

CHAPTER 86 - MEDICAL AND RADIOLOGICAL DEVICE MONITORING AND QUALITY
CONFORMANCE

SUBJECT: INSPECTION OF DOMESTIC AND FOREIGN MANUFACTURERS OF DIAGNOSTIC X-RAY EQUIPMENT		IMPLEMENTATION DATE 6/1/2008
		COMPLETION DATE 6/1/2011
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 (HFZ-240)
 1350 Piccard Dr.
 Rockville MD 20850

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

PART I - BACKGROUND

This compliance program provides guidance to FDA field and center staff for the inspection, field test and administrative/enforcement activities related to the Electronic Product Radiation Control (EPRC) provisions of the Federal Food Drug and Cosmetic Act (FFDCA, the Act) and regulations contained in Title 21 of the Code of Federal Regulations, Parts 1000 – 1050 (21 CFR 1000 – 1050). The intent of these requirements is to protect the public from unnecessary exposure to electronic products radiation. Manufacturers are responsible for producing products that do not emit hazardous or unnecessary radiation and that comply with all applicable radiation safety performance standards. All electronic product manufacturers must comply with applicable requirements in Title 21 CFR 1000, 1002, 1003, 1004 and 1005. If a mandatory radiation safety performance standard applies to a manufacturer's product, then the manufacturer must also comply with Title 21 CFR 1010 and the product must comply with the requirements of the specific standard found in 21 CFR 1020 – 1050. Manufacturers are required to self-certify their own products to be compliant with an applicable standard, based on a quality control testing program as described in 21 CFR 1010.2. The purpose of EPRC inspections and field tests are to verify that products comply with performance standards, and that the manufacturer's quality control testing program ensures such product compliance and radiation safety.

The Food and Drug Administration (FDA) is authorized to "review and evaluate" testing programs carried out by the industry to assure that the products minimize the delivery of unnecessary radiation to patients and to meet the standards issued regarding such products. Manufacturer compliance has been monitored through several mechanisms. The Center for Devices and Radiological Health (CDRH) and/or FDA's Office of Regulatory Affairs (ORA) reviews and evaluates manufacturer radiation safety reports, conducts field tests of products that have been installed and are in use, conducts laboratory testing of selected products, and inspects manufacturer sites to assess the adequacy of the QC testing and record keeping programs established by the manufacturer.

The focus of this compliance program will be the investigation and inspection of those x-ray products that have been designed and manufactured for use in the diagnostic medical irradiation of humans. The specific performance standards for diagnostic x-ray systems and their major components are contained in 21 CFR 1020.30 through 1020.33.

Firms covered under this program may produce either complete systems or individual components that are designed to be compatible with components produced by other manufacturers and assembled into a completed system at the final user location. Since manufacturers of such x-ray components may not produce complete systems, inspections under this program can be complex. Because of this complexity, investigators conducting inspections under this program must have in-depth knowledge of the EPRC provisions of the FFDCA and familiarity with radiation measurement techniques and instrumentation in addition to an understanding of medical device quality control processes. Training programs will be conducted by CDRH and ORA on an as-needed basis to assure that a sufficient number of properly qualified field personnel are available to meet the needs of the program.

Medical devices that emit electronic product radiation, such as diagnostic x-ray systems and components, are subject to EPRC requirements as well as Medical Device provisions of the Act and related regulations.

Medical device inspection and enforcement activities described in Compliance Program 7382.845, Inspection of Medical Device Manufacturers, may be conducted jointly with this program at CDRH and district discretion.

The EPRC provisions of the FFDCA mandate self-certification by manufacturers that their products meet the requirement of the regulations. Each manufacturer must determine the applicable requirements of the regulations and institute a program that assures the performance of their product. Prior to introduction into commerce, manufacturers are required to report this information to CDRH and properly label their products. To aid in this process, CDRH has published guidance in the form of reporting guides. The focus of these guides is to identify the pertinent information required for the specified certifiable components and to present an outline for a manufacturer to follow in preparing required information for certifiable components subject to the EPRC Performance Standards under 21 CFR 1020.30, 1020.31, and 1020.32. The reporting guides represent a mapping of the evaluation and self-certification of the conformance of diagnostic x-ray components to the applicable EPRC regulations. The guides have been created as a step-by-step process to lead manufacturers through the regulations and outline an acceptable format to establish and document programs leading to compliance for each type of regulated product.

There are currently three active guides available;

1. ["A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components"](#),
2. ["A Guide for the Submission of Initial Reports on Computed Tomography X-Ray Systems."](#), and
3. ["A Guide for the Submission of an Abbreviated Initial Report on X-Ray Tables, Cradles, Film Changers or Cassette Holders Intended for Diagnostic Use"](#)

The abbreviated guide recognizes that the requirements for the covered products focus on limited sections of the general guide and provides a less complex report for these products. It should be noted that it is acceptable for the manufacturers of these components to use the full format guide and many have done so. These references may aid investigators in preparing for and conducting diagnostic x-ray manufacturer inspections.

PART II – PROGRAM/IMPLEMENTATIONA. OBJECTIVES

This is a continuing, non-statistical compliance program intended:

1. To ensure that the regulated products and manufacturer quality control programs conform to EPRC regulations;
2. To identify diagnostic x-ray products which fail to comply with the applicable performance standard requirements;
3. To obtain correction of noncompliant products identified in 1 and 2 above by initiating appropriate administrative and/or regulatory action when necessary; and
4. To provide guidance to manufacturers regarding compliance with applicable EPRC laws and regulations administered by FDA

B. PROGRAM MANAGEMENT INSTRUCTIONS1. Planning Instructions

- a. The role of the individual investigator and field radiological health specialists is a critical factor for the effective implementation of this program. Field specialists such as X-ray Auditors and Regional Radiological Health Representatives have been specifically trained in general EPRC requirements and may have specialized training in the diagnostic x-ray performance standards.

Only individuals trained in EPRC requirements should perform these inspections. Contact CDRH/OCER Diagnostic Devices Branch (HFZ-240) and DFI (HFC-130) should the need for expertise, not otherwise available in the District, become apparent. At the discretion of CDRH and the district, radiological health specialists may be used to accompany a medical device investigator to conduct joint EPRC/medical device inspections. If an individual has training in both EPRC and medical device inspections, a single individual may conduct both portions of the inspection.

- b. Field radiological health specialists, their particular area of expertise, physical location and primary geographical areas of responsibility are listed in Part VI of this program.
- c. A list of foreign and domestic manufacturers covered under this program may be developed using available data systems including the Center Tracking System (CTS) and the Registration and Listing database. CDRH will provide access to necessary systems, help build queries to identify firms and assist in selecting firms for selection as needed.
- d. Based on the resources in the current FY workplan, field radiological health specialists

will develop assignments for their organization. The assignments will be reviewed by his or her supervisor and entered into FACTS. Workplans should include district inspections, field tests, and known CDRH assignments. The establishment inventory and guidance from CDRH should be used to determine inspection and field test locations.

2. Pre-announcement of Inspections

Because these inspections are intended to cover both EPRC and medical device Quality Systems Regulations, these inspections must be pre-announced according to medical device inspection compliance program. Refer to instructions provided in the Guide to Inspections of Quality Systems, August 1999, and IOM Section 5.2.1.1, Pre-Announcements.

If the inspection will only evaluate compliance with EPRC regulations pre-announcement remains necessary to facilitate the inspection. Pre-announcement ensures the firm is producing electronic products for the US market on the day of inspection, gives the firm time to collect all necessary procedures and records, and ensures appropriate individuals are available during the inspection. Section 537 of the Act permits inspection of any manufacturer for good cause, grounds for which may include introduction of any noncompliant product into US commerce, failure to comply with EPRC reporting requirements, or for purposes of investigating suspected problems with a manufacturer's quality control testing program and assessing product conformance with performance standards.

3. Inspection Priorities

Inspections and field testing of electronic product manufacturers should be prioritized using the following criteria:

- a. Manufacturers and products posing a potential risk to public health or with great public health impact. High-risk products may be identified by direction provided from CDRH, level of radiation emissions accessible to the public or volume of products on the US market.
- b. Manufacturers or products with known or suspected compliance problems discovered through field testing, report review, complaints or other reason.
- c. New manufacturers that have not yet been inspected
- d. Products incorporating technology new to the US market or a major change in existing product.

4. Resource Instructions

- a. Field personnel may require personal radiation monitors, such as thermal luminescent dosimeter badges, when performing tests under this program. Dosimeters must be worn when performing inspections of diagnostic x-ray manufacturers or diagnostic x-ray field tests. These monitors are available from the Winchester Engineering and Analytical

Center (WEAC) Radiation Safety Officer. Regional Radiological Health Representatives (RRHRs) may also be able to provide dosimeters upon request. Part VI of this program contains the current list of contacts for WEAC.

- b. Field personnel are responsible for contacting OCER and OSEL to arrange to have their radiation measurement equipment re-calibrated annually. Any personnel that do not have the appropriate radiation meters may request that equipment be loaned by another district or by CDRH, if available.

CDRH will be phasing out calibration services currently provided for a number of instruments in the field, and alternate sources of equipment maintenance and calibration services will be identified. CDRH will assist in identifying sources for these services, and will maintain an inventory of equipment that may be available for use by field staff on loan.

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PART III - INSPECTIONALA. OPERATIONS1. Inspectional Strategy

The purpose of electronic product manufacturer inspections is to evaluate the firm's quality control testing program to ensure product compliance with applicable performance standards and radiation safety. The inspection should also verify that EPRC requirements for reporting and recordkeeping are met by the firm.

2. Electronic Product Radiation Control Inspection

Review the firm's quality control testing program required under 21 CFR 1010.2 to ensure product compliance with the x-ray performance standards in 21 CFR 1020. These items may be reviewed in conjunction with review of QSIT elements when a joint EPRC/medical device inspection is conducted. The firm's quality control testing program ensuring compliance with the x-ray performance standard will be integrated throughout the firm's quality system required by 21 CFR 820.

Each manufacturer of a certifiable x-ray system or component is required to submit a radiation safety report for its specific product to CDRH prior to introducing products into commerce. Using the appropriate guide for the product under investigation and the general instructions from Chapter 5 of the IOM, the investigator will inspect pertinent records and files of the firm covering each of the following.

a. Items to cover

- i. The firm's product(s) comply with the applicable requirements of the standard to the extent that:
 - The product has the applicable performance features, labels, and instructions for operation, maintenance and service
 - The product emissions are properly characterized.
 - The brochures, catalogs and other promotional material contain any required warnings or label reproductions
- ii. The firm has procedures and documents for control of the manufacturing process appropriate to the product type and production volume including:
 - Stock and inventory control
 - Bills of materials
 - Control drawings and procedures that are authenticated and current
 - Incoming inspection, criteria for acceptance/rejection, and segregation of accepted from rejected parts
 - Disposition of rejected parts
 - Finished goods storage and inventory
- iii. The firm has adequate quality control testing procedures and records to demonstrate:
 - Production testing performed at the firm as described in the report submitted to CDRH

- In-production tests to verify product compliance during production
 - Final test and inspection of finished products
 - Maintenance and calibration of test equipment
 - QC/QA activities are contained in and reported to management organization other than the organization responsible for design and production
- iv. The firm maintains records required by the electronic product radiation control regulations:
- Distribution to first purchasers or distributors (note: dealers and distributors of certifiable products valued at \$50 or above are required to maintain detailed distribution records of the product(s). The distributor/dealer has the option to retain those records or to forward them to the original manufacturer. Determine if the manufacturer is receiving such records and if so, is maintaining them in a retrievable manner.)
 - Test results and data supporting product compliance with FDA performance standards
 - Safety related complaints, inquiries
 - Real or alleged injuries
 - Remedial actions taken for reports of non-compliant products, complaints, injuries
 - Reports submitted to CDRH
- b. Records to collect
- i. Organization chart identifying key individuals responsible for product design, manufacturing and quality control
 - ii. Copies of testing procedures and where possible photographic evidence showing that testing does not ensure product safety or compliance with applicable standards
 - iii. Samples of violative labels
 - iv. Copies of manuals, in part or whole, that fail to contain required materials
 - v. Copies of brochures and catalogs that fail to contain required warning or label reproductions
 - vi. Distribution records for any violative products

c. Foreign inspections

All foreign inspections should be conducted using this guide, and any special instructions contained in the inspection assignment. The failure of any foreign manufacturer to comply with these requirements may result in the article being refused admission into the United States.

Foreign inspections are subject to scheduling and time constraints as several manufacturers will be inspected in a single trip. Early planning is critical to conducting foreign inspections. Firms inspected must be notified as early as possible to ensure the firm will be producing for the US on the day of inspection, to give the firm time to collect all necessary procedures and records, prepare translations of needed documents, and make arrangements to have a translator available if needed.

Any investigator with appropriate training may conduct foreign EPRC or joint EPRC/medical device inspections.

d. Medical Device Inspections

Radiation-emitting medical devices are subject to both electronic product radiation control requirements and medical device requirements including the Quality System, Medical Device Reporting (MDR), Medical device Tracking, Corrections and Removal, and Registration and Listing regulations.

Based on district concurrence, a joint EPRC/medical device inspection covering the firm's compliance with both sets of requirements may be conducted under this compliance program and Compliance Program 7382.845 for Inspection of Medical Device Manufacturers.

- The EPRC portion of the inspection should follow the instructions provided specifically in this program to determine the firm's compliance with electronic product radiation control requirements for reporting and recordkeeping, certification to applicable performance standards, and a quality control testing program that ensures product compliance and radiation safety. Report EPRC time under the appropriate PAC identified in this program.
- The medical device portion of the inspection should follow instructions provided in the medical device inspection compliance program to assess the firm's quality system. Manufacturers of devices subject to the diagnostic x-ray radiation safety performance standards contained in 21 CFR Parts 1020.30 – 1020.33 should include in their device master and history records those procedures and records demonstrating compliance with the applicable standard, self-certification (21 CFR 1010), and reporting (21CFR 1002 – 1005). Report medical device time under the appropriate medical device PAC identified in Compliance Program 7382.845.

e. For-Cause Directed inspections

For-cause inspections are conducted in response to specific information that raises questions, concerns, or problems associated with the electronic product. Information can come from a variety of sources including:

- Sample analysis results
- Prior inspectional observations
- Questionable information in product reports
- Reports of injuries related to the firm's products
- Consumer or trade complaints about the firm.

For cause inspections are usually initiated at the request of CDRH. For-cause inspections will generally follow instructions provided in this compliance program, and additional instructions or issues will be provided in the assignment.

f. Inspectional Observations Review

Review inspectional observations with the most responsible individual and other technical experts at the firm prior to concluding the inspection. Record EPRC

observations on the Form FDA-483. This compliance program provides guidance concerning severity of violations observed to identify major deficiencies. Deficiencies should be noted on Form FDA-483 in order of descending importance (i.e. most serious first). If both EPRC and medical device observations are noted, they should be grouped separately on the form.

The district has discretion to offer annotation of the FDA 483 for an EPRC inspection, if the investigator and firm believe annotation will facilitate the inspection process. An offer to annotate the FDA 483 should be extended for all joint EPRC/medical device inspections. When a FDA 483 is annotated, it should be done in accordance with the IOM Chapter 5 (Section 5.2.3).

The following statement should be included on each FDA 483:

“This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective actions in response to an observation, you may discuss the objection or action with FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.”

For all medical device inspections the FDA 483 should contain the following additional statement:

“The observations noted in this form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self audits to identify and correct any and all violations of the quality system requirements.”

3. Investigations:

Investigations are to be made to determine whether a suspected firm is in fact a manufacturer of one or more electronic products. The investigation may be initiated in preparation for a possible inspection, as a result of trade complaints, or from discovery via the Internet or printed materials of promotion of products that may not comply with EPRC requirements.

4. Physical and Documentary Samples:

Under this program, physical samples will be collected only upon CDRH approval or under special request from CDRH. Documentary samples will be collected as necessary to document conditions of noncompliance and violations of EPRC standards.

Collect samples according to procedures defined in the Investigations Operations Manual, Chapter 4, and coordinate any sample collection activity with CDRH or WEAC to ensure proper procedures are followed and chain of custody is observed to maintain sample integrity.

PART IV - ANALYTICAL

No laboratory testing will be done under this program. CDRH or WEAC testing may be required on special assignments under Compliance Program for Lab Testing CP 7386.006 or as indicated in Part III.A.4 of this program.

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PART V - REGULATORY/ADMINISTRATIVE FOLLOW-UP

A. REGULATORY PHILOSOPHY AND STRATEGY

Diagnostic X-ray equipment is subject to radiation safety performance standards and is regulated under Subchapter C - Electronic Product Radiation Control of the FFDCA. Subchapter C provides authority to require product recalls for noncompliant or defective radiation-emitting electronic products. EPRC provisions specify that, for violations of sufficient severity, the Secretary of FDA may require the manufacturer to repair, replace or refund the cost of the violative products at no cost to the user/purchaser. In addition, because products covered under this compliance program are also medical devices, Subchapter A – Drugs and Devices of the FFDCA provides authority to require product recalls for medical devices that may cause a serious risk to health.

Violations of the EPRC provisions include:

- Introduction into commerce of any electronic product which is defective or does not comply with an applicable standard
- Failure to maintain or submit required reports
- Failure to maintain or make available distribution records
- Failure to certify products as compliant
- False certification of products.

When there is a choice, regulatory/administrative action is preferred under Subchapter C, but, for maximum effectiveness, both EPRC and medical device portions of the FFDCA may be used in conjunction.

Appropriate regulatory or administrative actions include issuance of a notification of defect or non-compliance letter (warning or untitled letter), requiring repurchase, repair or replacement of product under an approved corrective action plan, or imposition of civil penalties and/or injunction. Appropriate follow-up actions should be determined by CDRH or in consultation with CDRH to ensure consistency in how EPRC requirements are enforced.

Districts classify the EIRs and CDRH is generally responsible for the final review of inspections made under this program and for the issuance of letters resulting from inspections performed by field radiological health staff. Exceptions where the district has direct reference authority are noted below under section C, Regulatory Action. The intent of this program is to follow up on problems that pose a radiation safety hazard or are a flagrant violation of EPRC requirements.

B. DISTRICT RESPONSIBILITIES

1. Reporting inspection and test findings

a. Inspection reports

Provide a copy of Establishment Inspection Report (EIR) and exhibits. Refer to the IOM for EIR formats, and clearly indicate the scope of the inspection in the EIR. Document any corrections performed during the inspection or corrections promised with the timeframe for completion.

2. Recommending Action

a. Hazard Class for Non-Compliance

Class A, B, C, and D refer to the hazard class of the observations, related to the severity of the threat to health and safety posed by a particular non-compliant product or practice.

Attachment D of Compliance Program 7386.003 for Field Compliance Testing of Diagnostic (Medical) X-ray Equipment contains a more detailed discussion of Class A and B observations, with examples provided below.

- **Class A:** Conditions that pose an immediate radiation hazard to health and safety. Notify CDRH/OCER contacts identified in Part VI of this program immediately to discuss appropriate action to stop production or product use until corrective action has been taken. Consider contacting State Health Department or other local contacts to assist in addressing problems with product use, if warranted.

For example, Class A conditions include equipment malfunctions or quality control deficiencies resulting in the occurrence of an inadvertent exposure, excessive fluoroscopic exposure, or inadequate protective barriers to limit fluoroscopic exposure.

- **Class B:** Conditions that include radiation safety defects or items of noncompliance with the standard which, without corrective action, could pose a radiation hazard if the non-compliance or defect is not addressed.

For example, Class B conditions include equipment malfunctions or quality control deficiencies resulting in the occurrence of an excessive or insufficient (i.e. unusable, requiring a retake) exposure, or resulting in violations of established performance standard exposure limits.

Specific examples of Class B violations are discussed in Attachment D of Compliance Program 7386.003 in further detail.

- **Class C:** Labeling or user information fails to comply with a standard.
- **Class D:** No problems found.

b. Regulatory Response to Non-Compliance

The designations of a violation as Major, Minor, or Concern refer to the level of regulatory response required to correct deficiencies.

- Major: Non-compliance with a standard that always warrants regulatory action such as a warning letter.
- Minor: Non-compliance with a standard about which a manufacturer should be informed but is not severe enough to warrant a warning letter.
- Concern: Non-compliance which is not severe enough to mention unless also informing a manufacturer about a Major or Minor item.

c. Inspection Classification

Based on inspectional findings, the district will classify the inspection as OAI, VAI or NAI for further action.

If any major EPRC deficiencies exist, the district is expected to classify the inspection as OAI and recommend further regulatory action. Examples of findings that would result in an OAI classification include:

- Total failure to establish a quality control testing program capable of ensuring radiation safety of the product or compliance with applicable performance standards.
- Any single observation of a Class A condition
- Several observations consisting of Class B conditions

The inspection may be classified VAI for a limited number of Class B and C conditions, which are not expected to pose a radiation hazard if corrected voluntarily by the manufacturer.

If it is determined that the EPRC deficiencies are of a quantity and type to conclude there is minimal probability that the firm will produce unsafe or noncompliant products, the inspection will be classified NAI and Form FDA-483 will serve to inform the firm of any objectionable findings. Deficiencies identified as violations of concern will generally not require additional follow-up but should be discussed with the firm. Examples of deficiencies that would result in an NAI classification include:

- QC & T data exceed the test rejection limit but do not exceed the requirement(s) of the performance standard(s) applicable to the product under inspection;
- Failure to submit annual reports in a timely manner
- Using test equipment past calibration due date

Consult CDRH if additional guidance is required to classify inspection and test observations. If the inspection also covered firm compliance with medical device Quality Systems requirements, Compliance Program 7382.845, Part V, Quality System/GMP Regulatory/Administrative Follow-Up, should be consulted for appropriate regulatory and administrative follow-up.

C. REGULATORY ACTION

In determining appropriate regulatory action based on inspection and test findings, the district and CDRH should consider the significance of the product, the firm's history, whether the problem is widespread and continuing. Actions which may be considered include notification of noncompliance letters (warning and untitled letters), product repurchase, repair or replacement (recall), civil penalties and injunctions, and seizures (for radiation-emitting medical devices).

1. Notification of noncompliance letters (Warning and Untitled Letters)

The Electronic Product Radiation Control provisions of the Federal Food Drug and Cosmetic Act (Section 535) and related regulations (21 CFR 1003) require the Agency to notify manufacturers in writing when product noncompliance with a standard is found.

Manufacturers may also be advised in writing of a failure to comply with reporting and recordkeeping requirements (21 CFR 1002.31).

Issuance of all letters should follow Chapter 4 of the Regulatory Procedures Manual (RPM) http://www.fda.gov/ora/compliance_ref/rpm/. Consult the Warning Letter procedures in the RPM (Ch 4, Ex 4-1) for current instructions for obtaining Office of Chief Counsel (OCC) clearance; and the Office of Enforcement's (OE) Warning Letter page on ORA's intranet for templates and model letters approved by OCC. Letter templates must be used to satisfy Agency notification requirements in 21 CFR 1003.11. Where approved OCC templates are not available, consult CDRH for the current version of letter templates.

Districts have DIRECT REFERENCE AUTHORITY for EPRC letters in certain areas which are described in Chapter 4 of the RPM. For example, districts have direct reference authority to issue warning and untitled letters to assemblers of diagnostic x-ray equipment based on field test results; and may approve corrective action plans for x-ray assemblers.

For the majority of cases, where districts DO NOT have direct reference authority to issue EPRC letters, forward the report with exhibits and recommended action to CDRH for review and follow-up. CDRH will copy the accomplishing district on any such letters issued.

If the letter should contain both medical device and EPRC violations contact CDRH to discuss options for follow-up. For example, issuance of a single letter by the district, addressing both EPRC and medical device violations, may be possible with CDRH concurrence. CDRH is available for consult in assessing product noncompliance or developing regulatory and enforcement strategy.

a. Major Notification of Noncompliance Letter (Warning Letter)

This letter notifies the firm of major items of noncompliance and requires the firm to further notify purchasers and recall products. The firm is required to address all items in the letter, and submit a corrective action plan for CDRH approval.

Issue a major notification (warning) letter when the violation of the standard requires further regulatory action.

- All major violations must be addressed in a warning letter.
- Firms and products with several minor violations may also be issued a major notification letter, depending on the public health significance of the violation(s) and the number of products involved.
- Violations of concern may also be included in a major notification (warning) letter, but would not warrant issuance of a major notification (warning) letter on their own merit.

The firm's quality control testing program may also be disapproved upon issuance of a major notification letter, when the Agency believes that the manufacturer's quality control and testing program is not following good manufacturing practices. A program disapproval orders the manufacturer to cease certification of products (i.e. stop production and testing) until the program disapproval is rescinded, and places the firm's products on automatic import detention without prior examination, under authority of Section 534(h) of the Act and 21 CFR 1010.2 of the regulations. A program disapproval may be issued only by CDRH.

b. **Minor Notification of Noncompliance Letter (Untitled Letter)**

This letter notifies the firm of minor items of noncompliance and exempts the firm from further notifying purchasers and recalling products. The firm is instructed to address all items in the letter and make appropriate corrections for future production.

Issue a minor notification (untitled) letter when the violation of the standard does not justify further regulatory action at the time.

- Firms and products with a limited number of minor violations may be issued a minor notification letter, depending on the public health significance of the violation(s) and the number of products involved.
- Violations of concern may also be included in an untitled letter, but would not warrant issuance of an untitled letter on their own merit.

c. **Information Letter**

This letter is a tool used only for CDRH follow-up with manufacturers where conditions represent potential problems and no additional action is planned. Information letters advise manufacturers of inspectional findings and request a response to indicate completed or planned corrections.

Issue an information letter when no immediate action is required of the manufacturer or when the violation is administrative in nature.

- Firms that have not filed annual reports may be issued an information letter
- Violations of concern may also be included in an information letter, to advise the firm of inspectional findings and request status of promised corrections

2. **Repurchase, Repair, or Replacement of Electronic Products (Recall)**

The Electronic Product Radiation Control provisions of the Federal Food Drug and Cosmetic

Act (Section 535) and related regulations (21 CFR 1004) also provide for manufacturer repurchase, repair or replacement of the noncompliant electronic products.

Every major notification of noncompliance letter issued as a result of a major violation or several minor violations requires manufacturer repurchase, repair or replacement of the affected electronic products at no cost to the purchaser. The firm is required to address all items in the letter, and submit a corrective action plan for CDRH approval. Refer to RPM Chapter 7, Attachment E for approval of manufacturer's corrective action plans.

3. Refutation or Exemption from Notification or Correction Requests

Manufacturers can refute the noncompliance or be granted an exemption, by making a written request to CDRH. The exemption can be granted upon request by the manufacturer or by the Agency at its own initiative, and must show that the noncompliance does not create a significant risk of injury.

Within 15 days after notification of the noncompliance/defect by FDA, a manufacturer may refute the alleged noncompliance under 21 CFR 1003.11(a)(3) or request an exemption from purchaser notification and correction as specified under 21 CFR 1003.30. If a manufacturer refutes the alleged noncompliance, or requests an exemption, the evidence presented by the manufacturer is evaluated by CDRH before granting or denying the request for exemption or responding to the refutation. Refer to RPM Chapter 7, Attachment E for information on responding to exemption requests and refutations.

4. Timeframes for action

Immediately notify CDRH and State and local health authorities (through RRHR) for any Class A hazard.

For all inspections and tests that may require issuance of a letter, the EIR must be completed in a timely manner and recommendation should be provided to CDRH or the district compliance officer to allow sufficient time to review, draft, and secure approval for the letter. Timeframes for clearance of letters are provided in Chapter 4 of the RPM.

5. Civil Penalties/Injunctions

Civil penalties should be recommended for violations of Subchapter C of the Act after other actions have failed to achieve compliance, or for knowing and willful violations. More severe civil penalty assessments may be sought under Section 303(f). See CPG Sec. 390.300 and RPM Chapter 6, Civil Penalties - Electronic Product Radiation Control. Informal consultation with the Center at an early stage in the development of a regulatory action is encouraged in order to facilitate timely implementation of the action; contact Diagnostic Devices Branch Chief or Lead CSO at (240) 276-3332.

If an establishment has a continuing pattern of significant deviations in spite of past warnings, injunction will usually be the recommended action of choice. If a serious health hazard exists, the recommendation should include a request for a temporary restraining order

(TRO) to prevent the distribution of products that have been manufactured under the violative conditions documented by the inspection report per the instructions in Chapter 6 of the RPM. Civil penalties and injunctions may be recommended concurrently.

6. Detention/Seizure

Use administrative detention and recommend seizure of a defective or noncompliant radiation-emitting medical device if all three conditions below apply:

- There is a Class A health hazard
- The owner/operator refuses to remove the product from service or returns the product to use before the Class A hazard is corrected
- The EPRC provisions are ineffective in achieving timely correction by the manufacturer

Informal consultation with the Center at an early stage in the development of a regulatory action is encouraged; contact Diagnostic Devices Branch Chief or Lead CSO at (240) 276-3332.

D. FEDERAL/STATE RELATIONS

Some states have Radiation Control Programs within the State Health Department or Department of Environmental Health, which may have adopted portions of the EPRC requirements into their radiation safety regulations.

Districts should use all reasonable means available to encourage voluntary conformance of products with the performance standard regardless of the date of manufacture. It is recommended that the districts coordinate regulatory activity with appropriate state representatives through the RRHR and DFSR, particularly where local authority may assist in achieving correction of a deficiency. This may be particularly useful to address issues related to product use where the State may have regulatory authority, which extends beyond FDA authority to regulate the design, production or manufacture of the product.

E. MEDICAL DEVICE REGULATORY/ADMINISTRATIVE FOLLOW-UP

Regulatory follow-up for joint EPRC/quality systems inspections can be handled separately or in combination at the discretion of the district and CDRH. Refer to Part V in Compliance Program 7382.845, Quality System/GMP Regulatory/Administrative Follow-Up, for guidance on regulatory actions related to radiation-emitting medical devices. Enforcement actions on radiation-emitting medical device firms, which also include EPRC violations, require CDRH concurrence before implementation by the field. Contact CDRH for consultation when both EPRC and quality systems violations are noted during an inspection.

PART VI - REFERENCES, ATTACHMENTS AND PROGRAM CONTACTS

A. REFERENCES

1. Law

Federal Food, Drug, and Cosmetic Act, As Amended
Electronic Product Radiation Control Provisions (formerly known as the Radiation Control
for Health and Safety Act of 1968, Public Law 90-602, October 18, 1968)

<http://www.fda.gov/opacom/laws/fdcaact/fdctoc.htm>

2. Regulations

21 CFR 1000 – 1005, General Requirements for All Electronic Products which Emit
Radiation

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPartFrom=1000&CFRPartTo=1005>

21 CFR 1010, Performance Standards for Electronic Products: General

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1010>

21 CFR 1020 – 1050, Specific Performance Standards for Electronic Products

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPartFrom=1020&CFRPartTo=1050>

3. Regulatory Procedures Manual (RPM)

http://www.fda.gov/ora/compliance_ref/rpm/default.htm

4. Investigations Operations Manual (IOM) - Chapter 5

http://www.fda.gov/ora/inspect_ref/iom/default.htm

5. Compliance Program 7382.845 - Inspection of Medical Device Manufacturers

<http://www.fda.gov/cdrh/comp/guidance/7382.845.pdfversion.html>

6. FDA Web Sites

FDA home page

<http://www.fda.gov>

ORA home page

<http://www.fda.gov/ora/>

CDRH home page

<http://www.fda.gov/cdrh/>

Field Accomplishments and Compliance Tracking System (FACTS)
(visit ORA's home page, then click the FACTS icon.)

Electronic Product Radiation Control home page
<http://www.fda.gov/cdrh/radhealth>

Product Code Classification Database (searchable)
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/pcdsimplesearch.cfm>

Good Guidance Practices Database (searchable)
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfggp/search.cfm>

B. ATTACHMENTS

1. Attachment A – Diagnostic X-Ray Product Codes

C. PROGRAM CONTACTS

Center for Devices and Radiological Health

Office of Communication, Education and Radiation Programs, Division of Mammography Quality and Radiation Programs (DMQRP)

Contact for support in planning and executing inspections and field tests, classification of items of non-compliance, and for interpretation and current policy on EPRC requirements. Send all inspection and test reports to Chief, Diagnostic Devices Branch, FDA/CDRH Office of Communication, Education and Radiation Programs (HFZ-240), 1350 Piccard Drive, Rockville, MD 20850.

Name	Phone	Email	Mail Stop	Position/Expertise
Sean Boyd	(240) 276-3287	sean.boyd@fda.hhs.gov	HFZ-240	Chief, Diagnostic Devices Branch
Dr. Helen Barr	(240) 276-3275	helen.barr@fda.hhs.gov	HFZ-240	Director, DMQRP
Thomas Ohlhaber	(240) 276-3274	thomas.ohlhaber@fda.hhs.gov	HFZ-240	Deputy Director, DMQRP
Rosa Brown	(240) 276-3264	rosa.brown@fda.hhs.gov	HFZ-240	Program Analyst
Barbara Gullick	(240) 276-3277	barbara.gullick@fda.hhs.gov	HFZ-240	Consumer Safety Officer, diagnostic x-ray products
Charles Gunzburg	(240) 276-3286	charles.gunzburg@fda.hhs.gov	HFZ-240	Consumer Safety Officer, diagnostic x-ray products
Tommy Mosely	(240) 276-3311	tommy.mosely@fda.hhs.gov	HFZ-240	Consumer Safety Officer, diagnostic x-ray products
Ellyce Ratskoff	(240) 276-3265	ellyce.ratskoff@fda.hhs.gov	HFZ-240	Consumer Safety Officer, EPRC

Nick Walker	(240) 276-3266	james.walker@fda.hhs.gov	HFZ-240	workplanning Consumer Safety Officer, diagnostic x- ray products
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Office of Science and Engineering Laboratories

Contact for assistance with identifying appropriate instrumentation for use in measuring electronic product radiation emissions.

Name	Phone	Email	Mail Stop	Position
Mary Walker	(301) 796-2558	mary.walker@fda.hhs.gov	TBD	X-ray instrumentation and calibration

Office of Regulatory Affairs

Field Regional Radiological Health Representatives

Name	Phone	Email	Mail Stop	Position
Mike Leal	(508) 793-0422	michael.leal@fda.hhs.gov	HFR-NE2570	NE RRHR
Karen Smallwood	(615) 366-7823	karen.smallwood@fda.hhs.gov	HFR-SE350	SE RRHR
Rachel Evans	(312) 596-6518	rachel.evans@fda.hhs.gov	HFR-CE25	CE RRHR
Scotty Hargrave	(214) 253-4930	scotty.hargrave@fda.hhs.gov	HFR-SW19	SW RRHR
Terri Jones	(503) 671-9711 x36	terri.jones@fda.hhs.gov	HFR-PA3515	PA RRHR

Winchester Engineering and Analytical Center contacts

Name	Phone	Email	Mail Stop	Position
John Marzilli	(781) 729-5700 x749	john.marzilli@fda.hhs.gov	HFR-NE400	WEAC Director
Jim Cherniak	(781) 729-5700	james.cherniak@fda.hhs.gov	HFR-NE400	Radiation Safety Officer
Vacant	Vacant	Vacant	HFR-NE400	Engineering Branch Director, WEAC
Jane Driscoll	(781) 729-5700 x716	jane.driscoll@fda.hhs.gov	HFR-NE480	Metrology Supervisor
Joe Matrisciano	(781) 729-5700 x736	joseph.matrisciano@fda.hhs.gov	HFR-NE480	Engineering Supervisor

Headquarters contacts

Name	Phone	Email	Mail Stop	Position
Mei-Ying Li	(301) 827-2913	meiying.li@fda.hhs.gov	HFC-150	ORO, DFRS

DIAGNOSTIC X-RAY PRODUCT CODES

ID	Translation of Proposed Code	Product Name	RH Radiation Type	CDRH Panel Code	CDRH Medical Specialty Code	3 Letter Code
216	Dental Diagnostic X-Ray Equipment	Unit, X-Ray, Extraoral With Timer (Panoramic, Intraoral Dental System)	94	76	DE	EHD
218	Dental Diagnostic X-Ray Equipment	Unit, X-Ray, Intraoral Source	94	76	DE	EAP
219	Dental Diagnostic X-Ray Equipment	Dental X-Ray Film Holder*	94	76	DE	EGZ
220	Dental Diagnostic X-Ray Equipment	X-Ray Beam Aligner, Dental*	94	76	DE	EHA
221	Dental Diagnostic X-Ray Equipment	Cephalometer	94	76	DE	EAG
165	Medical Diagnostic X-Ray Equipment	Collimator, X-Ray	94	90	RA	EHB
166	Medical Diagnostic X-Ray Equipment	Collimator, Automatic Radiographic	94	90	RA	IZW
167	Medical Diagnostic X-Ray Equipment	Collimator, Manual Radiographic	94	90	RA	IZX
168	Medical Diagnostic X-Ray Equipment	System, X-Ray, Tomography, Computed	94	90	RA	JAK
169	Medical Diagnostic X-Ray Equipment	System, X-Ray, Topographic	94	90	RA	IZF
170	Medical Diagnostic X-Ray Equipment	Cradle	94	90	RA	KXH
171	Medical Diagnostic X-Ray Equipment	Film Changer	94	90	RA	KPX
172	Medical Diagnostic X-Ray Equipment	System, X-Ray, Photofluorographic	94	90	RA	IZG
173	Medical Diagnostic X-Ray Equipment	Fluoroscopic System, Image Intensified	94	90	RA	JAA
174	Medical Diagnostic X-Ray Equipment	Fluoroscopic System, Non-Image Intensified	94	90	RA	JAB
175	Medical Diagnostic X-Ray Equipment	Camera, X-Ray, Fluorographic Cine or Spot	94	90	RA	IZJ
176	Medical Diagnostic X-Ray Equipment	General Radiographic Mobile/Portable System	94	90	RA	IZL
177	Medical Diagnostic X-Ray Equipment	System, X-Ray, Stationary	94	90	RA	KPR
178	Medical Diagnostic X-Ray Equipment	Mammographic System	94	90	RA	IZH
179	Medical Diagnostic X-Ray Equipment	Mammographic System, Full Field Digital	94	90	RA	MUE

DATE OF ISSUANCE:

Attachment A

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* Product is not a certifiable diagnostic x-ray component. Manufacturers of only * components are not inspected under this program. Manufacturers of * components may be inspected if they manufacture certifiable components.

			PROGRAM		ATTACHMENT A	
			7386.003a			
180	Medical Diagnostic X-Ray Equipment	Radiation Therapy Simulation System	94	90	RA	KPQ
181	Medical Diagnostic X-Ray Equipment	Spot Film Device	94	90	RA	IXL
182	Medical Diagnostic X-Ray Equipment	Holder, Radiographic Cassette, Wall-Mounted	94	90	RA	IXY
183	Medical Diagnostic X-Ray Equipment	X-Ray Beam Limiting Device	94	90	RA	KPW
187	Medical Diagnostic X-Ray Equipment	Generator, High-Voltage, X-Ray, Diagnostic	94	90	RA	IZO
188	Medical Diagnostic X-Ray Equipment	Screen, Intensifying, Radiographic	94	90	RA	EAM
189	Medical Diagnostic X-Ray Equipment	X-Ray Table	94	90	RA	KXJ
190	Medical Diagnostic X-Ray Equipment	X-Ray Table, Stationary Top	94	90	RA	IXQ
191	Medical Diagnostic X-Ray Equipment	X-Ray Table, Tilting	94	90	RA	IXR
192	Medical Diagnostic X-Ray Equipment	X-Ray Table, Non-Tilting, Powered	94	90	RA	IZZ
193	Medical Diagnostic X-Ray Equipment	Diagnostic X-Ray Tube Housing Assembly	94	90	RA	ITY
194	Medical Diagnostic X-Ray Equipment	Tube, Mount, X-Ray, Diagnostic*	94	90	RA	IYB
195	Medical Diagnostic X-Ray Equipment	Radiographic Aperture	94	90	RA	IZS
196	Medical Diagnostic X-Ray Equipment	Radiographic Grid*	94	90	RA	IXJ
197	Medical Diagnostic X-Ray Equipment	Radiographic Film Cassette*	94	90	RA	IXA
198	Medical Diagnostic X-Ray Equipment	Radiographic Camera, Focal Spot	94	90	RA	IXH
199	Medical Diagnostic X-Ray Equipment	Holder, Head, Radiographic	94	90	RA	IWY
200	Medical Diagnostic X-Ray Equipment	Chair, Pneumoencephalographic	94	90	RA	HBK
201	Medical Diagnostic X-Ray Equipment	Barrier, Control Panel, X-Ray, Moveable	94	90	RA	IWX
202	Medical Diagnostic X-Ray Equipment	System, Computer, Digitizer for Screening Mammograms*	94	90	RA	MWE
203	Medical Diagnostic X-Ray Equipment	System, X-Ray, Angiographic	94	90	RA	IZI
204	Medical Diagnostic X-Ray Equipment	Solid State X-Ray Imager (Flat Panel/Digital Imager)	94	90	RA	MQB
213	Cabinet X-Ray Systems, Medical	Cabinet, X-Ray System, Medical*	94	90	RA	MWP
214	Medical Diagnostic X-Ray Equipment	Radiographic Cone	94	90	RA	IZT

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Attachment A

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		PROGRAM	7386.003a	ATTACHMENT A		
215	Dental Diagnostic X-Ray Equipment	Radiographic Cone, Lead-Lined	94	90	RA	EAH
217	Dental Diagnostic X-Ray Equipment	System, X-Ray, Extraoral Source, Digital (Panoramic, Intraoral Dental System)	94	90	RA	MUH
224	X-Ray Film and Film Processing Materials	Radiographic Film*	94	90	RA	IWZ
225	X-Ray Film and Film Processing Materials	Reusable Image Media*	94	90	RA	LQA
226	X-Ray Film and Film Processing Materials	Digital Image Storage Device*	94	90	RA	LMB
227	X-Ray Film and Film Processing Materials	Programmer, Changer, Film/Cassette, Radiographic*	94	90	RA	IZP
228	X-Ray Film and Film Processing Materials	Processor, Radiographic-Film, Automatic, Dental*	94	90	RA	EGY
229	X-Ray Film and Film Processing Materials	Processor, Radiographic-Film, Automatic*	94	90	RA	IXW
230	X-Ray Film and Film Processing Materials	Processor, Cine Film*	94	90	RA	IXX
231	X-Ray Film and Film Processing Materials	Dryer, Film, Radiographic*	94	90	RA	EGW
323	X-Ray Film and Film Processing Materials	Controlled Temperature, Radiographic*	94	90	RA	EGT
233	X-Ray Film and Film Processing Materials	System, X-Ray, Film Marking, Radiographic*	94	90	RA	JAC
274	X-Ray Bone Densitometers	Densitometer, Bone	94	90	RA	KGI
184	Medical Diagnostic X-Ray Equipment	X-Ray Controls – Combination, Medical Diagnostic X-Ray Equipment	94	94	RH	RBZ
185	Medical Diagnostic X-Ray Equipment	X-Ray Controls – Fluoroscopic, Medical Diagnostic X-Ray Equipment	94	94	RH	RCA
186	Medical Diagnostic X-Ray Equipment	X-Ray Controls – Radiographic, Medical Diagnostic X-Ray Equipment	94	94	RH	RCB
205	Medical Diagnostic X-Ray Equipment	C-Arm Fluoroscopic X-Ray System	94	94	RH	RCC
206	Medical Diagnostic X-Ray Equipment	X-Ray Image Receptor	94	94	RH	RCD
207	Medical Diagnostic X-Ray Equipment	Other	94	94	RH	RZZ
222	Dental Diagnostic X-Ray Equipment	Cephalometric Devices	94	94	RH	RCI
223	Dental Diagnostic X-Ray Equipment	Other	94	94	RH	RZZ
234	X-Ray Film and Film Processing Materials	Other*	94	94	RH	RZZ

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Attachment A

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