U.S. FOOD & DRUG ADMINISTRATION

Radiation-Emitting Medical Devices Update

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

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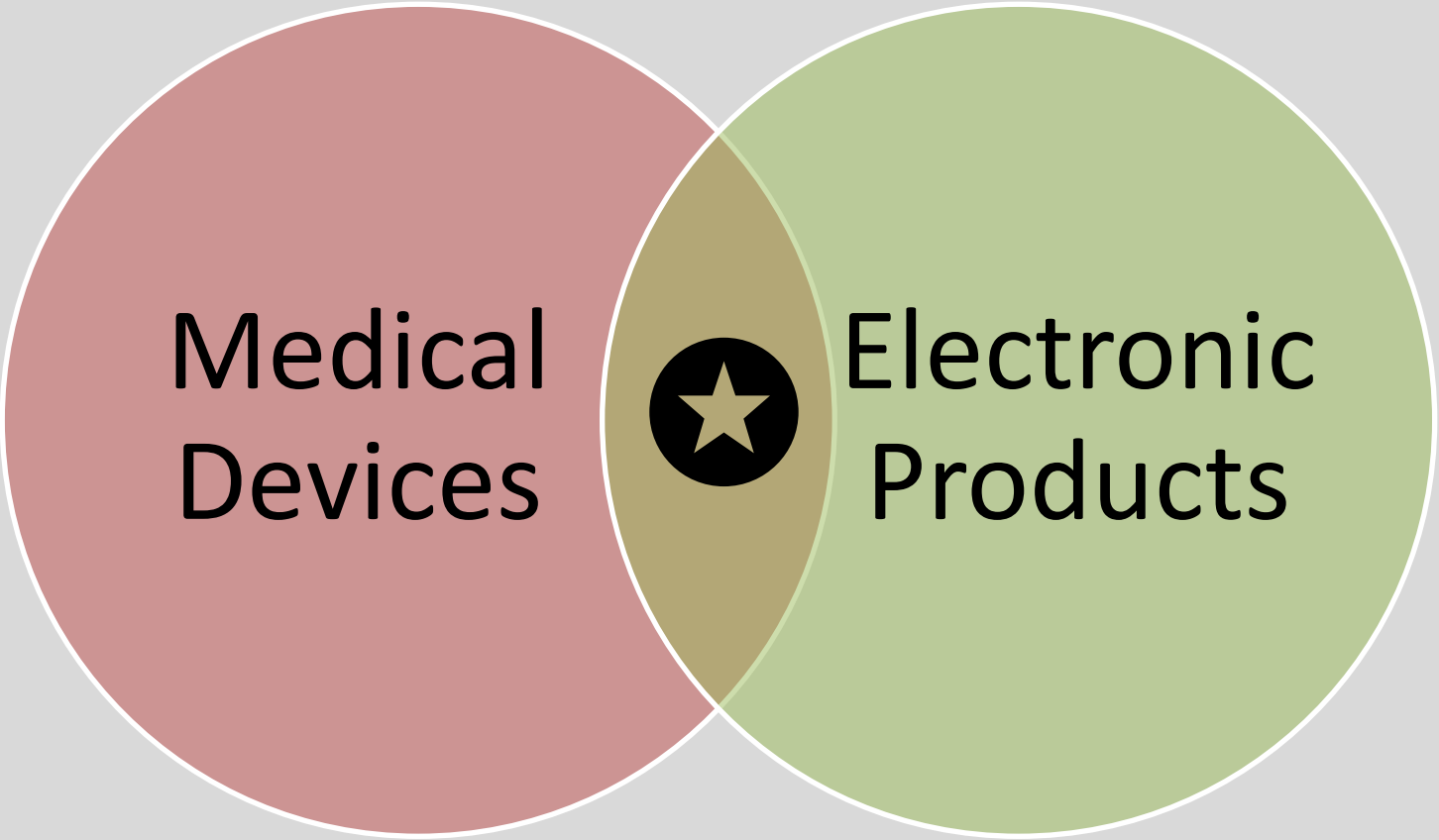
Learning Objectives

- Identify whether a medical device is also an electronic product
- Briefly discuss the Electronic Product Radiation Control (EPRC) regulatory requirements for electronic products
- Identify key changes to the EPRC regulations (effective Feb 2023) that impact medical devices.

Is Your Device an Electronic Product?


Medical Devices
Electronic Products

Electronic Product and **Electronic Product Radiation**

The Radiation Control provisions apply to any "electronic product" which is defined as:

any manufactured or assembled product or article, which is intended for use as a component, part or accessory of such product, when in operation,

i. **contains or acts as part of an electronic circuit** and
ii. **emits** (or in the absence of effective shielding or other controls would emit) **electronic product radiation.**

In accordance with Section 531 (1) of the FD&C Act, "Electronic product radiation" is defined as:

A. any **ionizing or non-ionizing electromagnetic** or **particulate radiation**, or
B. any **sonic, infrasonic, or ultrasonic wave**, which is **emitted from an electronic product as the result of the operation of an electronic circuit** in such product.

Medical Devices and Electronic Products

Electronic Product (EP) Radiation	Medical Device (also EP)
X-rays	Computed Tomography (CAT scan)
Ultrasound Waves	Diagnostic Ultrasound
Laser Light	Dermatology Laser
Microwaves	Microwave Ablation Device

Knowledge Check

Which of these medical devices is <u>not</u> an electronic product?

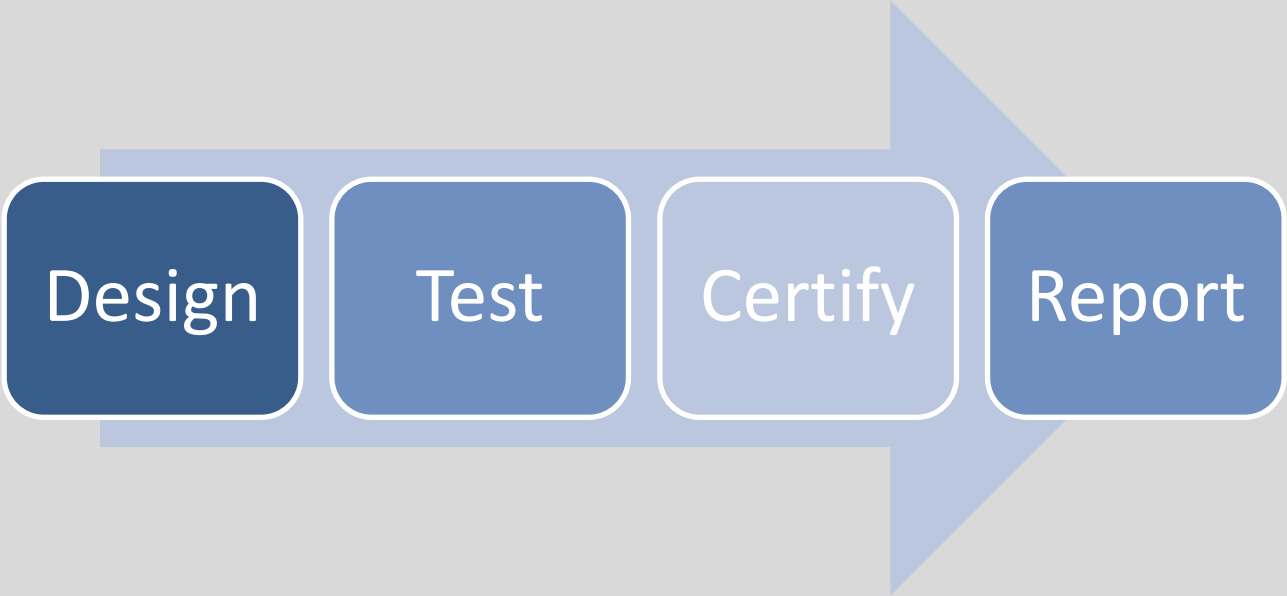
1. Sunlamp (tanning bed)
2. Electric Toothbrush
3. Surgical Laser

Regulatory Obligations for Electronic Product Manufacturers

www.fda.gov/radiation-emitting-products/laws-and-regulations-radiation-emitting-products/summary-electronic-product-radiation-control-provisions-federal-food-drug-and-cosmetic-fdc-act

Performance Standard	Applies to this Electronic Product Type
21 CFR 1020.10	Television Receivers with cathode ray tubes
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
21 CFR 1020.40	Cabinet X-ray Systems
21 CFR 1030.10	Microwave Ovens
21 CFR 1040.10	Lasers and Laser Systems
21 CFR 1040.11	Specific Laser Products
21 CFR 1040.20	Sunlamps and Sunlamp Products

Requirements for Electronic Products with Performance Standards



General Requirements

- Reporting and record keeping (21 CFR 1002-1005)
  - Report accidental radiation occurrences (AROs) – 1002.20
  - Provide notifications of defect/failure to comply, and repair/replace/refund (EPRC “Recall”) – 1003-1004

Changes to the EPRC Regulations

EPRC Amendments

- Effective February 2023
- Goals: Clarify, reduce outdated and duplicative requirements

FR Notice: www.federalregister.gov/documents/2023/01/20/2023-00922/radiological-health-regulations-amendments-to-records-and-reports-for-radiation-emitting-electronic

Ultrasonic Products

- Performance standard 21 CFR 1050.10 removed
- Ultrasonic products are medical devices with modern, frequently updated consensus standards
  - IEC 60601-2-5 Basic safety and essential performance of ultrasonic therapy equipment (2013)
  - IEC 61689 Ultrasonic Physiotherapy systems – field specifications and methods of measurement

Diagnostic X-ray Systems

- X-ray, dental X-ray, fluoroscopy, CT scanners
- All have performance standards (21 CFR 1020.30 – 33)
- Significant reductions in reporting for these products
  - No longer need to submit initial, abbreviated, or annual reports

Products	Manufacturer						Dealer & Distributor
	Product reports 1002.10	Supplemental reports 1002.11	Abbreviated reports 1002.12	Annual reports 1002.13	Test records 1002.30(a) [1]	Distribution records 1002.30(b) [2]	Distribution records 1002.40 and 1002.41
DIAGNOSTIC X-RAY [3](1020.30, 1020.31, 1020.32, 1020.33)	**21 CFR 1002.1 Table 1 – Modifications: Reporting Requirements By Product (X)**						
Computed tomography	X	X		X	X	X	X
X-ray system [4]	X	X		X	X	X	X
Tube housing assembly	X	X		X	X	X	
X-ray control	X	X		X	X	X	X
X-ray high voltage generator	X	X		X	X	X	X
X-ray table or cradle			X		X	X	X
X-ray film changer			X		X	X	
Vertical cassette holders mounted in a fixed location and cassette holders with front panels			X		X	X	X
Beam-limiting devices	X	X		X	X	X	X
Spot-film devices and image intensifiers manufactured after April 26, 1977	X	X		X	X	X	X
Cephalometric devices manufactured after February 25, 1978			X		X	X	

X-ray Reports of Assembly

- Diagnostic X-ray Reports of Assembly (Form FDA 2579) no longer submitted to FDA (1020.30(d))

				OTHER	KERMA DISPLAY DEVICE

5. ASSEMBLER CERTIFICATION

I affirm that all certified components assembled or installed by me, for which this report is being made, were adjusted and tested by me according to the instructions provided by the manufacturer(s), were of the type required by the manufacturer(s), were of the type required by the diagnostic x-ray performance standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installed in accordance with provisions of 21 CFR Part 1020. I also affirm that all instruction manuals and other information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser and, within 15 days following completion of the assembly, a copy of this form will be submitted to the purchaser and, where applicable, to the State agency responsible for radiation protection.

a. PRINTED NAME	b. SIGNATURE

Form FDA 2579: www.fda.gov/media/144454/download

Knowledge Check

X-ray Assemblers no longer need to complete a Report of Assembly (Form 2579)

1. True
2. False

Laser Products

- Many medical devices include lasers as a component
- Lasers are radiation emitting electronic products with performance standards (21 CFR 1040.10, 1040.11)
  - Remember: Design, Test, Certify, Report
- Goal: reduce burden for manufacturers who incorporate already-certified laser products, or for manufacturers of lower-risk laser products

Laser Product Regulation Changes

- Devices that incorporate already-certified laser components are considered certified as well
  - [if requirements are met (formalizing from LN 42)]
- Reduced reporting requirements for some laser products

Incorporating Certified Laser Systems

§ 1010.2(e) Certification

(e) Laser products under § 1040.10 of this chapter that incorporate a certified laser system (laser product) will be considered to have met the certification requirements in this section if all of the following conditions are met:

(1) The incorporated laser system is not a laser product intended for use as a component or replacement as described in § 1040.10(a)(1) and (2) of this chapter;

(2) The manufacturer of the incorporated laser system has certified such laser system under this section and meets the reporting requirements under part 1002;

(3) The product incorporating the certified laser system is not independently subject to additional reporting or performance standards requirements;

(4) The incorporated laser system is not modified as defined in § 1040.10(i) of this chapter, and all performance features that apply to the incorporated laser system under § 1040.10(f) are available on the product incorporating the certified laser system;

(5) All labeling requirements that apply to the incorporated laser system under §§ 1010.2, 1010.3, 1040.10(g), and 1040.11(a)(3) of this chapter are visible on the outside of the product incorporating the certified laser system, with the exception that the certification or identification labels need not be visible on the outside of products incorporating a certified Class I laser;

(6) The incorporated laser system is installed in accordance with the instructions provided by the manufacturer of the incorporated laser system, including instructions for placing additional externally facing labels found in paragraph (e)(5) of this section, and meeting the other conditions in paragraphs (e)(1) through (e)(8) of this section;

(7) The manufacturer of the product that incorporates the laser system provides the end user with information required under § 1040.10(h)(1) of this chapter as provided to them by the manufacturer of the incorporated laser system; and

(8) The labeling requirements under part 1010 and § 1040.10(g) of this chapter for the incorporated laser system would be met in any service configuration of the product incorporating the laser system or when the incorporated laser system is removed from the product into which it had been incorporated, and reproductions of such labels are found in the user information.

(Implementing and expanding flexibilities from FDA guidance document "Laser Notice 42")

www.ecfr.gov/current/title-21/chapter-I/subchapter-J/part-1010/subpart-A/section-1010.2#p-1010.2(e)

Laser Product Reporting Changes

Manufacturer							Dealer & Distributor
Products	Product reports 1002.10	Supplemental reports 1002.11	Abbreviated reports 1002.12	Annual reports 1002.13	Test records 1002.30(a)[1]	Distribution records 1002.30(b)[2]	Distribution records 1002.40 and 1002.41
Laser products (1040.10, 1040.11)							
Class I lasers and products containing such lasers [7,9]	X [8]			X	X		
Class I laser products containing class IIa, II, IIIa, lasers [7,9]	X			X	X	X	
Class IIa, II, IIIa lasers and products other than class I products containing such lasers [7,9]	X	X		X	X	X	X
Class IIIb and IV lasers and products containing such lasers [7]	X	X		X	X	X	X

[7] Determination of the applicable reporting category for a laser product shall be based on the worst-case hazard present within the laser product.

[8] Manufacturers are exempt from product reports (§ 1002.10) and abbreviated reports (§ 1002.12), except the first product or abbreviated report for each category of: television products; microwave ovens; and products that are Class I laser under any condition of operation, maintenance, service, or failure (e.g., Class I optical disc products, laser printers).

[9] Manufacturers that incorporate a certified laser system meeting the conditions of 21 CFR 1010.2(e) are considered distributors of the certified laser and only subject to the applicable distribution recordkeeping requirements under §§ 1002.40 and 1002.41 for the certified products.

Accidental Radiation Occurrences (ARO)s

- AROs now can be reported as quarterly summaries (if not associated with a death or serious injury)
- Clarify “accidental” – intentional re-emission of radiation by operator not an ARO
- No “minimum threshold” for an ARO

www.ecfr.gov/current/title-21/chapter-I/subchapter-J/part-1002/subpart-C/section-1002.20

Knowledge Check

Diagnostic X-ray manufacturers no longer need to certify their products

1. True
2. False

Summary

- Some medical devices are also electronic products subject to regulation under the Radiation Control Provisions of FD&C Act
- The EPRC Regulations were amended in February 2023:
  - Diagnostic X-ray Devices no longer need product reports
  - Devices that incorporate already-certified laser components are considered certified as well (if requirements are met)
  - ARO reports can be submitted as quarterly summaries (in most cases)

Resources

Slide Number	Cited Resource	URL
5	Examples of Radiation-Emitting Electronic Products	www.fda.gov/media/77753/download
10	Summary of the Electronic Product Radiation Control Provisions of the Federal Food, Drug, And Cosmetic (FD&C) Act	www.fda.gov/radiation-emitting-products/laws-and-regulations-radiation-emitting-products/summary-electronic-product-radiation-control-provisions-federal-food-drug-and-cosmetic-fdc-act
13	Laws and Regulations – Radiation Emitting Products	www.fda.gov/laws-and-regulations-radiation-emitting-products
15	FR Notice for Radiological Health Regulation Amendments (effective February 2023	www.federalregister.gov/documents/2023/01/20/2023-00922/radiological-health-regulations-amendments-to-records-and-reports-for-radiation-emitting-electronic
18 and 24	21 CFR 1002.1 – Table of Required Reports by Product	www.ecfr.gov/current/title-21/chapter-I/subchapter-J/part-1002/subpart-A/section-1002.1
19	Copy of Form FDA 2579 (Report of Assembly of Diagnostic X-ray System	www.fda.gov/media/144454/download
23	Certification and Incorporating Certified Lasers	www.ecfr.gov/current/title-21/chapter-I/subchapter-J/part-1010/subpart-A/section-1010.2#p-1010.2(e)
25	Regulation on the reporting of AROs	www.ecfr.gov/current/title-21/chapter-I/subchapter-J/part-1002/subpart-C/section-1002.20

Questions