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Medical X-Ray Imaging Devices Conformance with IEC Standards

Guidance for Industry and Food and Drug Administration Staff

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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Preface

Public Comment

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Medical X-Ray Imaging Devices Conformance with IEC Standards

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance describes FDA's policy regarding the regulation of medical x-ray imaging equipment that is subject to the Federal Food, Drug & Cosmetic Act (FD&C Act) and FDA's regulations that apply to medical devices and electronic products. In this 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 more efficient and consistent regulatory review of submissions for these products. The guidance also provides recommendations to industry on how to comply with the applicable requirements. FDA has determined that industry conformance to certain IEC standards would provide, at a minimum, the same level of protection of the public health and safety from electronic radiation as certain EPRC regulatory standards.

Manufacturers and importers of medical x-ray imaging equipment must follow the current EPRC regulations and procedures or provide a declaration of conformity to equivalent IEC standards, as outlined in this guidance, to fulfill the requirements of the EPRC regulation. Using a declaration of conformity to equivalent IEC standards reduces duplication of efforts by manufacturers and allows FDA to provide more efficient and consistent regulatory reviews of submissions relating to medical x-ray imaging devices.

For the current edition of the FDA-recognized consensus standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[1] For more information regarding use of consensus standards in regulatory submissions, please refer to FDA guidance

[1] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[2]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe 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.

II. 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[3] that apply to medical devices[4] and electronic products.[5]

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 guidance to clarify the relevant applicable standards and to help to ensure an efficient and consistent regulatory review of submissions for these devices. This guidance describes current Agency thinking in the following areas:

1) Product conformance to IEC standards; and

2) Compliance with EPRC performance standards.

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),

[2] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

[3] The regulations specific to medical devices and electronic products are found in 21 CFR Chapter I Subchapter H and Subchapter J, respectively.

[4] For additional information regarding medical device regulation, see https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation

[5] For additional information regarding electronic product regulation, see https://www.fda.gov/radiation-emitting-products/electronic-product-radiation-control-program/getting-radiation-emitting-product-market-frequently-asked-questions

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

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

- For Class II devices, manufacturers must comply with general controls and applicable special controls and are subject to premarket notification (510(k)) requirements prior to marketing, unless otherwise exempted (21 CFR 860.3(c)(2)).[6]

- 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 prior to marketing (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. By regulation, FDA identified types of electronic products,[7] 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, including, but not limited to:

- 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

[6] Certain radiologic devices were exempt from 510(k) submissions under section 510(m)(1)(A) of the FD&C Act in 82 FR 31976, subject to the limitations in 21 CFR 892.9.

[7] These types include: Television receivers (21 CFR 1020.10); Cold-cathode gas discharge tubes (21 CFR 1020.20); Diagnostic x-ray systems and their major components (21 CFR 1020.30); Cabinet x-ray systems (21 CFR 1020.40); Microwave ovens (21 CFR 1030); Laser products (21 CFR 1040.10); Sunlamp products and ultraviolet lamps intended for use in sunlamp products (21 CFR 1040.20); High-intensity mercury vapor discharge lamps (21 CFR 1040.30).

- 21 CFR 1020.32: Fluoroscopic equipment[8]
- 21 CFR 1020.33: Computed tomography (CT) equipment

C. Avoidance of Duplication

Industry has previously raised concerns about overlapping requirements in the medical device and EPRC regulations for products that are both medical devices and electronic products. The Agency has addressed this overlap through guidance and amendments to the EPRC regulations:

1. Laser Products (see "Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22; Laser Notice No. 50,"[9] and "Laser Products - Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1; Laser Notice No. 56"[10]), and

2. Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser and Ultrasonic Products.[11]

III. Scope

A. Devices Addressed in the Guidance

This 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.

[8] For additional information on complying with EPRC performance standards for fluoroscopic equipment, see the guidance titled "Policy Clarification for Certain Fluoroscopic Equipment Requirements" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-clarification-certain-fluoroscopic-equipment-requirements

[9] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/laser-products-conformance-iec-60825-1-and-iec-60601-2-22-laser-notice-no-50

[10] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/laser-products-conformance-iec-60825-1-ed-3-and-iec-60601-2-22-ed-31-laser-notice-no-56

[11] 88 FR 3638 available at https://www.federalregister.gov/documents/2023/01/20/2023-00922/radiological-health-regulations-amendments-to-records-and-reports-for-radiation-emitting-electronic

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

Regulation Number	Regulation Description	Associated Applicable 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 892.1170	Bone densitometer	KGI
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, RCC
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 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 892.1830	Radiologic patient cradle	KXH
21 CFR 892.1880	Wall-mounted radiographic cassette holder	IXY

Some imaging devices are hybrids; that is, they are combinations of more than one imaging component (e.g., Positron Emission Tomography (PET) and Computed Tomography (CT)). In the situation where one of the components has an applicable EPRC standard, the policy described in this guidance applies to that component.

This guidance does not address radiation therapy products because there are no EPRC performance standards promulgated for these products. These devices are cleared for market through the 510(k) process.[12]

[12] For a list of recognized consensus standards applicable to radiation therapy products, see FDA's product classification database at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm. Classification regulations for radiologic therapeutic devices can be found in 21 CFR 892 subpart F.

B. Standards Addressed in the Guidance

To avoid duplication and provide an efficient and consistent regulatory review of submissions relating to medical x-ray imaging devices, this guidance clarifies the relevant applicable voluntary consensus standards for medical x-ray systems and components. FDA has recognized the following IEC standards that apply to one or more of the devices covered by this 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*.

IV. Policy

FDA has determined that conformance to certain IEC standards would provide, at a minimum, the same level of protection of the public health and safety from electronic radiation as certain EPRC performance standards. FDA recommends that manufacturers elect to conform to a recognized and applicable IEC standard to meet certain requirements of the performance standards outlined in Table 3, below. Conformance must be to a version, including corrigenda and amendments, of the applicable IEC standards that is recognized by FDA at the time

conformance is declared.[13] For more information regarding transition periods associated with the recognition of newer versions of consensus standards, see "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[14]

A. Electronic Products - Performance Standards

The IEC standards described in section 3b of this 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 has determined that conformance to the identified IEC standards would provide, at a minimum, the same level of 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), and 1020.33 (in part) (see Table 3). Therefore, a manufacturer or importer that has submitted a declaration of conformity to the applicable IEC standards through the process discussed in sections 5 and 6 of this 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.

Table 3 – EPRC requirements deemed to be met based on conformity to applicable IEC standard(s)

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

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 guidance (see Appendix A). For these parts of the electronic product regulations, FDA has determined that 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.

[13] Section 514(c)(1)(B) of the FD&C Act.
[14] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

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 immediately below this table)
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

Note: 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 determine whether the device is an extra-oral device or an intra-oral device. FDA uses the location of the x-ray source to make the distinction (21 CFR 872.1800 and 21 CFR 872.1810). This difference in definitions means that some devices classified as an "Extra-oral source x-ray system" under 21 CFR 872.1800 will be defined as an intra-oral x-ray system by the IEC. In these cases, the applicable IEC standard is 60601-2-65 (for intraoral x-ray systems), and manufacturers who choose to conform to IEC standards should submit a declaration of conformity to IEC 60601-2-65.

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 a premarket approval application (PMA). This is done by showing their new device has the same intended use, and technological characteristics that either: are the same, or; are 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 "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices").[15] 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 complete testing reports for those aspects of the device addressed by the standards. While there are few mandatory FDA standards that apply to medical devices, there are numerous national and international voluntary

[15] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

consensus standards that the Agency has reviewed and recognized.[16] A discussion of the substantial equivalence review process is found in the guidance entitled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]."[17]

V. Submission of Declarations of Conformity

If manufacturers and importers elect to conform to a recognized and applicable IEC standard to meet the applicable requirements of an EPRC performance standard, they must complete 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) and include the declaration as part of a premarket submission, as applicable to the device type. If a premarket submission is not required for that device type, then the declaration should be kept as part of the manufacturer's records. Information on such declarations is available in the guidance entitled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[18]

VI. 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 a product, including major components for which there is an applicable EPRC performance, so as to be legible, readily accessible to view when the product is fully assembled for use, and in the English language (see 21 CFR 1010.2(b)).

The certification label or tag should include a modified statement of compliance, such as:

> "Complies with 21 CFR Subchapter J including section [insert FDA performance standard CFR number(s)], partially by conforming 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], in accordance with section 514(c)(1)(A) of the FD&C Act as

[16] For more information, see the FDA Recognized Standards Database, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[17] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k

[18] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

outlined in "Medical X-Ray Imaging Devices: Conformance with IEC Standards," dated [Insert date of final guidance issuance]."

For example, for a CT device:

> Complies with 21 CFR Subchapter J including sections 21 CFR 1020.30 and 1020.33, partially by conforming with IEC 60601-2-44 ed1.0 (2009), including Amendment 1 (2012), in accordance with section 514(c)(1)(A) of the FD&C Act as outlined in "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.

VII. Information to be Provided to Assemblers and Others

Manufacturers of diagnostic x-ray equipment components listed in 21 CFR 1020.30(a)(1) are required by 21 CFR 1020.30(g) to provide instructions for assembly, installation, adjustment, and testing, (AIAT) to assure that the product will comply with applicable performance standard provisions. This requirement in the performance standard helps to ensure that diagnostic x-ray equipment, the characteristics of which may require adjustment upon assembly, installation, and thereafter, will continue to comply with radiation safety requirements and thus protect the public from unnecessary exposure to radiation. As outlined in Table 4, section 1020.30(g) is not met through conformance to applicable IEC standards.

To comply with the instructions for the AIAT requirement of 21 CFR 1020.30(g), a manufacturer who elects to declare conformity to IEC standards to satisfy other sections of the EPRC performance standards outlined in Table 3 should include in their AIAT documentation a Radiation Safety Specification and Testing Comparison Document.[19] The Radiation Safety Specification and Testing Comparison Document (the "Document") should provide information that enables, for example, an assembler, qualified medical physicist, or state radiation control program inspector, to test the device and determine whether it conforms to the applicable IEC radiation safety specifications, and not the EPRC performance standards. Although the Document may be limited to only those specifications and would not indicate full compliance with the relevant EPRC performance standards, FDA recommends that manufacturers format their AIAT documentation so that all radiation safety specifications and test methods, including acceptance and constancy testing, are available in a format that is practical for users testing the equipment.

[19] An example Radiation Safety Specification and Testing Comparison Document can be found at https://www.nema.org/standards/view/radiation-safety-specification-and-testing-comparison-document-for-medical-x-ray-imaging-devices-general-radiography-and-fl

At minimum, the Document should include:

a. The radiation safety specifications that apply to the device, where those specifications would not otherwise meet the comparable EPRC performance standards;
b. The IEC document number, version, and specific clause(s) under which each such specification may be found;
c. The EPRC performance standard requirement being replaced by the IEC standard; and
d. The test method and acceptance criterion.

Availability of Documents online enables easy access by assemblers and other personnel. Access can be provided on an individual manufacturer's website or in a centralized database. Information on how to access the Document should be included with the device's accompanying documents. Additionally, if the device includes user documentation[20] that is provided electronically, inclusion of the Document as part of the electronic documentation may be helpful for assemblers and other personnel.

VIII. Compliance and Enforcement

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

If a manufacturer is using a declaration of conformity to comply with certain requirements, as discussed in this guidance, the manufacturer or importer must declare conformance to certain IEC standards, with that conformance being based on a testing program.[21] The manufacturer's quality system must address various aspects of radiation safety and conformity to standards through design verification and validation.[22] Testing results must be documented and placed in the firm's records as part of the design history file[23] for the device and are subject to inspection in accordance with 21 CFR 820.180. FDA will consider a product to be in violation of the electronic product performance standards 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 guidance, manufacturers declare that they have established design specifications that relate to radiation emission. When a diagnostic x-ray system fails to conform to design specifications relating to the emission of electronic product radiation, the system has an electronic product defect.[24] Thus, failure to meet any of the requirements relating to the emission of electronic

[20] This is the same as the IEC term "accompanying documents."
[21] See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices, for more information about testing that supports a declaration of conformity.
[22] 21 CFR 820.30.
[23] 21 CFR 820.30(j).
[24] 21 CFR 1003.2(b).

product radiation 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 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.

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, IEC 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 guidance. To determine which IEC standard(s) applies 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 an 'X' provide the names of the IEC standards that apply to that device.

Table 6 – Applicability of IEC Standards to Specific Medical Device Classifications

Classification Regulation	IEC 60601-1-3 Diagnostic X-ray Equipment	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 EHD, MUH	X						X	X
21 CFR 872.1810 EAP	X						X	
21 CFR 892.1170 KGI	X	X						
21 CFR 892.1600 IZI	X		X			X		
21 CFR 892.1610 KPW, IZW, IZX	X					X		
21 CFR 892.1630 IXK	X		X					
21 CFR 892.1650 JAA, OWB, OXO, RCC	X		X‡			X‡		
21 CFR 892.1660 JAB	X		X					
21 CFR 892.1670 IXL	X							

Classification Regulation	IEC 60601-1-3 Diagnostic X-ray Equipment	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 892.1680 KPR, MQB, MWP	X					X		
21 CFR 892.1700 IZO	X					X		
21 CFR 892.1710 IZH	X				X			
21 CFR 892.1715 MUE	X				X			
21 CFR 892.1720 IZL	X					X		
21 CFR 892.1730 IZG	X					X		
21 CFR 892.1740 IZF	X					X		
21 CFR 892.1750 JAK, OAS	X			X				
21 CFR 892.1760 ITY	X	X						
21 CFR 892.1830 KXH	X							
21 CFR 892.1860	X							

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Classification Regulation	IEC 60601-1-3 Diagnostic X-ray Equipment	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
KPX								
21 CFR 892.1880 IXY	X							
21 CFR 892.1980 KXJ, IXQ, IXR, IZZ	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 determine whether the device is an extra-oral device or an intra-oral device. FDA uses the location of the x-ray source to make the distinction (21 CFR 872.1800 and 21 CFR 872.1810). This difference in definitions means that some devices classified as an "Extra-oral source x-ray system" under 21 CFR 872.1800 will be defined as an intra-oral x-ray system by the IEC. In these cases, the applicable IEC standard is 60601-2-65, for intraoral x-ray systems, and manufacturers who choose to conform to IEC standards should submit a declaration of conformity to IEC 60601-2-65.

‡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 the FDA Recognized Consensus Standards Database[25] for a current list of FDA-recognized consensus standards.

[25] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm