EPRC Requirements of Radiation-Emitting Medical Devices

FDA Small Business Regulatory Education for Industry (REdI)

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Lowell Howard, PhD

Electrical Engineer

Office of Radiological Health (OHT8)

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

U.S. Food and Drug Administration

Undercover Product Testing

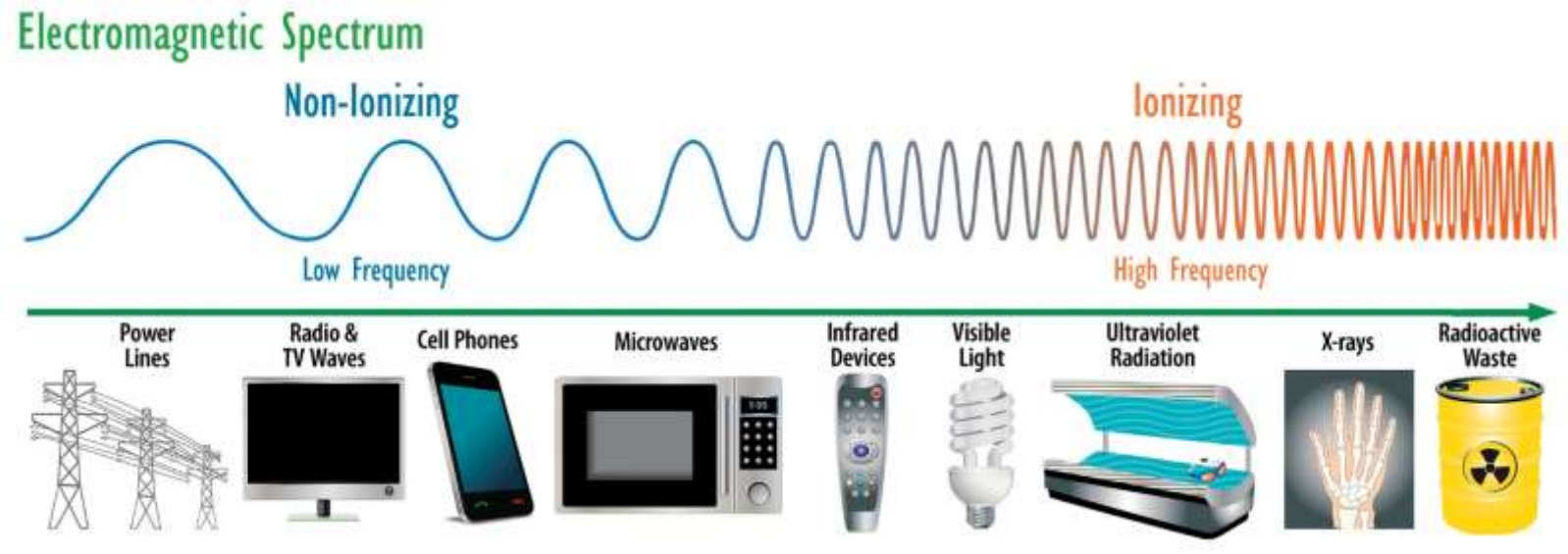
FDA's Winchester Engineering Analytical Center (WEAC)

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

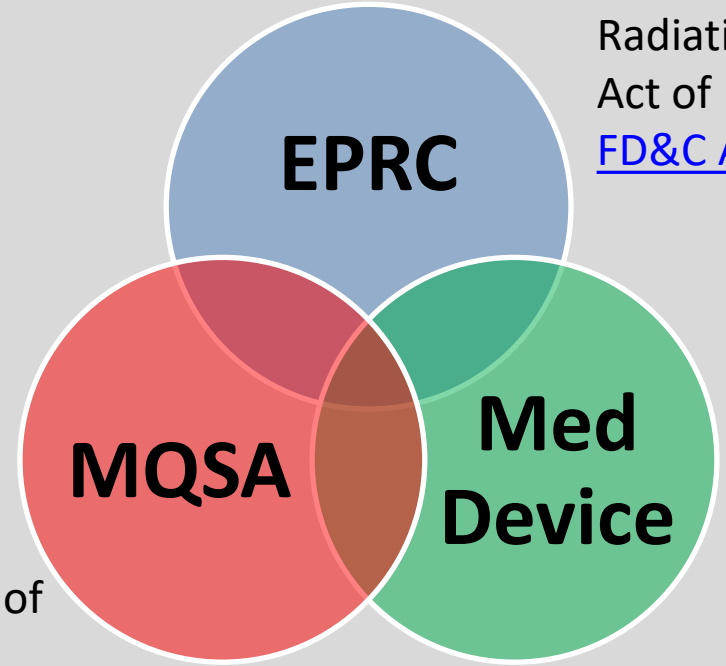
What is Electronic Product Radiation?



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

1976 Medical Device Amendments FD&C Act Chapter V

Mammography Quality Standards Act (MQSA) (as amended by MQSRA of 1998 and 2004)

FDA's EPRC Program for Medical Devices

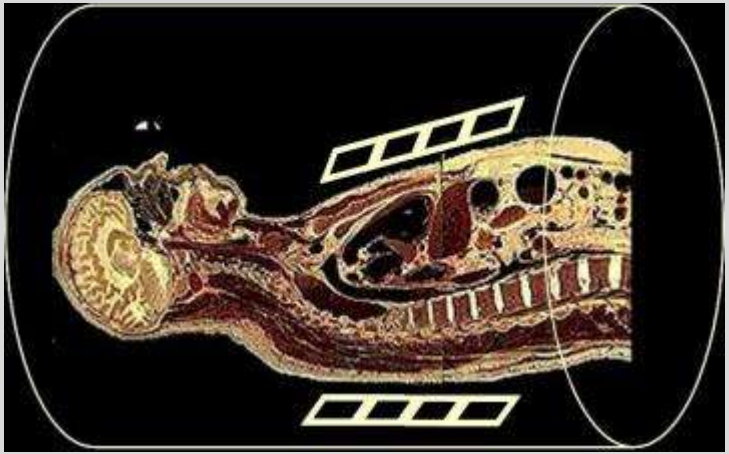
Diagnostic X-ray

Linear accelerator for radiotherapy

Photo credit: US Bureau of Labor and Statistics

Dual-Regulated Products

CT and laser



MR image

Image Credit: NIH

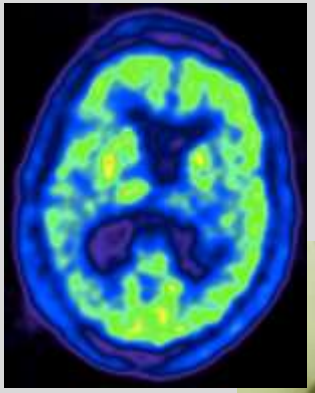
Suntanning bed

Diagnostic ultrasound

Examples of Medical Devices

Nuclear imaging scanner

Photo credits: NIH



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	www.fda.gov/media/82616/download
7386.001	Inspection and Field Testing of Radiation-Emitting Electronic Products	www.fda.gov/media/74525/download
7386.003	Field Compliance Testing of Diagnostic Medical X-Ray Equipment	www.fda.gov/media/74120/download
7386.003a	Inspection of Domestic and Foreign Manufacturers of Diagnostic X Ray Equipment	www.fda.gov/media/142160/download

Compliance Program Guidance: 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: *Surgical & Dermatology lasers, suntanning beds, UV disinfection systems for medical uses*
OHT5	Neurological, Physical Medicine
OHT6	Orthopedic
OHT7	In Vitro Diagnostics: *Laser flow cytometry systems*
OHT8	Radiological Health: *Diagnostic X-ray, radiation therapy, mammography, ultrasound, MRI, microwave blood warmers*

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm

Resources

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

Resources

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

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

RadHealthCustomerService@fda.hhs.gov