

# **EPRC Requirements of Radiation-Emitting Medical Devices**

**FDA Small Business Regulatory Education for Industry (REdI)**

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U.S. Food and Drug Administration

# Undercover Product Testing



**FDA's Winchester Engineering Analytical Center (WEAC)**

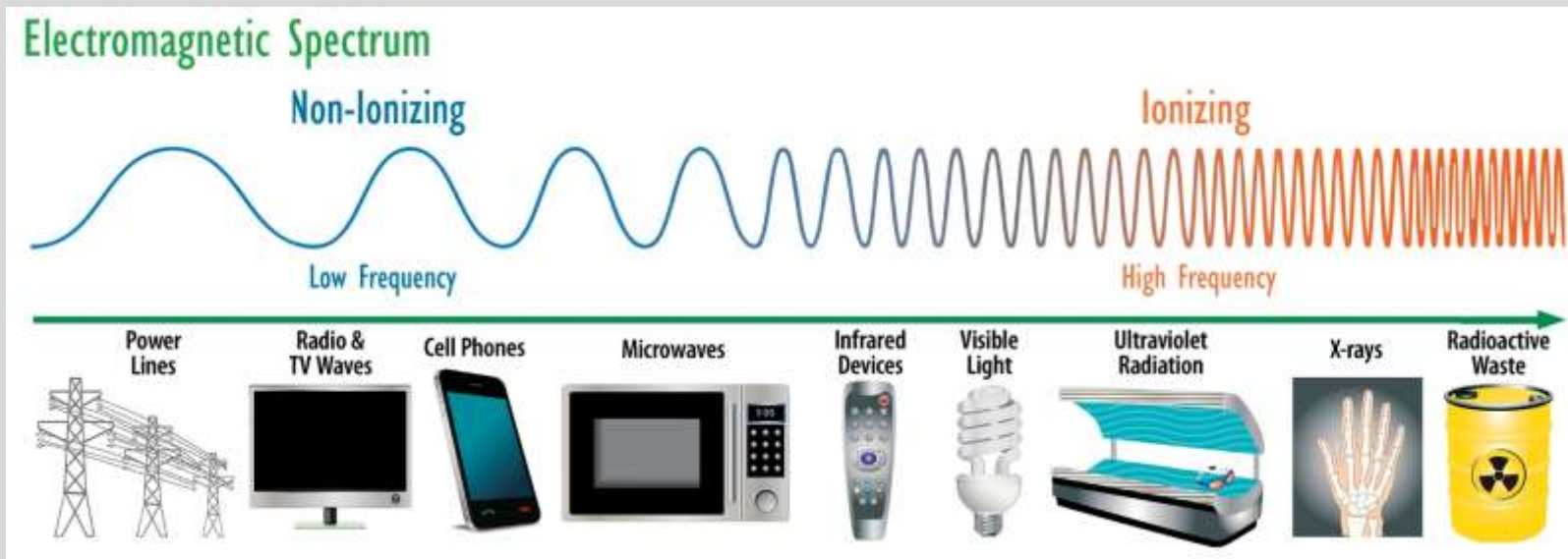


# Learning Objectives

- Describe Radiological Health's big picture
- List the devices that are also part of FDA's EPRC program
- Identify manufacturer responsibilities under EPRC
- Discuss relevant EPRC guidance documents
- Review and find regulatory information at FDA

# Radiological Health

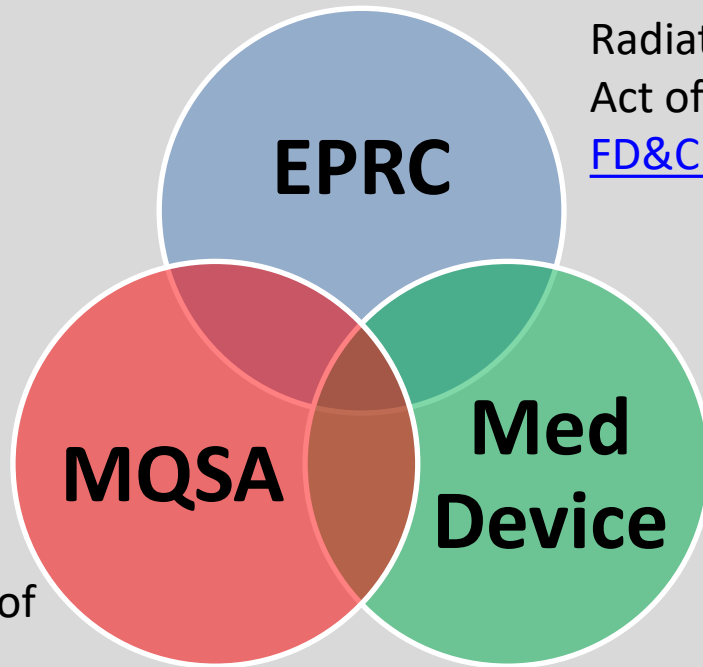
# What is Electronic Product Radiation?



Radiation produced by a circuit, that may be EM, particulate or acoustic.

Photo Credit: [National Institute of Environmental Health Sciences](#)

# Radiological Health Programs at FDA



Radiation Health & Safety  
Act of 1968, Now part of  
[FD&C Act Section 531-542](#)

[Mammography Quality  
Standards Act \(MQSA\)](#)  
(as amended by MQSRA of  
1998 and 2004)

1976 Medical Device  
Amendments  
[FD&C Act Chapter V](#)

# FDA's EPRC Program for Medical Devices



**Diagnostic X-ray**

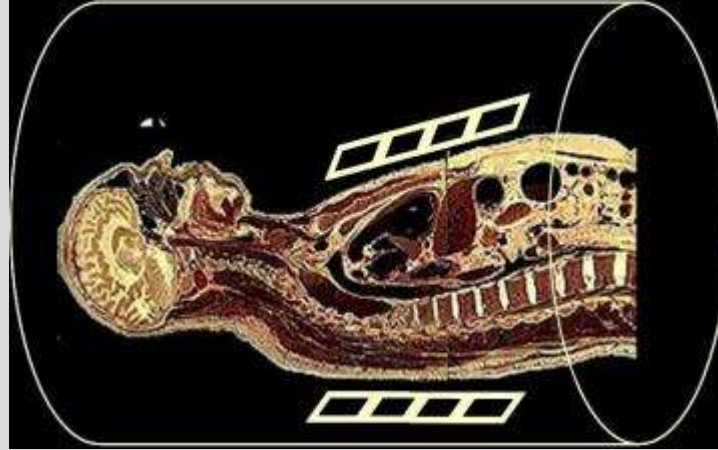


**Linear accelerator for radiotherapy**

Photo credit: [US Bureau of Labor and Statistics](https://www.bls.gov/)

# Dual-Regulated Products

CT and laser



MR image

Image Credit: [NIH](#)

Suntanning bed



Diagnostic ultrasound

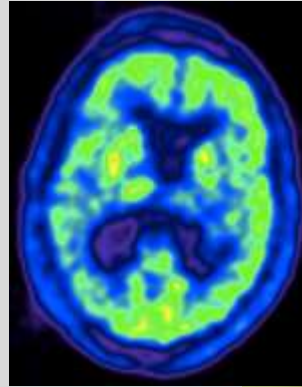


# Examples of Medical Devices



**Nuclear imaging scanner**

Photo credits: [NIH](https://www.nih.gov/)



**Cobalt therapy,  
Brachytherapy,  
Radiopharmaceuticals**



Photo credit: US Bureau of Labor and Statistics

# Examples of Electronic Products



**Microwave oven**

Photo credit: [EPA](#)



**Laser pointers**



**3D – computed tomography  
airport baggage scanner**

Photo credit: [TSA](#)

# Manufacturer's Responsibilities Under EPRC

[Summary Of The Electronic Product Radiation Control  
Provisions Of The Federal Food, Drug, And Cosmetic Act](#)

# Manufacturer's EPRC Responsibilities

- Design and manufacture EPs to comply with applicable performance standards
- Certification and reporting to FDA, as applicable
- Report accidental radiation occurrences (ARO)
- Reporting and correction of non-compliances and defects

# Design and Manufacture

- Identify applicable mandatory performance standards and guidance
- Maintain quality and test program records as evidence for certification
- Certify and report to FDA, if applicable

# Certification

- Self-certification is made by the manufacturer
- Only manufacturers of electronic products with mandatory FDA performance standards certify
- A variance may be petitioned

# Reporting

- File radiation safety reports if required by regulation
- Receipt of reports by FDA is acknowledged
- An accession number is not an FDA approval
- Manufacturers will only be contacted if FDA has questions

# Reporting of AROs

- Report injurious or *potentially* injurious exposures
- Filing an MDR fulfills ARO reporting requirements
- AROs have no injury threshold
- Report AROs using reporting FDA Form #3649



# Responsibility for Defects

- **Unintended EP Radiation**
  - creates a risk of injury or
  - fails to conform to specifications
- **Intentional EP Radiation**
  - fails to conform to specifications,
  - emits when not commanded or
  - fails to emit as needed to perform the product's function

# Reporting Defects and Corrective Actions

- Immediate notification to FDA
- Mandatory corrective action of defects by repair, replacement or refund
- Distribution records are required to be kept for 5 years

# **EPRC Guidance Documents**

# Compliance Program Guidance

Program #	Compliance Program Title	Online Link
7383.001	Medical Device Premarket Approval and Post-market Inspections	<a href="http://www.fda.gov/media/82616/download">www.fda.gov/media/82616/download</a>
7386.001	Inspection and Field Testing of Radiation-Emitting Electronic Products	<a href="http://www.fda.gov/media/74525/download">www.fda.gov/media/74525/download</a>
7386.003	Field Compliance Testing of Diagnostic Medical X-Ray Equipment	<a href="http://www.fda.gov/media/74120/download">www.fda.gov/media/74120/download</a>
7386.003a	Inspection of Domestic and Foreign Manufacturers of Diagnostic X Ray Equipment	<a href="http://www.fda.gov/media/142160/download">www.fda.gov/media/142160/download</a>

**Compliance Program Guidance:** [www.fda.gov/medical-devices/quality-and-compliance-medical-devices/center-devices-and-radiological-health-cdrh-compliance-programs](http://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/center-devices-and-radiological-health-cdrh-compliance-programs)

# Device Guidance

- [Medical X-Ray Imaging Devices Conformance with IEC Standards](#) (May 2019)
  - Avoidance of Duplication
- [Policy Clarification for Certain Fluoroscopic Equipment Requirements](#) (May 2019)
- Diagnostic Ultrasound [reporting letter](#) (1986)

# Recent Laser Guidance

- Laser Notice 56 allows substitution of IEC 60825-1:2014 for parts of 21 CFR 1040.10
- IEC 60601-2-22 is allowed to substitute for parts of 21 CFR 1040.11(a)

# Regulatory Information

# Burden Reduction Amendments

- Proposed Rule, April 1, 2019: 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

[Proposed Amendments to Records and Reports for EP](#)



# Office of Health Technology (OHT)



Office Title	Product Area
OHT1	Ophthalmic, Anesthesia, Respiratory, Ear, Nose and Throat (ENT), Dental
OHT2	Cardiovascular
OHT3	Gastro-renal, Obstetrics and Gynecology, General Hospital, Urology
OHT4	Surgical, Infection Control: <i>Surgical &amp; Dermatology lasers, suntanning beds, UV disinfection systems for medical uses</i>
OHT5	Neurological, Physical Medicine
OHT6	Orthopedic
OHT7	In Vitro Diagnostics: <i>Laser flow cytometry systems</i>
OHT8	Radiological Health: <i>Diagnostic X-ray, radiation therapy, mammography, ultrasound, MRI, microwave blood warmers</i>

# Resources

Slide Number	Cited Resource	URL
5	Definitions of Electronic Product (EP) and EP Radiation	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1000.3">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1000.3</a>
6	Overview of Laws and Regulations	<a href="http://www.fda.gov/radiation-emitting-products/laws-and-regulations-radiation-emitting-products/overview-laws-and-regulations">www.fda.gov/radiation-emitting-products/laws-and-regulations-radiation-emitting-products/overview-laws-and-regulations</a>
11	Summary of the EPRC Provisions	<a href="http://www.fda.gov/radiation-emitting-products/laws-and-regulations-radiation-emitting-products/summary-electronic-product-radiation-control-provisions-federal-food-drug-and-cosmetic-act">www.fda.gov/radiation-emitting-products/laws-and-regulations-radiation-emitting-products/summary-electronic-product-radiation-control-provisions-federal-food-drug-and-cosmetic-act</a>
13	Quality Test Program Records	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1002.30">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1002.30</a>
14	Certification to a Performance Std	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1010.2">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1010.2</a>
15	Reporting	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1002&amp;showFR=1&amp;subpartNode=21:8.0.1.3.38.1">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1002&amp;showFR=1&amp;subpartNode=21:8.0.1.3.38.1</a>
16	ARO Reporting	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1002.20">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1002.20</a>

# Resources

Slide Number	Cited Resource	URL
17	Defect in an EP	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1003.2">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1003.2</a>
18	Discovery of a Defect or Failure to Comply	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1003.10">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1003.10</a>
21	Medical X-Ray Imaging Devices Conformance with IEC Standards	<a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-x-ray-imaging-devices-conformance-iec-standards">www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-x-ray-imaging-devices-conformance-iec-standards</a>
21	Policy Clarification for Certain Fluoroscopic Equipment Requirements	<a href="http://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-clarification-certain-fluoroscopic-equipment-requirements">www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-clarification-certain-fluoroscopic-equipment-requirements</a>
21	reporting letter	<a href="http://www.fda.gov/media/99256/download">www.fda.gov/media/99256/download</a>
24	Proposed Amendments to Records and Reports for EP	<a href="http://www.federalregister.gov/documents/2019/04/01/2019-05822/radiological-health-regulations-amendments-to-records-and-reports-for-radiation-emitting-electronic">www.federalregister.gov/documents/2019/04/01/2019-05822/radiological-health-regulations-amendments-to-records-and-reports-for-radiation-emitting-electronic</a>
31	Radiation-Emitting Products Industry Assistance: Walk-through	<a href="http://www.fda.gov/radiation-emitting-products/getting-radiation-emitting-product-market-frequently-asked-questions/radiation-emitting-products-industry-assistance-walk-through">www.fda.gov/radiation-emitting-products/getting-radiation-emitting-product-market-frequently-asked-questions/radiation-emitting-products-industry-assistance-walk-through</a>

# Knowledge Check

Which product does not emit a type of Electronic Product Radiation?

- A. A hand-held dental x-ray
- B. Proton beam therapy accelerator
- C. Cobalt 60 radiotherapy machine

# Knowledge Check

**Which is a description of an Electronic Product Radiation Defect?**

- A. I just turned it on, and it burst into flames
- B. A proton therapy accelerator has a transient hotspot in the treatment beam that can sometimes overexpose the patient to radiation

# Knowledge Check

## True or False?

We just received our 510(k) clearance for a new X-ray diagnostic imaging device. Are we done with all the reporting paperwork?

A. True – you have no required reports

B. False – you had a reportable ARO

# Summary

- There are three radiological health laws
- Devices can be part of FDA's EPRC program
- Manufacturers have responsibilities under EPRC
- EPRC guidance documents are available
- EPRC is the only law that protects the public from non-medical electronic product radiation

# Questions



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