

Electronic Product Certification and Quality Testing Programs

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Learning Objectives

1. Summarize background information
2. Explain what Electronic Product Certification represents
3. Define manufacturer's certification responsibility
4. Define a quality testing program
5. Identify consequences of a poor quality testing program

Background

Radiation-Emitting Electronic Products

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

FDA Standards Apply to a 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)

How Does FDA Regulate Radiation-Emitting Electronic Products?

- **Federal Food, Drug, and Cosmetic Act (FD&C Act)**
 - Electronic Product Radiation Control (EPRC) provisions
 - [Sections 531 – 542, Certification is referenced in Section 534](#)
- **Code of Federal Regulations (CFR)**
 - Title 21, Parts 1000 – 1050,
Certification specified in [21 CFR 1010.2](#)

Note: Applies to Manufacturers only

Certification

What is Certification?

Certification is made by the manufacturer, based upon testing, that their product complies with applicable standards

21 CFR [1010.2](#)



Electronic Product Certification

- Only manufacturers of electronic products with mandatory FDA performance standards certify
- Self-certification does NOT indicate FDA clearance or approval

Electronic Product Certification

- **When is it done?**
 - Prior to entry into U.S. Commerce or import
- **How is Certification made?**
 - In form of label or tag, permanently attached to product
 - Certification statement must be in English language

Certification Differs from European Union Declaration of Conformance

- U.S. Agencies may each have different requirements, instead of one global declaration of conformance
- Documents are required prior to or when product is introduced into U.S. Commerce

Manufacturer's Certification Responsibility

Manufacturer's Certification

Responsibility: Total Product Life Cycle

- Awareness of requirement to certify
- Product design for compliance to applicable standards
- Manufacture and test of finished, compliant product
- Product reporting to FDA under [21 CFR 1002](#)
- “Sustaining Engineering” under [21 CFR 1002.30](#)

Example: Certification Statements

- Complies with 21 CFR, Subchapter J (Radiological Health)
- Product complies with applicable FDA standards under the Federal Food, Drug, and Cosmetic Act
- Product complies with applicable Federal standards under the Electronic Product Radiation Control provisions

Note: Laser Notice 53 provides certain alternate labeling situations without prior approval

Variations of Certification Statement

- FDA's Electronic Product Radiation Control Program may permit certification that represents conformance to other standards

Example: [Laser Notice](#) 50 and 56 permit IEC 60825-1

Quality Testing Program (QTP)

Purpose

- Assures consistency, repeatability, quality in product line manufactured over time
- Assures adequacy of employee training and performance
- Assures defects, noncompliances, and problems are caught prior to product shipment

Purpose

- To detect instances of non-compliance by design
 - report according to 21 CFR 1003.10
- Required by 21 CFR 1010.2 (c)
 - further explained in 21 CFR 1002.30

What Constitutes a QTP?

- Records of tests and measurements, [21 CFR 1002.30](#)
- Sales and distribution records that facilitate corrective actions, if they become necessary

Manufacturers' Records

21 CFR 1002.30

(a)(1) Description of the quality control procedures

(a)(2) Records of the results of tests for electronic product radiation safety, including:

- the control of unnecessary, secondary or leakage electronic product radiation;
- the methods, devices, and procedures used in such tests; and
- the basis for selecting such methods, devices, and procedures.

Manufacturers' Records

21 CFR 1002.30

(a)(3) For those products displaying aging effects, records of the results of tests for:

- durability and stability of the product
- the basis for selecting these tests

Manufacturers' Records

21 CFR 1002.30

(a)(4) Copies of all written communications:

- radiation safety
- complaints
- investigations
- instructions
- explanations

Manufacturers' Records

21 CFR 1002.30

(a)(5) Data on production and sales volume levels, if available

- Data provide insights during product corrective actions
- Data can be used to narrow the scope to include only the defective production

Product Compliance

Radiation-emitting electronic components or finished products are inspected as part of good manufacturing practices:

Example: Validate that a vendor's radiation-emitting electronic components perform to design specifications

Production Tests

Characterize product functions during assembly and integration process:

- Test the function of safety interlock when actuated
- Test at end of assembly for prescribed radiation parameters
- Test to check labeling for U.S. compliance

Common Issues

- Failure to identify nonperforming incoming components
- Sampling not statistically valid and if not 100% inspected
- Statistically valid sample not documented
- Manufacturer needs to document that statistical sampling is adequate to assure compliance of finished products

Consequences of a Poor Quality Testing Program

Consequences of a Poor QTP

- Non-compliance by design
- Non-compliance by product-aging effects

Consequences of a Poor QTP

- Violation of [Section 538.\(a\)\(5\)\(B\)](#) of the FD&C Act

NOTE: Ultimately the manufacturer is responsible for their product's compliance

Consequences of a Poor QTP

Inaccurate, incomplete, or fraudulent information in product reports or import documents can lead to:

- Increased surveillance of accession number assigned to product report
- Mandatory corrective actions of defects or non-compliances
- Import delays, product sampling for testing, or being placed on an FDA Import Alert
- Program disapproval

Notifications

- Notification of defects or noncompliance, 21 CFR [CFR 1003](#) and Plan of Action, [21 CFR 1004](#)
- Notify FDA of your defect and propose a plan to repair, replace, or refund the product at no cost to the purchaser
- FDA may approve your plans with added conditions

Import Alerts

- Import alerts inform FDA field staff and public
 - that FDA has enough evidence to allow for detention without physical examination of products
- Product appears to be in violation of U.S. laws and FDA regulations
- Import Alert list is public and searchable by potential customers and competitors
- Detention can result in import delays, storage fees, seizures and refusals

Program Disapproval

Program disapproval under [21 CFR 1010.2](#) (c)

- Testing program does not assure adequacy of safeguards against hazardous electronic product radiation
- Testing program does not assure that electronic products comply with standards prescribed under this subchapter

Summary

1. FDA has an important role in regulating electronic radiation-emitting products
2. Before electronic products enter the U.S. market, a manufacturer must:
 - Comply with applicable standards
 - Establish an adequate quality testing program
 - Certify the product, and report it to FDA, if required by 21 CFR 1002.1
3. Entry to commerce of noncompliant or defective products can have consequences

Resources/Reference

- **Radiation-Emitting Electronic Product Regulations**

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

- **Medical Device Requirements**

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

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2. Device Advice – Text-Based Education

- comprehensive regulatory information on premarket and postmarket topics: www.fda.gov/DeviceAdvice

3. Division of Industry and Consumer Education (DICE)

- Email: DICE@fda.hhs.gov
- Phone: 1-800-638-2041 or (301) 796-7100 (Live Agents 9 am – 12:30 pm; 1 – 4: 30 pm ET)

Your Call to Action

- Understand the requirements for a good quality testing program
- Manage your products to ensure they remain compliant and address detected problems effectively
- Document the use of valid statistical sampling

