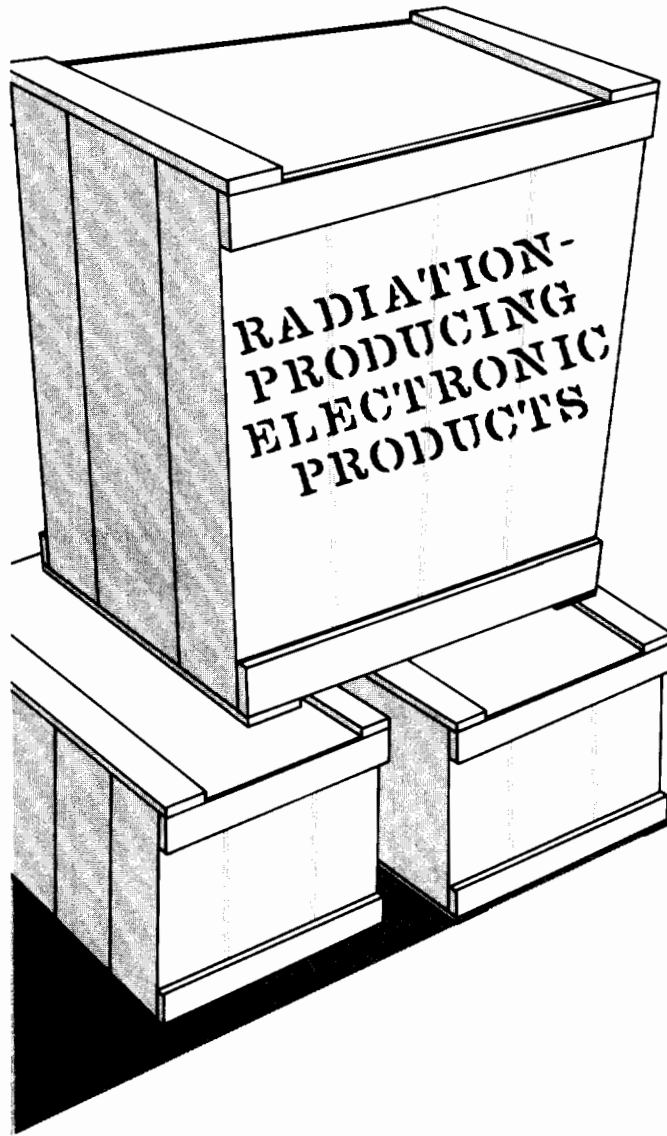


# IMPORTS



U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
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## INTRODUCTION

The Radiation Control for Health and Safety Act of 1968 (Public Law 90-602) declares that the public health and safety must be protected from the dangers of electronic product radiation. It directs the Secretary of Health and Human Services to set and enforce performance standards to control radiation emissions from electronic products. Such standards apply to products offered for sale or use in the United States, whether manufactured here or abroad.

The purpose of this booklet is to highlight procedures to be followed in importing certain electronic devices into the United States. Only products covered by performance standards issued under the Radiation Control for Health and Safety Act are affected by the import regulations discussed.

The Food and Drug Administration (FDA) is responsible for implementation of the Radiation Control for Health and Safety Act and has issued regulations governing importation of products subject to radiation performance standards. The U.S. Customs Service has issued companion regulations. The sections that follow cover import procedures established jointly by the two agencies.

For additional information, importers should refer to regulations of the Department of Health and Human Services (21 Code of Federal Regulations, Part 1005) and the Department of the Treasury (19 Code of Federal Regulations, 12.90 et seq.), or contact the nearest FDA District Office. A list of these offices is provided on the inside back cover.

## **IMPORT REGULATIONS**

Importers of electronic products for which Federal performance standards are in effect are required to submit certain information on each shipment to the U.S. Customs Service and the Food and Drug Administration. The requirement applies to commercial firms as well as travelers bringing products into the United States. The information must be satisfactorily provided before the products will be allowed to enter the country.

### **Entry Notice and Declaration**

In all cases, at least two forms must be filed for each shipment at the time of importation: the importer's entry notice (Form FD 701) and an electronic product declaration (Form FD 2877). The forms provide information needed to: (1) identify the product being imported, including manufacturer, importer, and port of entry, and (2) determine if the device is in compliance with the applicable standard.

The importer's entry notice, accompanied by a copy of the declaration, must be submitted to the FDA District Office by filing it with the U.S. Customs Service representative at the port of entry or as directed by local U.S. Customs Service procedures. Copies of these forms are available from any FDA office.

The declaration must describe the compliance status of the product by citing one of four affirmations. The importer must affirm that the product either:

- Was manufactured prior to the effective date of the applicable Federal standard, or

- Complies with the standard and has a label affixed certifying such compliance, or
- Does not comply with the standard, but is being imported only for purposes of research, investigations, studies, demonstrations or training, or
- Does not comply with the standard, but will be brought into compliance.

### **Product Entry**

**Products** declared either to have been **manufactured prior to the effective date of the applicable standard** or to be **in compliance with the appropriate standard** will be permitted entry to the United States upon confirmation by FDA that the statement is correct. Until an importer receives FDA clearance, the products may not be distributed. Clearance from U.S. Customs alone does not give an importer permission to distribute. Distribution prior to FDA clearance may lead to fines or a product recall. Products may also be detained until additional procedures have been completed.

If a **noncomplying product** is being **imported for research, investigations, studies, demonstrations, or training**, the importer must obtain an exemption from an FDA District Office before the device can be allowed into the country. Requests for exemptions must be submitted on a form FD 766 or in a letter attached to the form. The request should describe the product or component being imported, the purpose for which it is being imported, the person responsible for the product, how it will be used and for how long, and where it will be located. All entries for testing, evaluation, and demonstration shall be made under a U.S. Customs Service Temporary Import Bond (TIB) unless specifically exempted. Exemptions have been provided for

limited numbers of microwave ovens and television sets to be imported without the posting of a TIB.

It may be possible to obtain an exemption in advance of the expected importation date to avoid delays at the time of delivery. To file for an exemption in advance, the importer should complete the form FD 766 and submit it to the FDA District Office at the port of entry.

The FDA District Office will notify the importer that the exemption has been either granted or denied. When a shipment has been exempted, the district's notification of exemption must accompany the importer's entry notice and declaration at the time of entry.

If an exemption has not been obtained prior to entry, an exemption request must be submitted to the FDA District Office along with the other required entry papers. The product will be allowed to enter the country under bond, but will not be permitted to be used until the exemption has been granted. The bond, to be posted with the U.S. Customs Service, would be in an amount equal to the value of the shipment plus any import duties and taxes.

It should be noted that the granting of an exemption does not permit introduction of the product into commerce nor release it from bond. In fact, the product must be either exported or destroyed when its use as described in the approved FD 766 has been completed.

When an importer declares that a **product does not comply with an appropriate standard, but will be brought into compliance**, the product will be permitted entry into the country under bond, but will not be allowed to be used or introduced into commerce until corrections have been made, or a satisfactory initial or model change report has been submitted. The

importer must submit to the FDA District Office a form FD 766 stating the manner in which he will bring the product into compliance, i.e., by his intention to file an initial or model change report or by reconditioning the product.

FDA may approve or disapprove this submission. Upon receiving approval to recondition the product, the importer must submit a petition to FDA outlining plans to bring the product into compliance. If the petition is accepted, the importer must bring the product into compliance with the performance standard within 180 days in accordance with the approved corrective action plan. If necessary modifications are not made, the product will be exported or destroyed.

### **TEST SAMPLES**

The Radiation Control for Health and Safety Act specifically provides that test samples may be taken from any import shipment to determine whether a product complies with an applicable standard. FDA, as authorized by the U.S. Customs Service, may obtain samples from importers. These are returned after testing.

### **A WORD OF ADVICE**

Importers should order products manufactured in accordance with applicable U.S. standards and with appropriate certification labels affixed. Such orders should be readily filled, because there are many foreign manufacturers producing devices for export that comply with U.S. standards.

## **PRODUCTS COVERED BY PERFORMANCE STANDARDS**

The following section briefly describes Federal electronic product radiation safety performance standards currently in effect.

### **Television Receivers/Monitors**

Standard effective January 16, 1970. Applies to products designed to receive and display a television picture through broadcast, cable, or closed-circuit television. Includes home television receivers/monitors, electronic viewfinders on TV cameras, TV projectors, and video monitors used with x-ray and other medical imaging systems. The signal may be generated by transmitter, video recorder, camera or computer. Products commonly described as video display devices, video display terminals, graphic monitors, medical monitors and other similar products are subject to the performance standard **unless they are limited by design** to display only alphanumeric characters.

### **Demonstration-Type Cold-Cathode Gas Discharge Tubes**

Standard effective May 19, 1970. Applies to tubes in which an electron flow is produced and sustained for purposes of demonstrating electron flow or x-ray production.

### **Microwave Ovens**

Standard effective October 7, 1971. Applies to home and commercial devices designed to heat or cook food through the application of electromagnetic energy.

### **Diagnostic X-Ray Equipment**

Standard effective August 2, 1974. Applies to complete diagnostic x-ray systems, as well



as major components, including tube housing assemblies, x-ray controls, x-ray high voltage generators, fluoroscopic imaging assemblies, tables, cradles, film changers, cassette holders, and beam-limiting devices.

### **Cabinet X-Ray Devices**

Standard effective April 25, 1974, for systems designed primarily for the inspection of carry-on baggage; effective April 10, 1975, for other cabinet x-ray devices. Applies to all x-ray machines in enclosed free-standing cabinets.

### **Laser Products**

Standard effective August 2, 1976. Applies to all lasers and laser systems, as well as products that contain or are intended to contain a laser or laser system, except those excluded under 21 CFR 1040.10(a).

### **Ultrasonic Therapy Equipment**

Standard effective February 17, 1979. Applies to ultrasonic therapy equipment used in physical therapy as well as generators or applicators designed for use in such equipment.

### **Mercury Vapor Lamps**

Standard effective March 8, 1980. Applies to any mercury vapor discharge lamp designed, intended, or promoted for illumination purposes.

### **Sunlamp Products**

Standard effective May 7, 1980 and amended September 8, 1986. Applies to sunlamp products (i.e., suntanning beds and booths) and ultraviolet lamps intended for use in these products to induce skin tanning.

### **Importing for Testing and Evaluation or for Export**

Under certain conditions, importers are permitted to import (for export) noncertified multi-system television receivers which cannot accept the U.S. broadcast signal, and noncertified 220-volt microwave ovens without a U.S. power plug or adapter. In addition, certain shipments of television receivers, microwave ovens, and laser products that are Class I during operation, maintenance and service, may be imported for testing and evaluation when specific criteria for exemption from the appropriate performance standard have been met. Contact the nearest FDA District Office regarding the criteria for exemption.

### **ADDITIONAL INFORMATION**

For additional information, importers, dealers, distributors, and manufacturers should refer to pertinent Food and Drug Administration regulations (Code of Federal Regulations, Title 21, Parts 1000 to 1050) or contact the nearest FDA District Office.