CHAPTER 86 - MEDICAL AND RADIOLOGICAL DEVICE MONITORING AND QUALITY CONFORMANCE

SUBJECT:	IMPLEMENTATION DATE
INSPECTION OF DOMESTIC AND FOREIGN MANUFACTURERS OF DIAGNOSTIC X-RAY EQUIPMENT	6/1/2008
	COMPLETION DATE 9/14//2011

DATA REPORTING

PRODUCT CODES	PROGRAM ASSIGNMENT CODES
See Attachment A	86003

FIELD REPORTING REQUIREMENTS

- Submit copies of 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: Diagnostic Devices Branch
  10903 New Hampshire Avenue
  Silver Spring, MD 20993-0002

  When an inspection has been conducted under both Medical Device and Radiological Health Authorities, also follow the SOP for submission of Medical Device EIRs.

  Original documents are maintained by the home district.

- 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 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.

FACTS

- All FACTS data should be entered by the investigator of record.

- Comprehensive inspections are reported in FACTS for manufacturing plants producing certified diagnostic radiation-emitting electronic products on a recurring basis.

- If the firm is not manufacturing or has not introduced any products into commerce, this time should be reported as investigations. Report all time spent for telephone calls and reviewing documentation that do not lead to on-site inspections under Operations Code 13 "Domestic investigations".

- Report time spent on operations leading to on-site inspections of manufacturers as below;
  - Domestic inspections – use OP Code 12
  - Foreign inspections – use OP Code 11

- Any training related to this program should be reported as below;
  - Training received – use OP Code 84
  - Training given – use OP Code 83