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

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Hello, my name is Lowell Howard with the Food and Drug Administration, Center for Devices and Radiological Health, or CDRH. In this presentation, I'll describe the basic process for how to get your electronic products on the U.S. market.

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There are hundreds of electronic radiation-emitting products being invented and being introduced on the market every day. Most American homes have TVs, microwave ovens, DVD or Blu-ray players, and cell phones and wireless devices. Any traveler will have his or her baggage examined by airport security. Hundreds of thousands of people enjoy laser light shows every year. And most hospitals have a variety of diagnostic x-ray systems, surgical lasers, ultrasound machines, maybe magnetic resonance and radiation therapy systems as well. These products are effective and low-risk when used following the manufacturer's instructions. However, they can be hazardous if not manufactured correctly. The Food and Drug Administration has been authorized to regulate all these electronic products and devices. That's what we will be discussing today.

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The purpose of this presentation is to inform new manufacturers and importers of FDA's requirements for radiation emitting electronic products. The learning objectives include explaining why the FDA regulates electronic products. Then we'll define and explain significant terms, roles, and examples for manufacturers, products, and components. We'll discuss performance standards, manufacturer's certification and reporting requirements. And lastly, we'll provide you with methods of communicating with the FDA.

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As background, why does FDA regulate radiation-emitting electronic products? The purpose of the FDA's regulations is to protect the public from hazardous or unnecessary exposure to radiation from electronic products. This is the agency's mission.

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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 industry understands these requirements and our responsibility to ensure product safety.

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Now let's cover some of the key terms, industry roles, and provide some examples.

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Let's start with some basic definitions. Who is a Manufacturer? According to the Law, a manufacturer is defined as: "Any person engaged in the business of manufacturing, assembling or importing electronic products." Note that the definition includes "importers" of electronic products who may be held responsible for meeting FDA radiation safety requirements for products that they import. Also, FDA regulations place responsibility on dealers and distributors of electronic products for purposes of recordkeeping, so that purchasers of electronic products can be identified.

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The term "Electronic Product" is defined in the Law as any manufactured or assembled product, or component, part, or accessory of such product, which, when in operation, (1) contains or acts as part of an electronic circuit and (2) emits, or in the absence of effective shielding or other controls would emit, electronic product radiation. In plain language that means: any electrically-powered product that emits radiation.

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But what do we mean by Electronic Product "Radiation?" Again, this is defined in the Act as any ionizing or non-ionizing electromagnetic or particulate radiation, or 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.
Which, in plain language, means: any form of machine-produced radiation.

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Electronic radiation-emitting products may be either non-medical or medical. Examples of non-medical electronic products include: microwave ovens used for food preparation, laser pointers, police speed radars, and airport security scanners. Examples of electronic products that are also medical devices include: diagnostic x-ray machines, surgical lasers, lithotripters, and tanning beds.

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It's important to note that if your electronic product is also a medical device, it would be subject to FDA's medical device requirements, in addition to our radiation safety requirements. If you're planning to market a medical device, your firm must: one, register your establishment and register the U.S. Agent for foreign firms; two, list your medical devices with FDA; and three, submit any required premarket notification or approval applications.

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The regulation defines an electronic product component as a functional part of a sub-assembly or finished product which may affect radiation emission of the finished product. For example: X-ray equipment components such as controls, tables, image receptors and others listed in 21 CFR 1020.30, are subject to performance standards and must be certified and reported to FDA. On the other hand, certain laser products are addressed in 21 CFR 1040.10, and specifically components and replacement parts. The laser performance standard does not apply if the laser products are labeled as components and FDA is notified of their status.

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Next, let's discuss performance standards and certification.

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FDA has established mandatory radiation safety performance standards that apply to many, but not all, radiation-emitting electronic products and devices. Performance standards establish design, testing, and labeling requirements that are intended to protect the public from radiation emissions. There are several performance standards contained in 21 CFR 1010 through 1050. Links to applicable regulations will be provided at the end of this presentation.

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Standards apply to a wide range of products. This slide lists all the products to which FDA performance standards apply. Please note, for televisions, this excludes LCD, LED, and flat panel TVs.

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Electronic products must comply with all applicable performance standards before the product leaves the place of manufacture for sale in the U.S. Manufacturers must certify their electronic products, which means that manufacturers assure that their products comply with the applicable FDA standard. A manufacturer must have an in-house quality control inspection and testing program, which demonstrates that each manufactured product complies with the applicable standard. Please be aware that there is no requirement that a product must be sent to a test lab for a report or certificate.

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It's important to clarify that certification does NOT result in or indicate FDA approval. It is a self-certification by the manufacturer.

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Now, let's discuss the manufacturer reporting requirements. FDA evaluates product compliance and manufacturer quality control and testing programs by reviewing reports as needed.

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Depending on reporting requirements, manufacturers may be required to submit reports to FDA that describe the manufacturer, the product, its radiation safety specifications, any product labeling, and the quality control testing program in place used to ensure compliance. In plain language, a product report tells the FDA how the product complies with the performance standard. The report must be complete and include detailed responses to all requests for information.

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Part 21 CFR 1002 contains specific reporting and recordkeeping requirements for product, supplemental, and abbreviated reports. These must be submitted before introduction of the product into the U.S. market.

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Many manufacturers are also required to submit annual reports to FDA. These describe annual production levels, summary results of required compliance testing, and a summary of radiation concerns and user safety inquiries received over the year. The annual report is due each September 1st, for the prior reporting period of July 1 through June 30. An example is listed on this slide. The annual report is valid for one year.

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There are three ways to submit your report to FDA. First, you may prepare an electronic copy and submit it electronically. Second, you may prepare an electronic copy and mail, or email that to us. And finally, you may prepare a hard copy and mail that, or email a pdf file. I'll review each method, including the benefits of some, so you may choose the method you prefer to use, but we are not encouraging hardcopy submissions.

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First, let's review preparing and submitting your report electronically.

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In this option, you prepare an electronic report using FDA's software called eSubmitter. eSubmitter is free and may be downloaded at the link shown on this slide. eSubmitter will properly format your electronic report so it's ready to be sent.

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Once the report is formatted through eSubmitter, you then send it electronically to FDA through FDA's Electronic Submissions Gateway, or ESG. ESG is an FDA-wide method for accepting various electronic regulatory submissions. It allows you to send reports securely to us.
To use the ESG, you need to have an ESG account. If you don't have one, you can set up an account. Note that it involves several preparatory steps and may take several weeks to set up an ESG account, so please keep this timing in mind. Information on how to set up an account is available at the link shown on this screen. The benefit of submitting your report though the ESG is that FDA will immediately email you an acknowledgement of receipt of the report. We realize that this can be important to many of our manufacturers.

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Now let's review the second method, which is to prepare your report electronically and mail, or email it to FDA.

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In this method, you'll start by preparing your report using eSubmitter, just like the prior method. You'll then save your files in the pdf format and email to RadHealthCustomerService@fda.hhs.gov.
FDA will generally take several days to process submissions received through this method, after which you'll receive an electronic acknowledgment letter by email. This is the easiest method if you don't already have an ESG account. The submission of physical media is no longer encouraged.

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And finally, we'll review the third method, which consists of preparing a hard copy of your report and mailing it to FDA. Note that this method is the least commonly used.

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First download the proper form from the FDA Forms page, which is found at the link shown on this slide. Fill out the form completely, print off a hard copy, and mail the hard copy to FDA for processing.
FDA will send an acknowledgement, usually within 30 days upon receipt. Please note the timing as you consider which of the three methods you choose.

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The CDRH mailing address to send electronic or paper reports is available at the link shown on this slide. Please keep this link handy for future reference.

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The acknowledgement letter that you'll receive serves several purposes: first, it will let you know that we received the report. Second, you'll be informed that we'll contact you if we have any questions about the report. And finally, the report will be assigned an Accession number. The Accession number is a unique FDA-assigned identifying number that should be used as a reference in any follow-up communications. Be sure to provide a correct email address so that FDA can respond electronically.

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Remember that an Accession number is only a document number for the report. It does not indicate that your product has been approved, because this is not a device premarket approval process. It only indicates that a manufacturer has met the reporting requirement for a product. Once the manufacturer has submitted the required report, if it is not a medical device that requires premarket clearance or approval, the company is free to market the products in the U.S. Foreign manufacturers will need an Accession number to ship the product to the U.S.

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Remember that an acknowledgement letter does not indicate that FDA reviewed the report, nor does an accession number indicate that your product has been approved. You self-certified your product as compliant with FDA requirements, and the report is a tool FDA will use to evaluate product safety.

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So, let's review what we discussed in this module. First, we discussed that FDA has regulations and plays an important role in regulating electronic products. Next, we learned about the role manufacturers have, and the steps needed, to get their electronic products to the U.S. market. This includes complying with applicable standards and sending certain reports to FDA. And finally, we reviewed that Electronic Product Requirements differ from medical device requirements. Both sets of regulations may apply to your product, and both need to be satisfied before marketing the product in the U.S.

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We hope that you now have a better understanding of how to get your electronic product on the U.S. market, and that we've provided enough information to get you started. I'd like to share some other resources that may be helpful. The first set of resources are specific to radiological health, or more specifically, radiation-emitting electronic products. These resources include the Radiation-Emitting Products Industry Assistance Walk-Through website. This provides one-stop shopping for important information such as guidances, policies, procedures, and reporting documents. The second link on this slide takes you to the regulations that address the actual electronic product requirements, including the individual performance standards, certification, and reporting.

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The top link on this page provides important device information, such as the medical device requirements for registration, listing, and premarket notifications. And the 2nd link takes you to FDA's website for radiation-emitting products. This site features comprehensive information that you may find helpful.

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In addition, we encourage you to use other industry education resources we've developed especially for you, as shown on this slide. Of note, for comprehensive regulatory information, please contact CDRH's Division of Industry and Consumer Education. We look forward to helping you. Thank you for watching this program.

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