BACKGROUND

Subchapter C of the Federal Food, Drug & Cosmetic Act (Electronic Product Radiation Control)—formerly the Radiation Control for Health and Safety Act of 1968—was enacted to protect the public from unnecessary exposure to radiation from electronic products. Pursuant to the Act, an electronic product radiation control program was established by the Secretary of the Department of Health and Human Services. This program is conducted by the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA). Performance standards for certain electronic products have been promulgated under the Act and FDA is responsible for assuring that manufacturers comply with the provisions of these standards.

FDA established the Winchester Engineering and Analytical Center (WEAC), in Winchester, Massachusetts, to conduct laboratory tests of selected radiation-emitting electronic products and determine their compliance with applicable Federal performance standards (21 CFR Chapter I, Subchapter J). WEAC also conducts tests to acquire information and data on products that are the subject of consumer/user complaints, recalls or corrective actions.

WEAC performs compliance tests on the following electronic products:

- Television Receivers & Video Display Monitors
- Diagnostic X-Ray Systems
- Microwave Ovens
- Sunlamp Products & Ultraviolet Lamps
- Mercury Vapor Lamps
- Ultrasonic Therapy Units

HOW FDA OBTAINS PRODUCTS FOR TESTING

Each year, WEAC tests a number of each type of radiation-emitting electronic product. When a unit is needed for endurance- or life-testing, CDRH contacts the manufacturer/importer to arrange for purchase.

In most cases, however, manufacturers and/or importers provide units on loan; these are returned after testing. CDRH sends a letter to each manufacturer/importer whose product is selected for testing, to explain the loan process, shipping logistics and other pertinent information. Units to be tested are shipped to WEAC, freight collect, and return shipping is prepaid by WEAC.

EXAMINATION AND TESTING

WEAC inspects all products to check the adequacy of user instructions and service manuals and to confirm that labeling includes the following required information: manufacturer name and address, model number, serial number, month and year of manufacture, warnings, and certification statement. WEAC also conducts product-specific examinations and tests, as listed below.

Television Receivers and Video Display Monitors

- Critical component warning label
- Design-center chassis power curve
- Worst-case (Phase III) chassis power curve
- X-radiation measurements under design-center and Phase III conditions

Mercury Vapor Lamps

- Self-extinguishing function when outer envelope is broken or punctured
- Lamp packaging and advertising

Ultrasonic Therapy Units

- Generator label
- Applicator label
- Operator and service control labeling
- User manual
- Service manual
- Power calibration
- Timer accuracy
- Frequency determination
- Waveform description
- Pulse duration
- Pulse repetition rate
- Duty factor
- Ratio of temporal peak to average intensity
- Effective radiating area
- Beam nonuniformity ratio
- Applicator type
- Endurance, as appropriate

TEST RESULTS

WEAC forwards the test report to CDRH for review, evaluation of the results and any necessary followup with the manufacturer/importer. If a recall, a corrective action plan or a similar measure is required, CDRH notifies the manufacturer/importer and encloses a copy of the test report.

For further information, please contact:

Center for Devices and Radiological Health
Office of Compliance (HFZ-300)
2098 Gaither Road
Rockville, Maryland 20850
(301) 594-4692

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DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration [redacted] (HFZ-342)
Center for Devices and Radiological Health
Rockville MD 20857

Official Business
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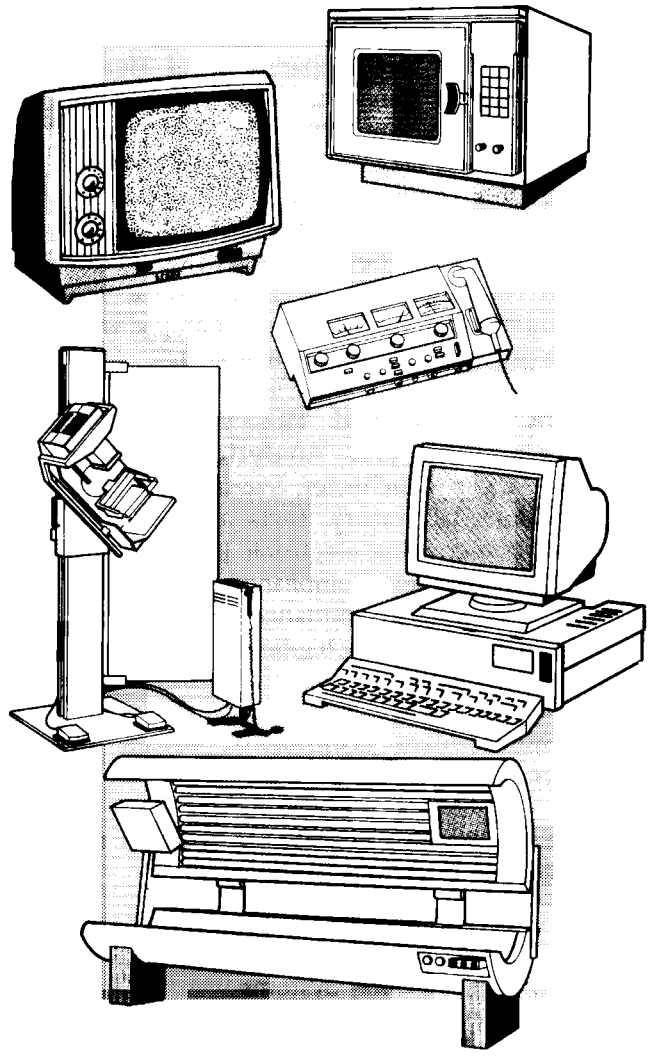
FDA Compliance Testing Program for Radiation-Emitting Devices



Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health