

# Technical Electronic Product Radiation Safety Standards Committee (*TEPRSSC*): Introduction, Scope and History

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# TEPRSSC Disclosure

The content of all presentations provided for this meeting are for discussion and summary purposes only and do not describe the full extent of requirements applicable to electronic products. Please see the Federal Food, Drug, and Cosmetic Act and 21 CFR Subchapter J for a full list of requirements.

- TEPRSSC
- Definitions
- History
- Agenda

# TEPRSSC

- Established by the Radiation Control for Health and Safety Act of 1968 (*see* section 534 of the Federal Food, Drug and Cosmetic Act [the “FD&C Act” or the “Act”], 21 U.S.C. § 360kk):
- “The Secretary shall establish a ***Technical Electronic Product Radiation Safety Standards Committee***...which he shall consult before prescribing any standard under this section.”
- “Standard” refers to performance standards for electronic products to control the emission of electronic product radiation.

# TEPRSSC Charter

- The Committee provides advice and consultation...on the ***technical feasibility, reasonableness, and practicability*** of performance standards for electronic products to control the emission of radiation from such products, and ***may recommend electronic product radiation safety standards*** to the Commissioner for consideration. [emphasis added]

- TEPRSSC may also make recommendations on any other matter it deems necessary or appropriate in fulfilling the purposes of the Act (21 CFR 14.122(a)(3)).
- Purpose of the Act: “...protect the public health and safety from electronic product radiation.” (21 U.S.C. § 360ii)

# Definitions

# Electronic Product Radiation

- 21 CFR 1000.3(k)

(1) Any ionizing or nonionizing electromagnetic or particulate radiation,

or

(2) Any sonic, infrasonic, or ultrasonic wave that is emitted from an electronic product as the result of the operation of an electronic circuit in such product.



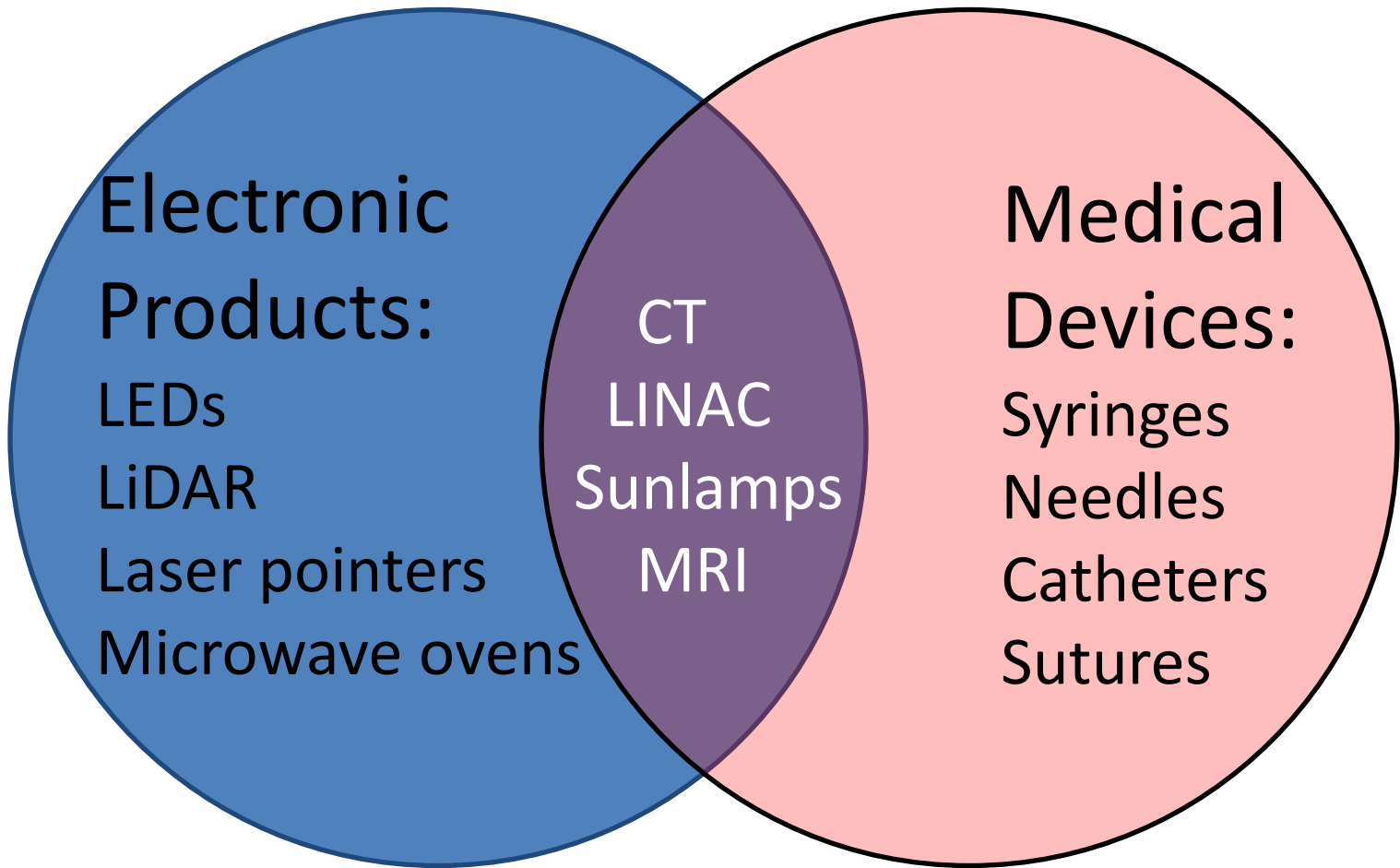
*(Electronic) Products*  
and  
*(Medical) Devices*

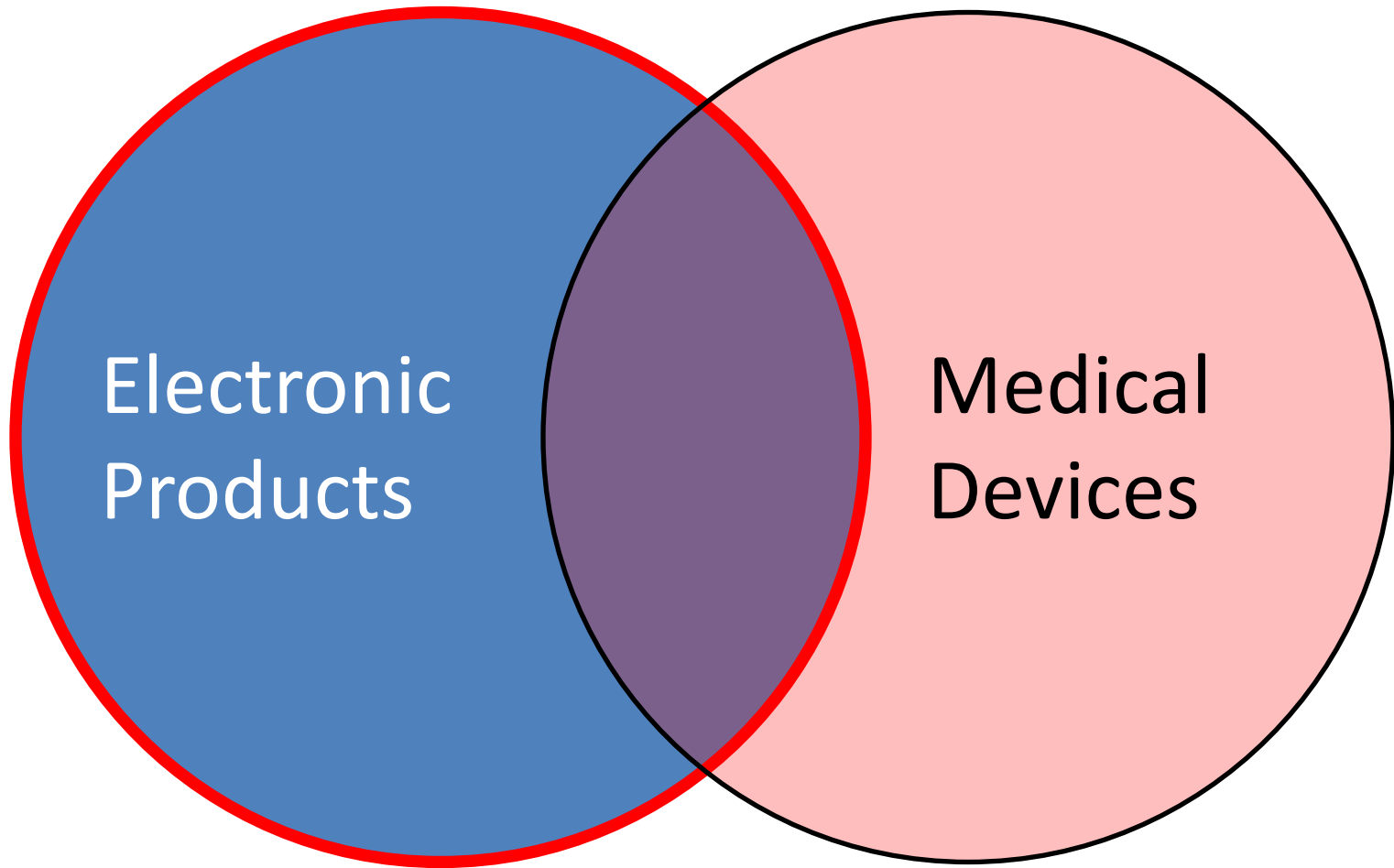
# Electronic Product (21 CFR 1000.3)

- Any manufactured or assembled product which, 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
- A component, part or accessory of such a product that emits (or in the absence of effective shielding or other controls would emit) electronic product radiation

# Medical Device (21 U.S.C. § 321(h))

- Defined at 21 U.S.C. § 321(h)
- The full definition is in the briefing materials
- Definition available at <https://www.gpo.gov/fdsys/granule/USCODE-2010-title21/USCODE-2010-title21-chap9-subchapII-sec321/content-detail.html>





- With regard to medical devices that are also electronic products, TEPRSSC will only consider aspects related to control of the emission of electronic product radiation.

# EPRC

- Useful acronym
- Electronic Product Radiation Control
- You will probably hear it many times in the next two days

# History



## (Recent) History

- TEPRSSC met annually from 1999-2003
- 1999: CT, sunlamps, security screening systems
- 2000: Lasers, sunlamps, security screening systems, CT
- 2001: CT, digital radiography, cellphones
- 2002: CT, sunlamps, security screening systems
- 2003: sunlamps, fluoroscopy, security screening systems

# 2003 Meeting Topics

- Six amendments to the standard for sunlamp products
- Amendments to the fluoroscopy standard
  - Brief discussion of possibility of using IEC standards instead of FDA performance standards
- Emerging issues in ionizing radiation security systems

# Activity since 2003

- 2005: Fluoroscopy amendments Final Rule
- 2007: Laser Notice No. 50 (IEC conformance)
- 2008: Ultrasound guidance
- 2013: Proposed laser amendments
- 2015: Draft MRI guidance
- 2015: Proposed sunlamp amendments

# Non-Regulatory Activity

- 2010: Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging
- 2010: CT Dose Check
- 2012: Public Workshop: Device Improvements for Pediatric X-ray Imaging
- Ongoing work with industry and national and international organizations, including professional societies and standards development organizations

# Agenda

# TEPRSSC Agenda 2016 (Day 1)

Electronic products that are not medical devices (with one exception)

- Radiofrequency Radiation Products
  - Microwave Ovens
  - Wireless Power Transfer

# TEPRSSC Agenda 2016 (Day 1)

- Laser Products
  - Amendments to the Laser Rule
  - LIDAR
  - Remotely Controlled Mobile Systems
  - Laser pointers
  - Lamps for general illumination and LIPs
  - Infrared Applications
- Sunlamp Products (these are medical devices)
- Non-Coherent Light Sources (LEDs, UVC)

# TEPRSSC Agenda 2016 (Day 2)

EPRC issues associated with electronic products that are medical devices

- Radiation Therapy
- Computed Tomography (CT)
- Radiography & Fluoroscopy
- Diagnostic and Therapeutic Ultrasound
- IEC Standards vs. Performance Standards for EPRC in Medical Devices



# Thank You

## Questions from the Committee?

