

## Electronic Product Certification and Quality Control Testing Programs

### Slide 1

Hello, my name is Lowell Howard. I'm an Electrical Engineer with the Food and Drug Administration, Center for Devices and Radiological Health, or CDRH. The purpose of this presentation, Electronic Product Certification and Quality Testing Programs, is to inform new manufacturers and importers about FDA's requirements for radiation-emitting electronic products.

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The learning objectives are: To Summarize background information, to Explain what Electronic Product Certification represents, to Define manufacturer's Certification responsibilities, to Define a quality testing program and finally, to identify the consequences of a poor quality-testing program.

### Slide 3

Let's start with a little background information about FDA's Electronic Product Radiation Control Program. In the next few slides, I'll give some examples of radiation-emitting electronic products and explain FDA's Electronic Product Radiation Control Program, which is used to regulate these products and to protect the public health.

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There are hundreds of radiation-emitting electronic products being invented and being introduced to the market every day. For example, microwave ovens, DVD or Blu-ray players, cell phones and wireless devices that are found in many American homes. An air traveler may be searched by a body-scanner and his or her baggage will be examined by airport security x-ray scanners. Also, hundreds of thousands of people enjoy laser light shows every year. These are all examples of radiation-emitting electronic products.

Most hospitals have a variety of diagnostic x-ray systems, surgical lasers, ultrasound machines and maybe magnetic resonance and radiation therapy systems that are examples of radiation-emitting electronic products as well. The FDA has been authorized to regulate all of these radiation-emitting electronic products and devices.

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This slide lists products that have federal performance standards for electronic product radiation. As you can see from this list, it is a wide range of products.

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FDA's authority to accomplish this mission is described in the Federal Food, Drug, and Cosmetic Act. Specifically, in the Electronic Product Radiation Control provisions of the Act, Sections 531 through 542, with specific regulations in Title 21 of the Code of Federal Regulations, or CFR, Parts 1000 through 1050. Our regulatory authority in this area applies to manufacturers only. We want to be sure that industry understands these requirements and our responsibility to ensure product safety.

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Next, we'll discuss electronic product certification and performance standards and also what self-certification represents.

### Slide 8

What is Certification? Certification is a manufacturer's self-certification that their product complies with applicable FDA standards. The pyramid-diagram on the right side of this slide depicts how the regulations work together. Certification is based on a test, in accordance with the performance standard, of the individual article to which it is attached, or upon a testing program which is in accordance with good manufacturing practices.

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Only manufacturers of radiation-emitting electronic products that have a mandatory performance standard in 21 CFR 1020 through 1050 must certify their electronic products. Other US Federal Agencies may have different Certification requirements. Manufacturers should not assume that Certification is the same for each Federal agency. It's important to clarify that self-certification is not granted by the FDA. Certification does NOT result in or indicate FDA clearance or approval. There are no delays for FDA review of manufacturers self-certification.

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Certification must be made prior to entry into US Commerce. It is important to know that Importation is considered US Commerce as is commerce between states and wholly within the District of Columbia. Each Performance Standard specifies unique requirements for certification labeling. The Certification label or tag is permanently attached to the product. The certification statement must be in the English language.

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FDA Certification is not the same as a European Union Declaration of Conformity. As we know, the U.S. Government consists of a number of different agencies. US agencies each have different oversight responsibilities and different regulatory requirements. In plain language, there is no single certification of regulatory compliance for the United States. In contrast to the EU, FDA requires supporting documents upon entry to US Commerce and not upon request.

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Next, let's look more closely at a manufacturer's responsibilities for self-certification.

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The total product life cycle of a radiation-emitting electronic product can be broken down into parts. First, a manufacturer needs to be aware of the regulatory requirements for certification, and needs to design the electronic product to comply with any applicable federal performance standards. More than one US Federal Agency may be involved. It is the manufacturer's responsibility to be aware of US Federal agency requirements.

Next, the product needs to be manufactured and tested, and all required records need to be kept for compliance. Report the product to FDA as required in 21 CFR 1002. And finally, the provisions of 21 CFR 1002.30 specify that what is often called "sustaining engineering" or "reliability engineering" for maintaining the product's safety over its life-cycle must be met.

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Electronic Products must bear a Certification Statement. This slide includes some examples of acceptable wording as certification statements on labels. For example, “Complies with FDA radiation performance standards, 21 CFR Subchapter J” ; “Product complies with applicable FDA standards under the Federal Food, Drug, and Cosmetic Act”; and “Product complies with applicable Federal standards under the Electronic Product Radiation Control provisions.” Please note that Laser Notice 53 provides alternate labeling for certain laser product labeling situations without prior approval of CDRH.

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Certain International Electrotechnical Commission, or IEC, standards are permitted by FDA policy to substitute for applicable requirements in the CFR. A voluntary, international consensus standard cannot be recognized by FDA for the purposes of replacing a radiation-emitting electronic product’s performance standard. This is because radiation performance standards for electronic products are non-voluntary regulations. They have a different regulatory process than those used for consensus standard recognition. One international consensus standard which is permitted by FDA guidance to substitute for certain parts of the federal performance standard is IEC 60825-1 for laser products.

An example certification statement could be: “Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 56, dated May 3<sup>rd</sup>, 2019” or “Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 56.” Certification statements are covered under the guidance available for individual product families.

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So, what does a quality testing program for radiation-emitting electronic products actually look like?

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The reasons to implement a quality testing program are many. The Consistency and repeatability of the product’s manufacturing processes are monitored and controlled by the quality testing program. Manufacturing processes are enhanced when employees are adequately trained. It is safer and more cost-effective to catch and correct a noncompliance or defect before the product enters U.S. commerce.

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The quality testing program also serves to detect non-compliance that is caused by a failure to design radiation-emitting electronic products that meet applicable Federal Performance Standards. Whatever the cause, manufacturers must report radiation safety defects or failures to comply with a performance standard as part of 21 CFR 1003.10. Finally, manufacturers need a Quality Testing Program because the FDA requires it to support the Certification of Electronic Products by regulations 21 CFR 1010.2(c) and 21 CFR 1002.30.

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21 CFR 1002.30 specifies the records that a Quality Testing Program must keep. The form of the Quality Testing Program is only specified as being consistent with Good Manufacturing Practices. We’ll cover those required records in the next few slides.

Sales and distribution records are required to facilitate corrective action of non-compliant or defective products if they become necessary.

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The scope of a radiation-emitting electronic product's quality program is limited to radiation safety. The first requirement is to have quality and testing procedures in record form. The second is that radiation safety product tests must be defined by rational, scientific methods and placed into record form.

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While some aging effects in electronic products tend to reduce radiated emissions, there are certain components whose age-related failure can increase radiated emissions. So third, it is important to know what these effects are and to test for increases in radiated emissions.

Examples of emission-increasing effects might involve the failure of adhesives used to fix a filter or attenuator into a beam path, or the burn-through of a plastic diffuser or phosphor converter.

An example of aging testing would be accelerated-aging tests conducted at elevated temperatures, or at high humidity levels to identify components and manufacturing processes that fail before the specified lifetime of the product.

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Manufacturers of electronic products must also keep records of radiation-safety issues that affect the continuing operations and maintenance of a product over its life cycle.

These activities are more commonly known as Sustaining Engineering, Life Cycle Engineering, Reliability Engineering or Forensic Engineering. As stated by the regulation, manufacturers must also keep records of safety complaints and of any investigations made in response to those complaints as well as instructions and explanations.

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Since nonconforming or defective products must be repaired, replaced or refunded by corrective action, accurate records of production are needed to define the scope of the corrective action.

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Some examples of common radiation emitting electronic component testing are: the incoming inspection of laser diode threshold current; X-ray tube beam alignment and leakage radiation tests; X-ray detector Signal to Noise Ratio and Image quality tests; and sun-tanning bed timer accuracy tests. By implementing effective testing, the need for corrective actions resulting from the incorporation of non-compliant components can be prevented.

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Testing should be performed to characterize product functions during the assembly and integration process. One example of assembly testing would be to test the functions of a safety interlock for a product's loading door when the interlock is installed and wired.

Another example might be a Half Value Layer, or HVL test for an X-ray tube near the end of an X-ray system's assembly or integration. Finally, product labeling should be tested for US compliance before the product enters U.S. commerce.

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Not conducting incoming testing may lead to a failure to identify nonconforming incoming components. Since the Certifying Manufacturer is responsible for the product, a failure to identify nonperforming incoming components can result in the need for Corrective Action. Another common issue is a failure to

conduct and document statistically valid sampling. The manufacturer decides which fraction of the components to test, and ultimate responsibility remains with the manufacturer as well.

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Next, let's look at some of the things that can go wrong and how these problems could have been prevented by a good Quality Testing Program

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Design validation testing establishes objective evidence that electronic products conform to Federal Performance Standards. Design validation testing can prevent non-compliance by design. Products must comply with their radiation specifications throughout their specified design lifetimes. The effects of product aging can lead to noncompliance with radiation safety standards. If no design lifetime is specified, it may be assumed that the product will "run to failure".

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Test houses or laboratories that fraudulently represent the manufacturer's quality testing program or product compliance are placing the manufacturer in violation of Section 538 (a)(5)(B) of the Federal Food Drug and Cosmetic Act.

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FDA may increase surveillance of Accession Numbers assigned if the product report contains incomplete or inaccurate information. If defective products enter US commerce, they may require corrective-action and public notice to the purchasers. Imported electronic products may be subject to detention for product sampling or testing. The product may be placed on an FDA Import Alert. If the quality testing program that supports self-certification is determined to be fraudulent or non-existent, its use to Certify electronic products may result in program disapproval.

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Manufacturers have an obligation to report electronic product defects or non-compliances to FDA under 21 CFR 1003. The Action Plan required under 21 CFR 1004, for the product defect or non-compliance, will need approval by FDA. FDA may modify the proposed Action Plan to fully comply with FDA regulations and protect the public.

#### Slide 32

Import alerts inform FDA field staff and the public that the agency has enough evidence to allow for Detention Without Physical Examination of products. Products on Import Alert have evidence that they appear to be in violation of US laws and FDA regulations. The Import Alert list is public and is searchable by both potential customers and competitors. Detention of imported products can result in delays, storage fees, seizures, and refusals of entry.

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The Director for FDA's Center for Devices and Radiological Health may disapprove a quality testing program if it does not safeguard the public from hazardous electronic product radiation or if electronic products fail to comply with federal performance standards.

In plain language, program Disapproval means: You must stop selling your products in the US market until your Quality Testing Program problems have been remedied to the satisfaction of the FDA.

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In summary, we discussed that FDA has regulations and plays an important role in regulating radiation-emitting electronic products. Manufacturers of radiation-emitting electronic products have several steps to follow before their products may enter the U.S. market.

These steps include: complying with applicable standards; establishing a quality testing program based on good manufacturing practices; Certifying and reporting the product to FDA; and permanently affixing certification and identification labels to their products.

Finally, we learned that placing defective or noncompliant products into US commerce can have consequences that can include implementing corrective-action at no cost to the purchaser.

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The actual radiation-emitting electronic product requirements, including the individual performance standards, certification, and reporting requirements can be found at this first web link. In addition, medical device requirements for registration, listing, and premarket notifications can be found at the second web link on this screen.

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For general information about FDA's requirements on medical devices, see CDRH Learn and Device Advice. You may also contact the Division of Industry and Consumer Education directly. Links to all of these resources are included on this slide.

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To ensure that your quality testing program supports the certification of your radiation-emitting electronic products, your call to action is to: first, understand the requirements for a good quality testing program; second, manage your products to ensure they remain compliant and address detected problems effectively; and third, document the use of valid statistical sampling. Thank you for watching.

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