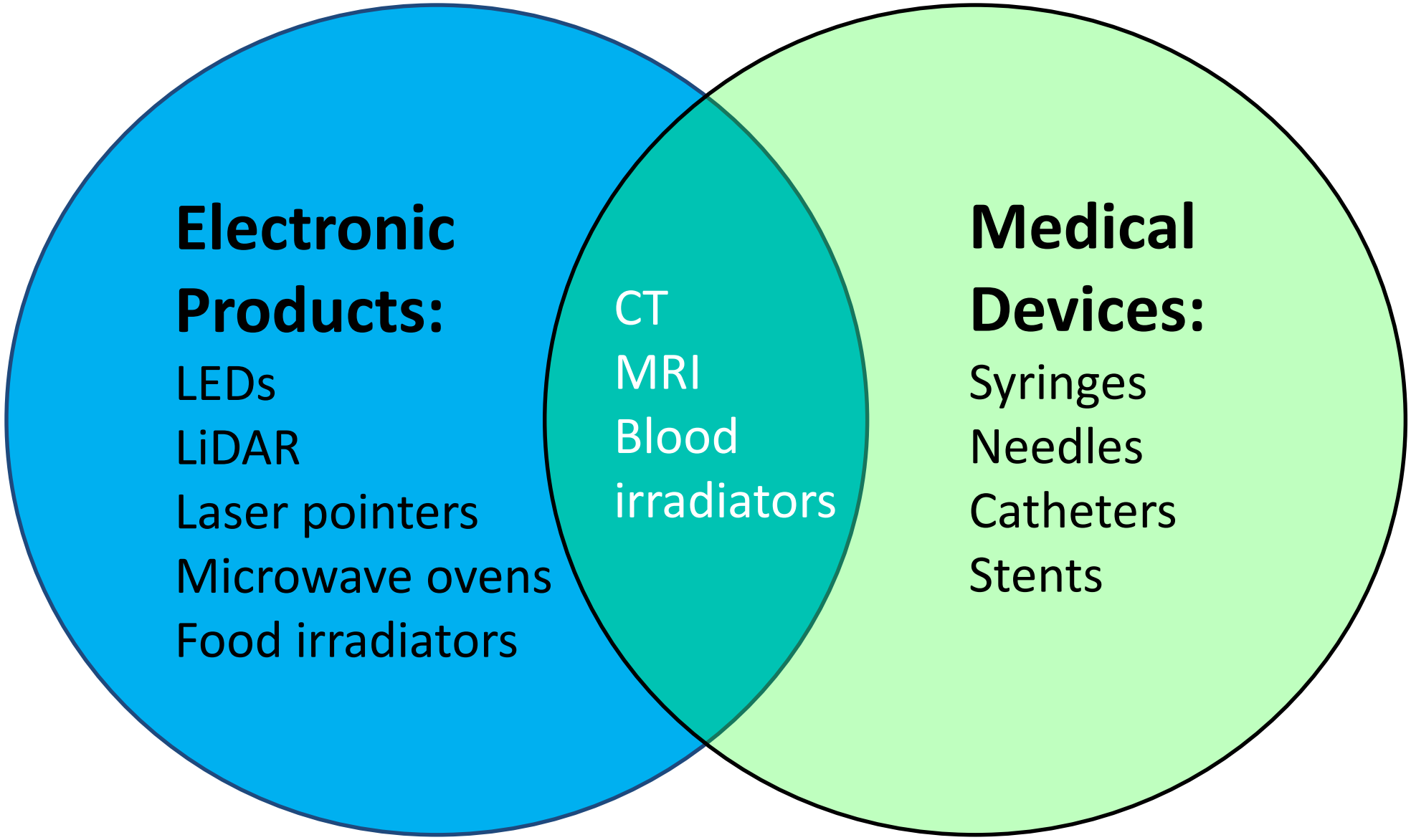
# FDA's Role in the Regulation of Radiation Generating Devices and Irradiated Medical Products

Donald L. Miller, M.D., FSIR FACR
Chief Medical Officer for Radiological Health
OHT7 – Office of In Vitro Devices and Radiological Health
Center for Devices and Radiological Health
donald.miller@fda.hhs.gov

The extracts and paraphrases of the laws and regulations presented here do not describe the full extent of the requirements applicable to electronic products, medical devices, food or blood.  Please see the relevant laws and regulations for a full list of requirements.

# Outline

- Regulation of radiation-generating equipment
  - Electronic products
  - Medical devices
- Regulation of irradiated products
  - Blood
  - Food


Electronic Products:
LEDs
LiDAR
Laser pointers
Microwave ovens
Food irradiators
CT
MRI
Blood irradiators
Medical Devices:
Syringes
Needles
Catheters
Stents

FDA U.S. FOOD & DRUG ADMINISTRATION

# Electronic Products

# Electronic Product (21 CFR 1000.3)

- Contains or acts as part of an electronic circuit, and when in operation, emits (or potentially emits) *electronic product radiation*
- A component, part or accessory of such a product that emits (or potentially emits) *electronic product radiation*

# 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 Product Radiation Control (EPRC)

- Radiation Control for Health and Safety Act (1968)
  - Subsequently incorporated into the Food, Drug, and Cosmetic Act
- FDA regulates manufacturers; State agencies and OSHA regulate use

# EPRC Requirements

- All manufacturers of electronic products shall
  - Report accidental radiation occurrences to FDA (21 CFR 1002.20)
  - Notify FDA of radiation safety defects or failure to comply with applicable mandatory performance standards (21 CFR 1003)
- Specific requirements exist for repair, repurchase or replacement of defective or noncompliant electronic products (21 CFR 1004)
- Manufacturers of some electronic products have additional requirements (21 CFR 1002)
  - Radiation safety report submitted before sale
  - Annual report
  - Records

# EPRC Performance Standards

- Product-specific and mandatory
- X-ray blood irradiators and food irradiators are regulated as “cabinet x-ray systems” (21 CFR 1020.40)
- General performance standards also apply (21 CFR 1010)
  - Certification by manufacturer
  - Certification, identification, and warning labels
  - Variance or exemptions from performance standards

FDA U.S. FOOD & DRUG ADMINISTRATION

# Medical Devices

# What Is a Medical Device?

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  - intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes

# History

- Not regulated prior to the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act in 1976
- Many subsequent amendments to the Food, Drug, and Cosmetic Act
- Medical device classification based on risk: Class I (lowest risk) to Class III (highest risk)

# Class I Devices

Simple, Lowest risk

- Safety/effectiveness well established
- Well understood or simple technology
- Often exempt from premarket review
- Subject to general controls
- May or may not be exempt from manufacturing under the Quality Systems Regulation
- Examples: Bandages, hospital beds, manual surgical instruments, enriched culture media

# Class II Devices

## More complex, moderate risk

- Usually require premarket review and clearance through a 510(k) submission
- A 510(k) submission has a number of required elements (21 CFR 807.87)
- Required to demonstrate "*substantial equivalence*" to legally marketed (predicate) device
- No new type of question of safety or effectiveness
- Examples:  RF ablation surgical probes, CT scanners, surgical lasers

- Blood irradiators are generally Class II

# Substantial Equivalence

In comparison to a legally marketed device:

- Has the same intended use, and has the same technological characteristics as the predicate device, or:
- Has the same intended use, and has different technological characteristics but the information in the 510(k):
  - Does not raise new questions of safety and effectiveness, and
  - Demonstrates it is at least as safe and effective as the predicate

# Class III Devices

Most complex, highest risk

- Breakthrough technology or high risk (life sustaining, life supporting)
- Premarket review and approval required through a marketing application: Premarket Approval Application (PMA)
- Required to demonstrate *reasonable assurance of safety and effectiveness*
- Clinical data almost always necessary
- Examples:  High intensity focused ultrasound, drug eluting coronary stents, deep brain stimulators

# Medical Devices vs. Electronic Products: Before Entry into Commerce

- Medical devices – require FDA action
  - Premarket notification (510(k))– requires clearance as substantially equivalent
  - Premarket application (PMA) – requires approval
- Electronic products – require manufacturer actions
  - Submit radiation safety report (some products)
  - Certify products meet requirements of applicable performance standards
- Medical devices that are also electronic products
  - Manufacturer complies with *both* types of requirements (premarket submission, radiation safety report & manufacturer certification)

U.S. FOOD & DRUG ADMINISTRATION

# Irradiated Products

U.S. FOOD & DRUG ADMINISTRATION

# Blood

# Who Regulates Blood Irradiation?

- Center for Devices and Radiological Health (CDRH)
  - Radiation-emitting aspects of electronic products
  - Blood irradiators for *inactivation of immunologically active cells* in whole blood, red blood cells and platelets, with CBER consultation (as medical devices)
- Center for Biologics Evaluation and Research (CBER)
  - Procedures for irradiation of blood
  - Blood irradiators for *in process inactivation of HIV or other pathogens* in blood products, licensed biological products, etc., with CDRH consultation (as medical devices)
- October 31, 1991 MOU between CDRH and CBER

# Useful Blood Irradiator Information

- Radiological Devices Advisory Panel meeting on blood irradiators, April 12, 2012:
  - Regulatory history
  - Historical agreements and guidance documents
  - Risks and mitigations
- Executive Summary: https://wayback.archive-it.org/7993/20170404135758/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/RadiologicalDevicesPanel/UCM299255.pdf

# CDRH POC for Blood Irradiators

Michael O’Hara, Ph.D.
Deputy Director
Division of Radiological Health
301-796-0294
michael.ohara@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

# Food

# Who Regulates Food Irradiation?

- Center for Food Safety and Applied Nutrition (CFSAN)
- Radiation is regulated as a *food additive*

# How is Food Irradiation Regulated?

- Irradiation of both food and packaging materials in contact with food is subject to premarket approval (21 CFR 179)
- Foods currently permitted to be irradiated are listed in 21 CFR 179.26(b) [Table 1]
- Irradiation with x-rays is permitted as long as the energy is no greater than 500 kVp

# Requirements

- General requirements of the current good manufacturing practice for manufacturing, packaging or holding human food (21 CFR 110)
- Radiation dose used is the minimum dose required to achieve the intended technical effect and does not exceed the level specified in the regulations.
- Packaging materials used during the irradiation treatment must comply with the requirements in 21 CFR 179.45 (or alternative requirements)
- Irradiated food must be properly labeled

# Useful CFSAN Information

- https://www.fda.gov/food/food-ingredients-packaging/irradiation-food-packaging
- https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/regulatory-report-irradiation-food-packaging-materials
- Office of Food Additive Safety (HFS-200)
  Phone: (240) 402-1200

FDA U.S. FOOD & DRUG ADMINISTRATION

# Summary:

It’s complicated!


FDA
U.S. FOOD & DRUG
ADMINISTRATION