# The New IEC/FDA Regulatory Paradigm for X-ray Devices: FDA Perspective

AAPM Spring Clinical Meeting
March 30, 2019
Robert Sauer
U.S. Food and Drug Administration

# CDRH's Mission

The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

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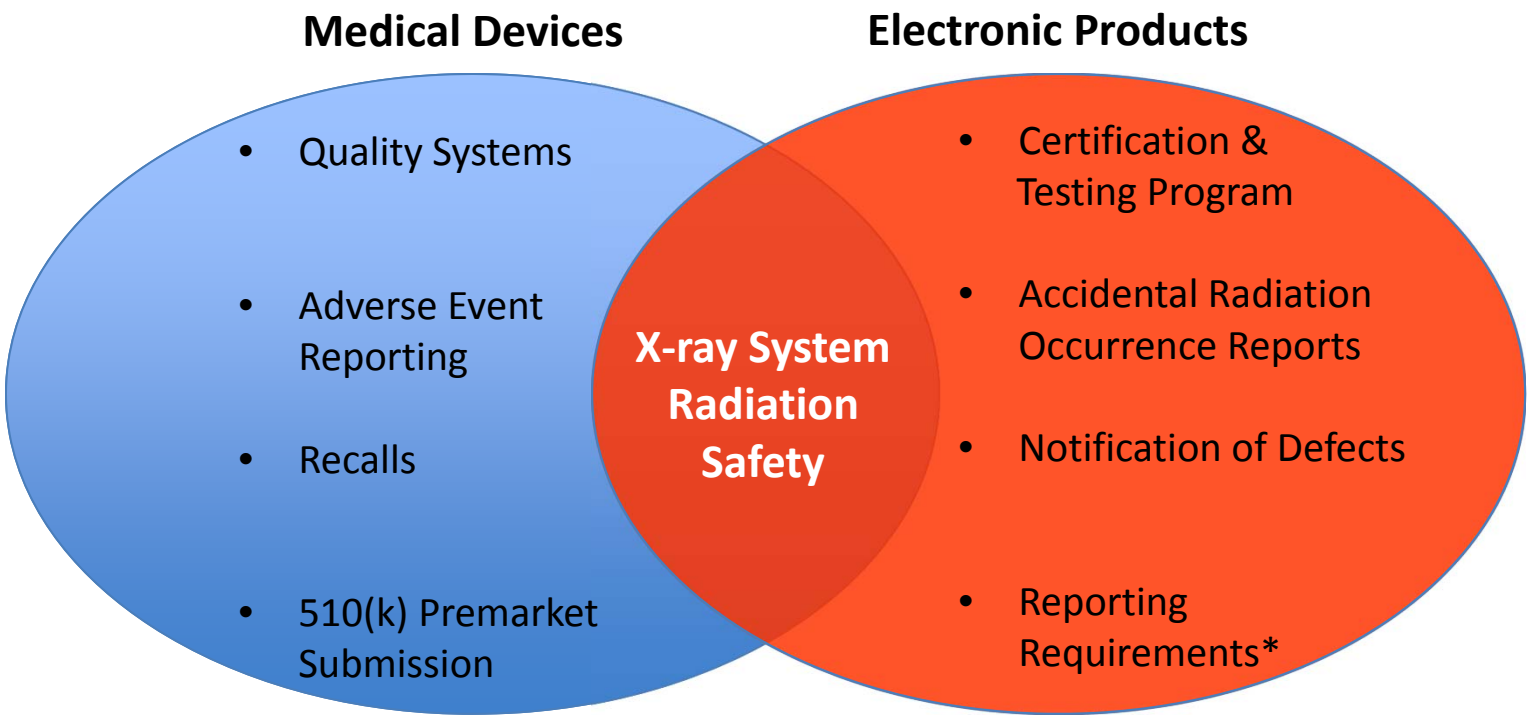
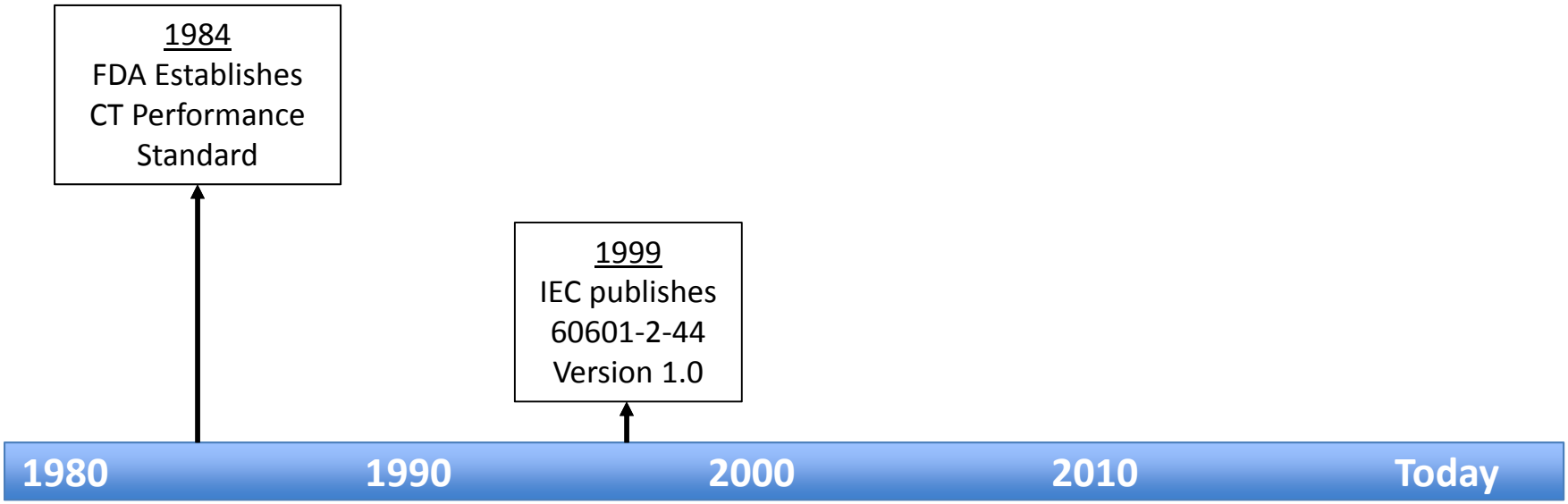
# Two sets of FDA regulations apply to X-ray systems




https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm
https://www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/default.htm

# FDA hasn't significantly updated the CT performance standard since 1984

# Consensus standards organizations like IEC publish updates regularly

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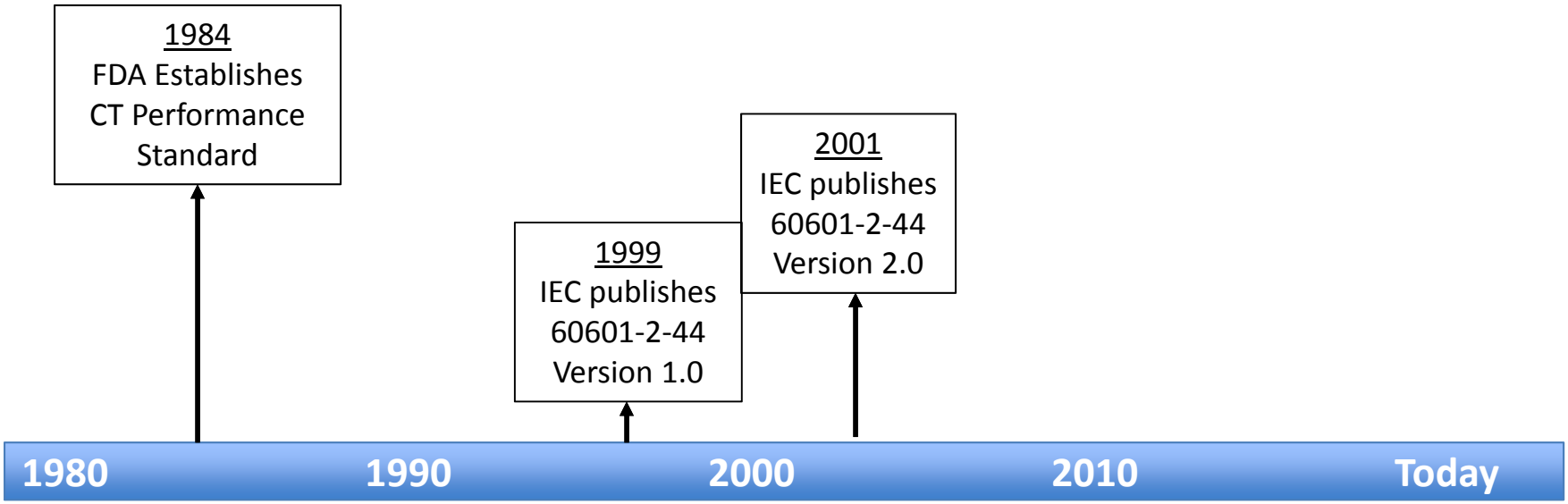


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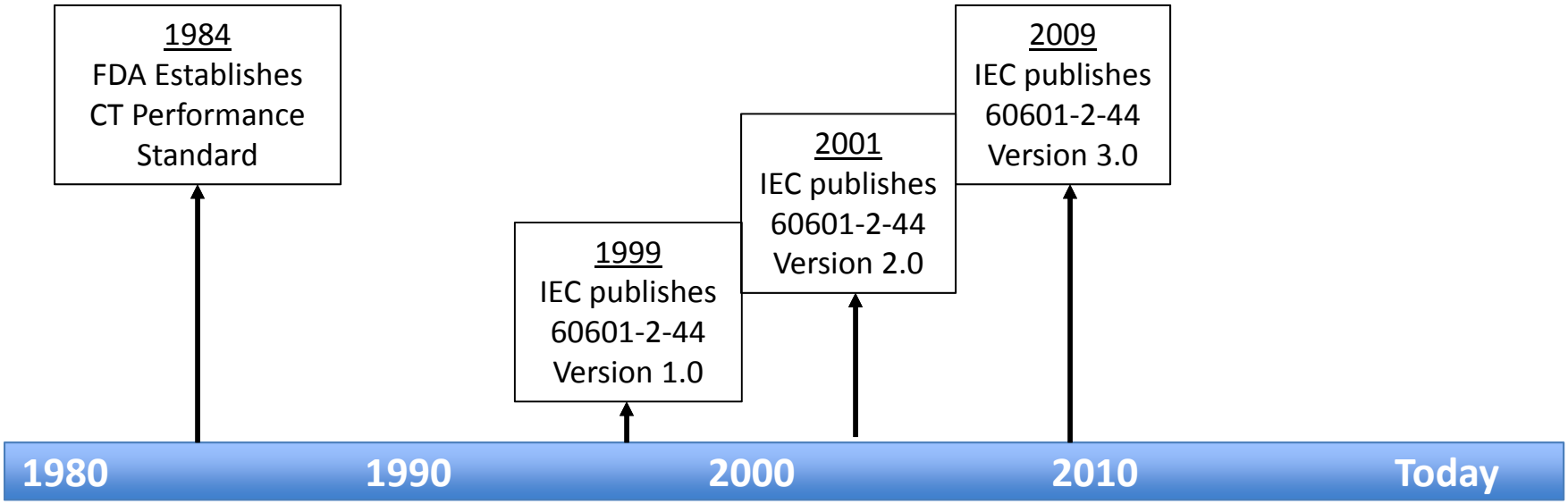


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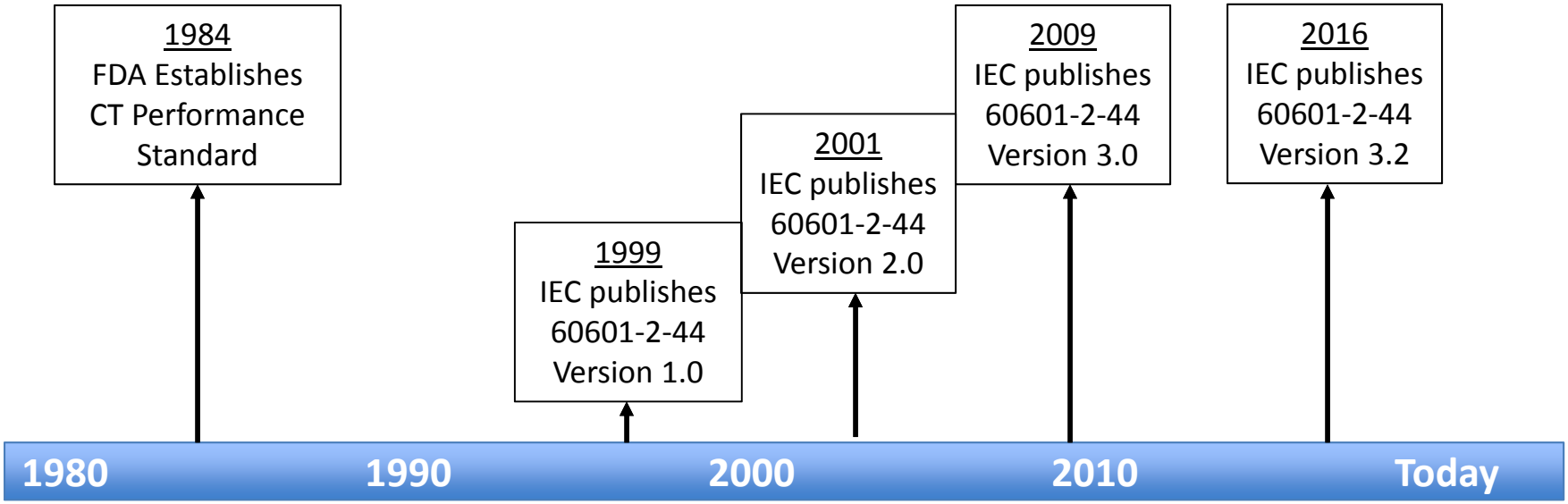


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- Broad membership
- Standards stay current
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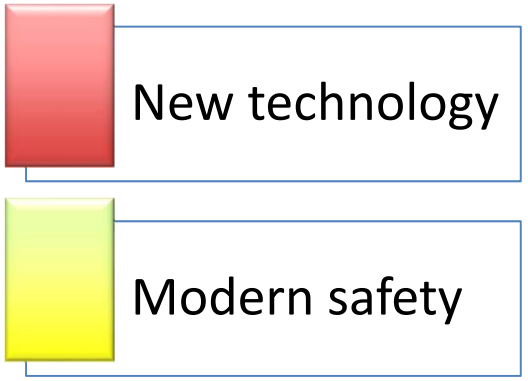

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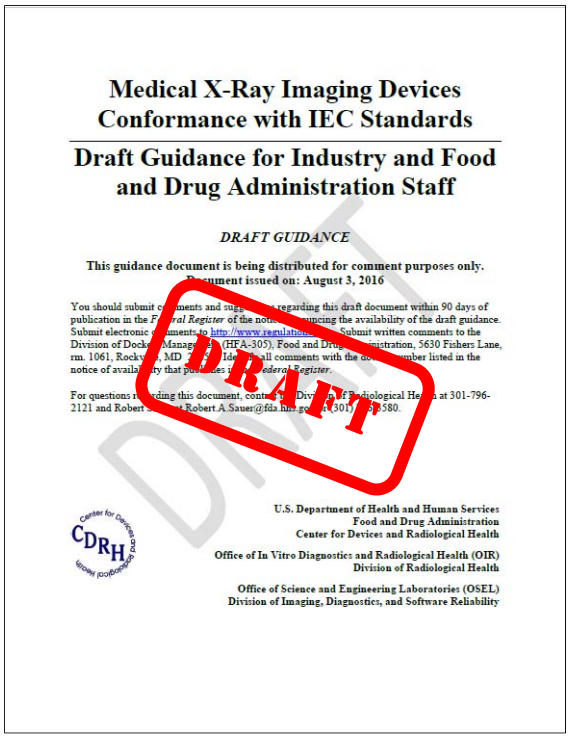
- Broad membership
- Standards stay current
- **Harmonized with other countries**

# To improve safety, FDA is encouraging the use of IEC standards



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

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

*DRAFT GUIDANCE*

**This guidance document is being distributed for comment purposes only.**

**Document issued on: August 3, 2016**

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the document number listed in the notice of availability that publishes in the *Federal Register*.

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Food and Drug Administration
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Office of In Vitro Diagnostics and Radiological Health (OIR)
Division of Radiological Health

Office of Science and Engineering Laboratories (OSEL)
Division of Imaging, Diagnostics, and Software Reliability

- Voluntary program for manufacturers of diagnostic x-ray equipment to choose IEC over EPRC Standard
- Leverages existing FDA standards program
- Maintain strong enforcement capabilities
- Keeps comprehensive medical device premarket review

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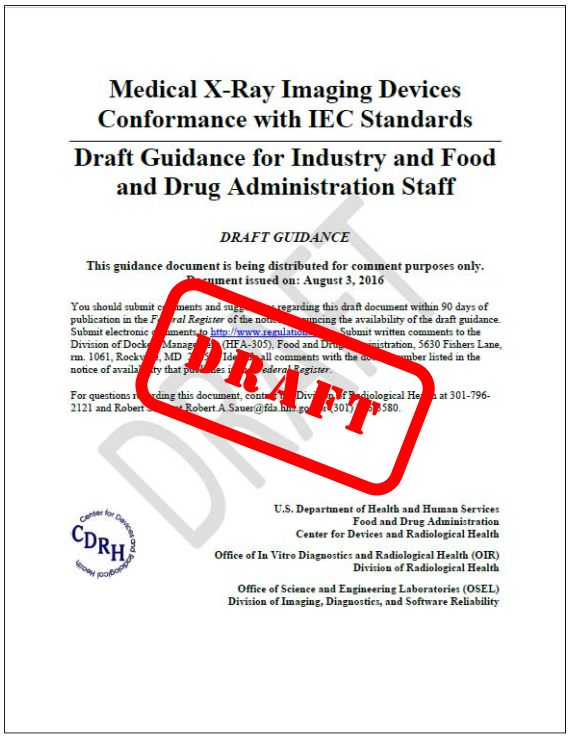

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- Manufacturers opt-in with a declaration of conformity to a recognized standard
- FDA will enforce the radiation safety specifications in the standard to which they declare conformity
- Scope:
  - Radiographic Equipment
  - Fluoroscopic Equipment
  - Computed Tomography Equipment
  - Components

# Guidance comments highlighted practical issues

- Implementation and enforcement by FDA

- Ensuring users have appropriate information to test these systems

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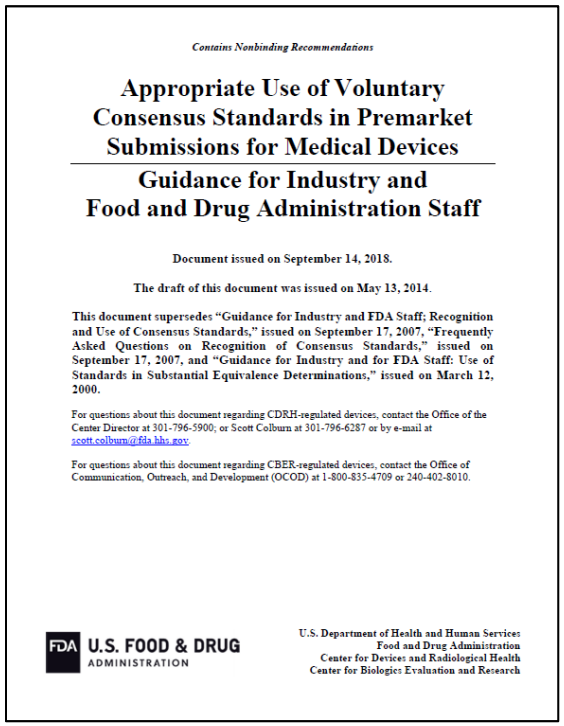
  **Outreach around FDA standards program and EPRC enforcement**

- Ensuring users have appropriate information to test these systems

  **Providing more information to end users**

# CDRH has over 20 years of experience with our standards program



*Contains Nonbinding Recommendations*

**Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices**

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

Document issued on September 14, 2018.

The draft of this document was issued on May 13, 2014.

This document supersedes "Guidance for Industry and FDA Staff; Recognition and Use of Consensus Standards," issued on September 17, 2007, "Frequently Asked Questions on Recognition of Consensus Standards," issued on September 17, 2007, and "Guidance for Industry and for FDA Staff: Use of Standards in Substantial Equivalence Determinations," issued on March 12, 2000.

For questions about this document regarding CDRH-regulated devices, contact the Office of the Center Director at 301-796-5900; or Scott Colburn at 301-796-6287 or by e-mail at scott.colburn@fda.hhs.gov.

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

FDA U.S. FOOD & DRUG ADMINISTRATION

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

- Started in 1997
- Frequently used to meet premarket requirements for many types of devices
- Many x-ray systems already conform to these standards

# FDA's standards program is robust and flexible

- Active participation in standards development
- Flexible recognition process
- Transparency

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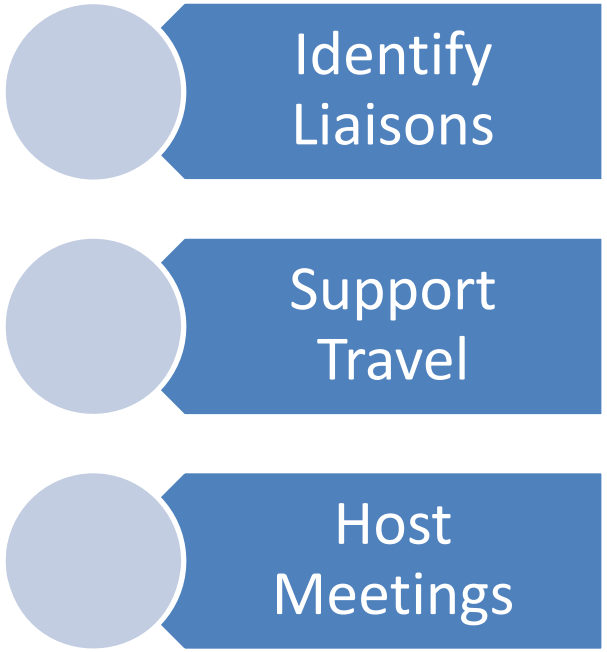

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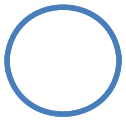
Full Recognition

Partial Recognition



Non-recognition

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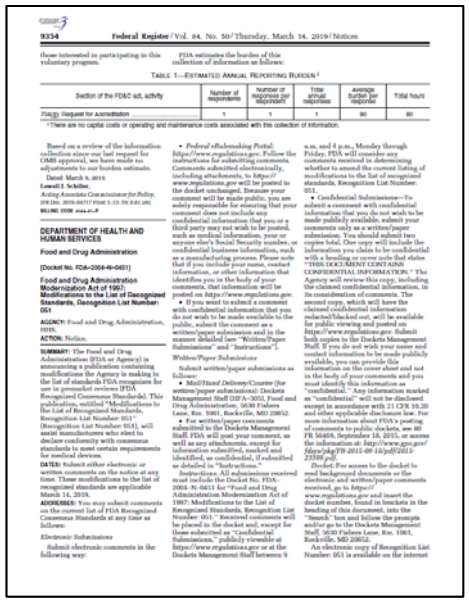
Federal Register Notice



9354 Federal Register / Vol. 84, No. 50 / Thursday, March 14, 2019 / Notices

those interested in participating in this voluntary program.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Section of the FD&C act; activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 514(c); Request for accreditation | 1 | 1 | 1 | 80 | 80 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: March 8, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997; Modifications to the List of Recognized Standards, Recognition List Number: 051

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews [FDA Recognized Consensus Standards]. This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 051" [Recognition List Number: 051], will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments on the notice at any time. These modifications to the list of recognized standards are applicable March 14, 2019.

ADDRESSES: You may submit comments on the current list of FDA Recognized Consensus Standards at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA–2004–N–0451 for "Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 051." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 051.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of Recognition List Number: 051 is available on the internet

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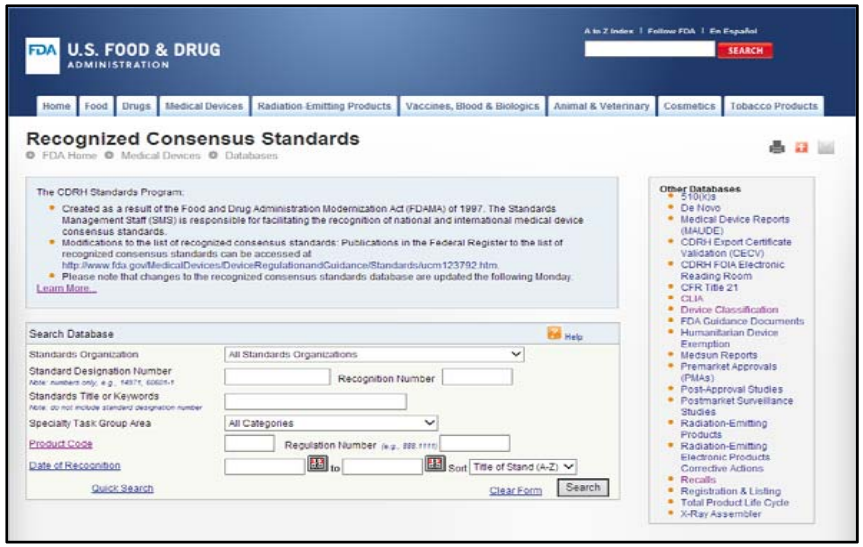
Online Standards Database




https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm

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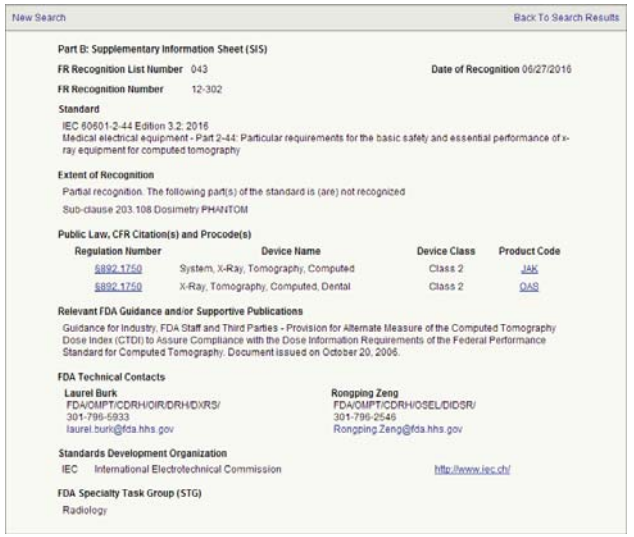
Supplementary Information



New Search | Back To Search Results

**Part B: Supplementary Information Sheet (SIS)**

**FR Recognition List Number** 043 **Date of Recognition** 06/27/2016

**FR Recognition Number** 12-302

**Standard**

IEC 60601-2-44 Edition 3.2: 2016
Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography

**Extent of Recognition**

Partial recognition. The following part(s) of the standard is (are) not recognized

Sub-clause 203.108 Dosimetry PHANTOM

**Public Law, CFR Citation(s) and Procode(s)**

| Regulation Number | Device Name | Device Class | Product Code |
|---|---|---|---|
| §892.1750 | System, X-Ray, Tomography, Computed | Class 2 | JAK |
| §892.1750 | X-Ray, Tomography, Computed, Dental | Class 2 | OAS |

**Relevant FDA Guidance and/or Supportive Publications**

Guidance for Industry, FDA Staff and Third Parties - 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. Document issued on October 20, 2006.

**FDA Technical Contacts**

**Laurel Burk**
FDA/OMPT/CDRH/OIR/DRH/DXRS/
301-796-5933
laurel.burk@fda.hhs.gov

**Rongping Zeng**
FDA/OMPT/CDRH/OSEL/DIDSR/
301-796-2546
Rongping.Zeng@fda.hhs.gov

**Standards Development Organization**

IEC International Electrotechnical Commission http://www.iec.ch/

**FDA Specialty Task Group (STG)**

Radiology

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Outreach

# FDA is maintaining strong enforcement capabilities

- Continue to receive premarket submissions
- Monitoring adverse events & safety signals
- Collaborating with investigators in the Office of Regulatory Affairs
- Declaring conformity to an IEC standard sets radiation safety specifications for an electronic product
- FDA has authority to enforce compliance with radiation safety specifications that the manufacturer sets

# Guidance comments highlighted practical issues

- Implementation and enforcement by FDA

  **Outreach around FDA standards program and EPRC enforcement**

- Ensuring users have appropriate information to test these systems

  **Providing more information to end users**

# FDA asked for help coming up with a solution

- Met with state regulators and medical physicists to better understand their needs
- Discussed with manufacturers and end users what was practical
- Proposed solutions went through many iterations

# Manufacturers will fill in the gaps

Manufacturers will provide a radiation safety specification and testing document that includes:

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

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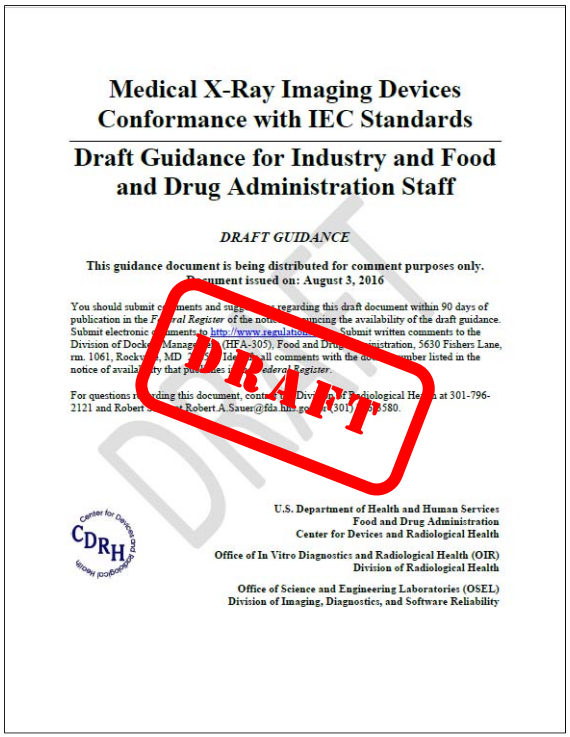

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# Thank You