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

CDR Sean Boyd
Chief, Diagnostic Devices Branch
U.S. Food and Drug Administration
Center for Devices and Radiological Health

December 2008
How to get your electronic product on the U.S. market

Purpose
– To inform new manufacturers (and importers) of FDA’s requirements for radiation emitting electronic products

Questions we will answer:
– Who is a manufacturer?
– What is an electronic product?
  – What if it’s a medical device?
  – What if it’s a component?
– Is my product subject to a performance standard?
– What product certification means?
– Is my product subject to reporting requirements?
Electronic Product Radiation Control

Mission
- To protect the public from hazardous or unnecessary exposure to radiation from electronic products

Authority
- Electronic Product Radiation Control Provisions of the Federal Food Drug and Cosmetic Act
  - Sections 531 – 542
- Title 21 of the Code of Federal Regulations
  - Parts 1000 – 1050
- Applies to MANUFACTURERS only
Who is a manufacturer?

“Manufacturer” defined

- “Any person engaged in the business of manufacturing, assembling or importing electronic products”
- Dealers and distributors also responsible for recordkeeping
What is an Electronic Product?

“Electronic Product” defined

– any manufactured or assembled product (or component, part, or accessory of such 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.

– Any electrically-powered product that emits radiation
What is Electronic Product Radiation?

"Electronic product radiation" defined

- (A) any ionizing or non-ionizing electromagnetic or particulate radiation, or (B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

- Any form of radiation
Consumer and Industrial Electronic Products

- Televisions receivers and monitors
  - Cathode ray tubes only
  - Not LCD or plasma displays
- X-ray security systems
- Microwave ovens
- Laser products
  - From CD players to light shows and welding lasers
- Metal halide lighting
Medical Electronic Products

- Sunlamps
- Ultrasound therapy
- Laser therapy and surgical devices
- Radiation therapy
- Medical diagnostic x-ray systems
  - Radiographic equipment
  - Fluoroscopic equipment
  - Computer tomography (CT) equipment
What if it’s a Medical Device?

- FDA medical device requirements apply *in addition to* radiation safety requirements
  - Registering your establishment
  - List devices
  - Premarket notification or approval, and
  - Registering the U.S. Agent
Components

Some components are also subject to FDA regulation, others are exempt

X-ray equipment
  – Controls, tables, image receptors and others listed in 21 CFR 1020.30

Laser products
  – Laser component or replacement part described in 21 CFR 1040.10
Radiation Safety Performance Standards

- Establish specific requirements for electronic products
- Intended to protect public from radiation emissions
- Contained in 21 CFR 1010 – 1050
Radiation Safety
Performance Standards

- Television Receivers and Monitors (Cathode Ray Tubes)
- Cabinet X-Ray Systems
- Microwave Ovens
- Lasers and Specific Purpose Laser Products
- Sunlamps and Sunlamp Products
- High-intensity Mercury Vapor Discharge Lamps
- Therapy Ultrasound Products
- Diagnostic x-ray systems and their major components
  - Radiographic equipment
  - Fluoroscopic equipment
  - Computed tomography (CT) equipment
Product Certification

- Products must comply with all applicable performance standards
- Products must be certified by the manufacturer
  - Certification means that the manufacturer ensures its own products comply with the applicable FDA standard
  - Certification is based upon the manufacturer’s own quality control testing program
  - Certification does NOT indicate FDA approval
Reporting Requirements

- Manufacturers must submit reports to FDA
  - Reports describe the manufacturer, the product, radiation safety specifications, labeling, quality control testing program
- 21 CFR 1002 contains specific reporting and recordkeeping requirements for product, supplemental and abbreviated reports
- Reports must be submitted before introduction of the product to the U.S. market
Reporting Requirements

- Annual Reports
  - Reports describe annual production, results of testing, and user safety inquiries
  - Due September 1st every year for the reporting period July 1 through June 30
  - Report is valid through September 1st of the current year
Electronic reporting

- Required reports may be prepared electronically using FDA's eSubmitter software

  Download for free at [www.fda.gov/cdrh/cesub/](http://www.fda.gov/cdrh/cesub/)

- And submitted through FDA’s Electronic Submissions Gateway (ESG) with immediate acknowledgement of receipt from FDA

  Account setup instructions at [www.fda.gov/esg/](http://www.fda.gov/esg/)

- Reports prepared using CeSub may also be submitted on CD
  - Acknowledgement of receipt will follow within a few days
Paper Reporting

- Alternatively, paper reports may be submitted via regular mail:
  
  Center for Devices and Radiological Health
  ATTN: Electronic Product Reports
  Radiological Health Document Control (HFZ-309)
  Office of Communication, Education, and Radiation Programs
  9200 Corporate Blvd
  Rockville, MD 20850

  [Link]

- Acknowledgement letters for paper reports should be received within 30 days
Acknowledgement letters

- Provided as feedback to manufacturers after receipt of report
  - “We received your report”
  - “If we have any questions, we’ll get in touch with you”
  - “It has been assigned this ACCESSION NUMBER”
Accession numbers

- Document control number for FDA records
- NOT an approval number
- Indicates that a manufacturer has met the reporting requirement for a product
In Review

- Described FDA’s requirements for radiation emitting electronic products
- Discussed
  - Who is a manufacturer?
  - What is an electronic product?
  - What if it’s a medical device?
  - What if it’s a component?
  - Performance standards
  - Product certification
  - Reporting requirements
For More Information

- Visit us on the web at
  www.fda.gov/cdrh/radhealth/
  Contact information is provided

- Send an email to the Division of Small Manufacturers, International and Consumer Assistance
  dsmica@cdrh.fda.gov