How To Get Your Electronic Product on the U.S. Market

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Electronic Radiation-Emitting Products

- Homes: TVs, microwave ovens, DVD/Blu-ray players, cell phones and wireless devices
- Airports: Body and baggage security screening
- Entertainment: Laser Light Shows
- Hospitals: X-ray machines, surgical lasers, ultrasound, MRI, and radiation therapy

Learning Objectives

1. Explain why FDA regulates electronic products.

2. Define key terms, roles, and examples for manufacturers, products, and components.

3. Discuss performance standards, manufacturer's certification, and reporting requirements.

4. Describe methods to communicate with FDA.

Why Does FDA Regulate Radiation-Emitting Electronic Products?

FDA's mission: Protect the public from hazardous or unnecessary exposure to radiation from electronic products

FDA's Authority

- **Federal Food, Drug, and Cosmetic Act (FD&C Act)**
  - Electronic Product Radiation Control (EPRC) provisions
  - Sections 531 – 542
- **Code of Federal Regulations (CFR)**
  - Title 21, Parts 1000 – 1050
- **Applies to Manufacturers only**

Key Terms, Roles, and Examples

Manufacturer

- Any person (or company) who manufactures, assembles, or imports electronic products

Note: Dealers and distributors are responsible for recordkeeping

Electronic Product

- **Any manufactured or assembled product**
  - or component, part, or accessory
- **Contains an electronic circuit and**
- **Emits electronic product radiation**
  - or would emit without effective shielding/controls

➢ **Any electrically-powered product that emits radiation**

Electronic Product Radiation

- **Ionizing or non-ionizing electromagnetic or particulate radiation** OR
- **Sonic, infrasonic, or ultrasonic wave**
  - emitted from electronic product
  - due to electronic circuit

➢ **Any form of <u>machine-produced</u> radiation**

Examples of Non-medical and Medical Electronic Radiation-Emitting Products

Non-medical Products

- Microwave ovens
- Laser pointers
- Police speed radars
- Airport security scanners

Medical Devices

- Diagnostic x-ray equipment
- Surgical lasers
- Lithotripters
- Tanning beds

Both Electronic Product and Medical Device?

- **Must comply with both:**
  - FDA medical device requirements
  - FDA radiation safety requirements
- **FDA Medical Device Requirements**
  - Register establishment
    - Foreign firms: register the U.S. Agent
  - List medical devices
  - Submit premarket notification or approval application

Components

- **21 CFR 1020.30: X-ray equipment components**
  - Controls, tables, image receptors and others
  - Subject to performance standards
  - Certify and report to FDA

- **21 CFR 1040.10: Laser Products**
  - Components or replacement parts
  - Laser performance standard not applicable
    - if labeled and status reported to FDA

Performance Standards and Certification

Radiation Safety Performance Standards

- Mandatory for many radiation-emitting electronic products/devices
- Establish requirements
  - design, testing, and labeling
- Protect public from radiation emissions
- Codified in 21 CFR 1010 – 1050

Standards Apply to Range of Products

- Microwave Ovens
- Lasers
- Sunlamps/tanning products
- High-intensity Mercury Vapor Discharge Lamps
- Therapy Ultrasound
- Television receivers/monitors
  - only cathode ray tube type
  - not LCD, LED, flat panel
- Cabinet X-ray systems
- Diagnostic X-ray systems/major components
  - radiographic
  - fluoroscopic
  - computed tomography (CT)

Electronic Product Certification

- Comply with all applicable performance standards prior to marketing in U.S.
- Certified by manufacturer
- Based on manufacturer's quality control testing program
  - shows product complies with applicable standard

Electronic Product Certification

- Certification does NOT indicate FDA clearance/approval

- Self-certification by manufacturer only

Reporting Requirements

Reporting Requirements

- **Manufacturers must submit reports to FDA describing:**
  - manufacturer
  - product radiation safety specifications
  - product labeling
  - quality control testing program
- **Report describes how product complies with performance standard**

Reporting Requirements

- **21 CFR 1002**
  - specific reporting and recordkeeping requirements
  - product, supplemental and/or abbreviated reports
- **Submitted to FDA before the product is introduced to U.S. market**

Annual Reports (21 CFR 1002)

- Describe annual production, compliance testing results, radiation concerns, and user safety inquiries
- Due each September 1st for prior reporting period from July 1 - June 30
  - **Example**: September 1, 2019 for period of July 1, 2018 – June 30, 2019
- Valid for one year

Three Ways to Report to FDA

1. Prepare and submit electronically

2. Prepare electronically and mail

3. Prepare hard copy and mail

Prepare and submit your report electronically

1. Prepare/Submit Electronically

- Prepare report electronically using FDA's free eSubmitter software:

  www.fda.gov/ForIndustry/FDAeSubmitter/default.htm

1. Prepare/Submit Electronically

- Submit electronic report to FDA:
  - FDA Electronic Submissions Gateway (ESG)
  - Requires ESG Account: www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

- FDA emails acknowledgement **immediately**

Prepare electronically and mail

2. Prepare Electronically and Mail

- Prepare report using eSubmitter (as prior method)
- Transfer to Physical Media (e.g., CD, DVD, memory stick)
- Mail to FDA for processing
- FDA emails acknowledgement, usually **within a few days**

Prepare hard copy and mail

3. Prepare Hard Copy and Mail

- Prepare paper report:
  www.fda.gov/AboutFDA/ReportsManualsForms/Forms/RadiologicalHealthForms/default.htm
- Mail to FDA for processing
- FDA sends acknowledgement, usually **within 30 days**

FDA/CDRH Addresses for Reports and Recordkeeping

www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/RecordsandReporting/ucm118122.htm

FDA Acknowledgement Letter

- Acknowledgement that the report was received
- FDA will contact submitter if there are questions
- An assigned **Accession Number**
  - used as reference for follow-up

Accession Numbers

- Document control number to track report
- NOT an approval number (e.g., for premarket approval)
- Indicates that FDA has received report
- Manufacturer may market product in United States
  - after required report has been submitted AND
  - product is not an unapproved medical device

Reminder

- **Acknowledgement Letter**
  - only indicates that FDA received report
  - does not indicate that FDA reviewed report
- **Accession Number**
  - does not indicate that product is approved by FDA
- Manufacturer self-certifies compliance with FDA requirements
- Report is tool FDA uses to evaluate product safety

Summary

1. FDA has an important role in regulating electronic products.

2. A manufacturer has key roles before electronic products may enter the U.S. market. This includes complying with applicable standards and sending reports to FDA.

3. Electronic product requirements differ from device requirements. Both sets of requirements may apply to your product.

Resources: Radiological Health

- **Walk-Through**

  www.fda.gov/Radiation-EmittingProducts/ElectronicProductRadiationControlProgram/GettingaProducttoMarket/ucm202505.htm

- **Performance Standards**

  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPartFrom=1000&CFRPartTo=1050 `

Resources: Radiological Health

- **Medical Device Requirements**

  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=807

- **Radiation-Emitting Products Website**

  www.fda.gov/Radiation-EmittingProducts/default.htm

Industry Education: Three Resources for You

1. **CDRH Learn: Multi-Media Industry Education**
   - over 125 modules
   - videos, audio recordings, power point presentations, software-based “how to” modules
   - mobile-friendly: access CDRH Learn on your portable devices

   www.fda.gov/Training/CDRHLearn

2. **Device Advice: Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/MedicalDevices/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: www.fda.gov/DICE


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