specific characteristic of all equipment covered by the general standard that is not fully addressed in the general standard (e.g., alarm systems). Particular standards apply to specific types of equipment (e.g., IEC 60601-2-43 for interventional fluoroscopy systems), and may replace, add to, amend or remove conditions contained in the general or collateral standards, as appropriate for the specific type of equipment under consideration. Particular standards may also add other basic safety and essential performance conditions.

In particular standards, the term "this standard" is used to make reference to the general standard, any applicable collateral standards and the particular standard, taken together. Therefore, conformance to a particular standard includes conformance to any collateral standards and the general standard in the same series (e.g., IEC 60601), as well as to any other particular standards included as normative. However, a condition in a particular standard takes priority over any conflicting conditions in collateral and general standards in the same series and normative particular standards (e.g., conditions in IEC 60601-2-43 take precedence over any conflicting conditions in IEC 60601-2-54, 60601-1-3 and IEC 60601-1).

The chart below indicates the IEC standards that apply to different devices classified in the CFR after taking into consideration the IEC's tiered structure system. The far left column lists the classification regulation numbers for devices within the scope of this draft guidance. To determine which IEC standards apply to a device:

1. Find the row containing the classification regulation in the left column
2. Trace the row across the rest of the table and note which columns are marked with an 'X'
3. The column headings for the columns marked with a 'X' provide the names the IEC standards that apply to that device

411 **Table 6 – Applicability of IEC Standards to Specific Medical Device Classifications**
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Classification Regulation	IEC 60601-1-3 General	IEC 60601-2-28 X-Ray Tube	IEC 60601-2-43 Interventional X-ray Equipment	IEC 60601-2-44 Computed Tomography	IEC 60601-2-45 Mammography	IEC 60601-2-54 Radiography and Radioscopy	IEC 60601-2-63 Extra-Oral Dental Equipment	IEC 60601-2-65 Intra-Oral Dental Equipment
21 CFR 872.1800							X†	X†
21 CFR 872.1810							X	
21 CFR 892.1600			X			X		
21 CFR 892.1610						X		
21 CFR 892.1630			X					
21 CFR 892.1650			X‡			X‡		
21 CFR 892.1660			X					
21 CFR 892.1670	X							
21 CFR 892.1680						X		
21 CFR 892.1700	X							
21 CFR 892.1710					X			
21 CFR 892.1715					X			
21 CFR 892.1720						X		
21 CFR 892.1730						X		
21 CFR						X		

Classification Regulation	IEC 60601-1-3 General	IEC 60601-2-28 X-Ray Tube	IEC 60601-2-43 Interventional X-ray Equipment	IEC 60601-2-44 Computed Tomography	IEC 60601-2-45 Mammography	IEC 60601-2-54 Radiography and Radioscopy	IEC 60601-2-63 Extra-Oral Dental Equipment	IEC 60601-2-65 Intra-Oral Dental Equipment
892.1740								
21 CFR 892.1750				X				
21 CFR 892.1760		X						
21 CFR 892.1830	X							
21 CFR 892.1860	X							
21 CFR 892.1880	X							
21 CFR 892.1980	X							

† The FDA medical device regulations and IEC use different definitions of extra-oral and intra-oral x-ray systems. IEC standards 60601-2-63 and 60601-2-65 use the location of the image receptor to define the devices. FDA uses the location of the x-ray source to make the distinction (21 CFR 872 1800 and 21 CFR 872.1810). Manufacturers should provide a declaration of conformity to either IEC 60601-2-63 or IEC 60601-2-65 for devices classified as "Extra-oral source x-ray system" devices under 21 CFR 872.1800, depending on whether the device design meets the IEC definition of extra-oral or intra-oral. Devices classified as "intra-oral source x-ray system" devices under 21 CFR 872.1810 should conform to IEC 60601-2-63.

‡IEC 60601-2-43 applies to devices under 21 CFR 892.1650 that are intended to be used in interventional procedures. The applicable standard for all other devices under 21 CFR 892.1650 is IEC 60601-2-54.

See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm for a current list of FDA recognized consensus standards.