

CHAPTER 86 - MEDICAL AND RADIOLOGICAL DEVICE MONITORING AND QUALITY
CONFORMANCE

SUBJECT: Inspection and Field Testing of Radiation-Emitting Electronic Products		IMPLEMENTATION DATE
		10/31/2007
		COMPLETION DATE
		09/13/2011
DATA REPORTING		
PRODUCT CODES		PRODUCT/ASSIGNMENT CODES
95RH-XXX (See Attachment B for detail)		86001
95RH-XXX (See Attachment C for detail)		86002
94RH-XXX (See Attachment D for detail)		86004

This compliance program consolidates and supersedes the following compliance programs:

- **7386.001 – Inspection of Manufacturers of Laser Products**
- **7386.002 – Field Implementation of the Sunlamp and Sunlamp Products Performance Standard As Amended**
- **7386.004 – Field Compliance Testing of Cabinet X-Ray Equipment**

FIELD REPORTING REQUIREMENTS

- Submit all Establishment Inspection Reports (EIRs) and field test reports, attachments, exhibits, correspondence between the district and firm, and other documentation to:

Center for Devices and Radiological Health
Office of Communication, Education and Radiation Programs
ATTN: Electronic Products Branch
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

- Copies of the EIRs and field test reports, attachments, exhibits, correspondence between the district and firm and other documentation should be routed to appropriate Radiological Health staff, as identified in Part VI of this program, to the accomplishing district and to the district where the firm is located (if located in a different district from the accomplishing district).
- All FACTS and PODS data should be entered by the accomplishing district where the operation

was performed.

This document represents the agency's current thinking on the enforcement of the Federal Food Drug and Cosmetic Act Electronic Product Radiation Control provisions and related regulations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.