

Guidance for FDA Staff

Compliance Program Guidance Manual CP 7386.003 Field Compliance Testing of Diagnostic (Medical) X-ray Equipment

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**This document supersedes Field Compliance Testing of Diagnostic
(Medical) X-ray Equipment issued on October 1, 2000**

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Diagnostic Devices Branch
Division of Mammography and Radiation Programs
Office of Communication, Education, and Radiation**

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852.

When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

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Table of Contents

You can CTRL+click on any location on the following list of parts and attachments to go directly to the listed page:

Parts

[Cover Sheet](#)

[Part I – Background](#)

[Part II – Implementation](#)

[Part III – Inspectional](#)

[Part IV – Analytical \(blank\)](#)

[Part V – Regulatory/Administrative Strategy](#)

[Part VI - References, Attachments, and Program Contacts](#)

[Part VII - Center Responsibilities](#)

Attachments

[A - List of CDRH Personnel to Contact on Procurement, Maintenance, and Repair of Instrumentation.](#)

[B - List of CDRH Personnel to Contact on Test Procedures, Use of Instrumentation, and Data Entry Problems.](#)

[C - General Communications List.](#)

[D - Classification of Items of Noncompliance and Defects.](#)

[E - Sample Report of Assembly of a Diagnostic X-ray System \(FDA-2579\).](#)

[F - Form FD-2766 Claim for Damages to Electronic Products.](#)

[G - Contacts for Manufacturers of Diagnostic X-ray Systems Controls.](#)

[H - Notification letter to the Assembler \(Incomplete or incorrect FDA-2579 Report of Assembly\).](#)

[I - Notification letter to Assembler - Standards Violation Found During Review of FDA-2579's or Records Review at the Assembler.](#)

[J - Notification letter to the Assembler \(Failure to File FDA-2579 Report of Assembly\).](#)

[K - Notification letter to the Assembler \(Notification of Defect or Noncompliance on FD-2786 Field Test\).](#)

[L - Field Correction Status Report.](#)

[M - Notification Letter to the User \(Notification of Noncompliance Attributable to User Actions or Inaction\).](#)

[N - Responsibility for Defects or Noncompliances.](#)

[O - Listing of Qualified X-ray Auditors.](#)

[P - Sample Warning letter-Noncompliance Declaration With District Ordered Assembler Recall Letter to X-ray Assemblers.](#)

[Q - Guidance for Evaluating an Assembler Response to a Noncompliance Declaration With District Ordered Assembler Recall Letter.](#)

[R - Sample User Notification Letter for District Ordered Assembler Recall and CAPs.](#)

[S - Sample CAP Approval Letter to X-ray Assemblers.](#)

Guidance for FDA Staff

Compliance Program Guidance Manual

CP 7386.003

Field Compliance Testing of Diagnostic (Medical) X-ray Equipment

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Article I. Introduction

This document is intended to provide guidance to FDA field personnel. It represents the Food and Drug Administration's (FDA) current thinking on the final regulations implementing Subchapter C – Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act. This document revises the previous guidance document of the same title issued on October 1, 2000 and addresses:

1. Reporting requirements for program accomplishments
2. Inspection program guidance and procedures
3. Guidance and procedures for recommendations for regulatory actions
4. Names and information for CDRH contacts
5. Reference information on inspection program

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and

Contains Nonbinding Recommendation

should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at <http://www.fda.gov/cdrh/ombudsman/>.

**Article I. FOOD AND DRUG ADMINISTRATION
COMPLIANCE PROGRAM GUIDANCE MANUAL**

PROGRAM

7386.003

SUBJECT: Field Compliance Testing of Diagnostic (Medical) X-ray Equipment		IMPLEMENTATION DATE 2/8/2006
		COMPLETION DATE September 30, 2006
DATA REPORTING		
PRODUCT CODES		PRODUCT/ASSIGNMENT CODES
90IZF 90IZL 90KPR 90IZG 90JAA 90IZH 90JAB 90IZI 90JAC 90IZJ 90KPQ		86003

FIELD REPORTING REQUIREMENTS

A. General

Routine Compliance Tests - Subsequent to accomplishing district auditor review, the auditor will distribute Field Test Record forms as follows:

- Original (White Copy) Information Processing and Office Automation HFZ-307
- 1st (White Copy) Home district auditor for review and filing
- Blue Copy Regional Radiological Health Representative (RRHR) for State file
- Yellow Copy Surveyor

The following field test records are listed in the order of priority for field testing:

- | | |
|--------------|---|
| FDA 3071 | General Information |
| FDA 2784 | Above-table X-ray Source Radiographic Systems |
| FDA 2786 | Under-table X-ray Source Fluoroscopic and Spot Film Systems |
| FDA 3068 | Peak Kilovoltage Determination |
| FDA 3260 | C-Arm Fluoroscopic and Spot Film Systems |
| FDA 3069 | Above-table X-ray Source Fluoroscopic and Spot Film Systems |
| FDA 3261 | Vertically Mounted Cassette Holder Radiographic Systems |
| FDA 2783 | Mobile Radiographic Systems |
| FDA 3297 | Head and Neck Radiographic Systems |
|
FDA 2785 |
Dental Radiographic Systems |

FDA 3070 Mammographic Systems
FDA 2782 Field Test Record Continuation Sheet

- * Since October 1, 1994, routine compliance testing of mammographic equipment has not been conducted by this compliance program, however, approval under special consideration by the RRHR may be granted. The RRHR will contact the Center for Devices and Radiological Health (CDRH) to receive authorization for such tests. The owner of the equipment needs to be made aware that the test is not an MQSA test and compliance actions are against the manufacturer and not the facility. In addition, testing of dental units will not be conducted routinely. The RRHR should be contacted to approve special testing for dental units. *
- * NOTE: The Accomplishing District is the FDA district with regulatory authority over the installation site of the diagnostic x-ray equipment (based on installation address). The Home District is the district that has regulatory authority over the assembler (based on the assembler business address). *
- * The Accomplishing District will verify corrections, review the CDRH status report of the Field Correction Action Report (FCAR) and ensure updates have been added to the CDRH computer. The Accomplishing District will also review incorrect or incomplete Reports of Assembly FDA 2579, obtain any necessary corrections from the assembler, and notify HFZ-307 of corrections. When the Accomplishing District is not the Home District, copies of correspondence to the assembler will be sent to the Home District. The Home District will be responsible for Warning Letters and any regulatory action initiated against the assembler. *
- * Submit all violative assembler inspection reports to the District Compliance Branch for review, evaluation, and classification prior to referral to CDRH, Division of Mammography Quality and Radiation Programs, HFZ-240. Do not send non-actionable inspection reports to HFZ-240. *

B. FACTS Reporting

- The rules for what activities should be reported under each of the operation codes has not changed with the implementation of FACTS V.4.6. Therefore, the following guidelines should continue to be used:
- Report all time spent in reviewing and correcting FDA 2579s (Reports of Assembly) under Operation Code 13 (Investigations) in the FACTS "Maintain Investigations" screen. Time spent in correspondence (verbal/written) regarding FDA-2579s should be reported under this operation code also.
- * FDA individuals will report all time spent in preparing for, conducting and reporting the field test in FACTS as a Field Exam. In FACTS, navigate to "Investigative Operations," then "Field Exams." Click on "New Exam" and complete the screen using the assembler FEI number, date of field test, PAC code 86003 and product code for the type of x-ray system tested. Under Exam type, click on "X-ray Field Test." Under lot number, enter the field test number (i.e., AR12345A). Under "Number of Units Examined", enter "1." Click on "no" for adverse findings and in remarks you may enter the final field test classification if known (CLASS A, B, C, or D). YOU MUST ENTER A SEPARATE LINE FOR EACH FIELD TEST NUMBER TO GET CREDIT FOR ALL TESTS CONDUCTED. For example, AR12345A and UF12345B would be

separate lines on the Field Exam Screen. Systems installed by different assemblers and systems tested on different days would be entered as different Field Exams. *

- * Special Auditor Instructions: When performing an on-site audit of an x-ray surveyor, a special entry must be made in FACTS. The FDA auditor will credit time as an audit and the person audited (if an FDA individual) will record time as a field test. Auditor time shall be reported as a field test (Operation Code 53) and includes preparation time, on-site time, test evaluation time, and audit result reporting time. In the Description Field, enter the words "Joint Test" followed by the code for the State or FDA District of the individual being audited. Enter also the GI test ID for the test that was conducted. *

Example: Joint Test NJ GI12344
Joint Test DET GI12345

Also, report as Operation Code 92, (Coordination/Technical Assistance) in the FACTS "Miscellaneous Operations Accomplishment Hours" screen time spent as an Auditor for Field Test Record (FTR) review, Notification Letter or Warning Letter correspondence, FCAR submissions and updating of CDRH database, FTR data entry, FTR computer updating, and response to FTR questions of compliance. The description field should list "Diagnostic X-ray Coordination." Time should be reported on a routine basis (weekly or quarterly depending on the volume) and may be combined for that time period.

C. Special

Special procedures for reporting field tests are necessary when an x-ray system or component does not comply with the Federal standard. These procedures are detailed under the Operation Instructions of Part III A.1.d.7 & 8.

Special Compliance Tests - A data format for reporting special tests to the Diagnostic Devices Branch (HFZ-240) will be provided by CDRH on assignment.

- * Send copies of all correspondence generated under this program to HFZ-240. This includes Warning Letters, Untitled Letters, assembler's response when the response is a disputed noncompliance, and assembler's response where the assembler claims the original equipment manufacturer is responsible for the noncompliance. Include all evidence to support the allegation of manufacturer responsibility. Additionally, copies of Warning Letters should be sent to HFC- 210. *

PART I - BACKGROUND

- * The Diagnostic X-ray Performance Standard (Reference 1) was promulgated in August 1974 to protect the public from unnecessary radiation hazards of diagnostic x-ray equipment. Since 1974, FDA and State personnel have conducted over 72,000 field tests of certified diagnostic x-ray systems for compliance with the standard.

The most prevalent items of major noncompliance identified under this program over the past five years have been:

- Incorrect indication of the source to image receptor distance.
- Excessive mis-sizing of the x-ray beam by the PBL system.
- Excessive fluoroscopic entrance exposure rate.
- Excessive misalignment of the fluoroscopic x-ray field with the image intensifier.
- Excessive misalignment of the x-ray field with the spot film image receptor.
- Insufficient illuminance of the light localizer for radiographic collimators.

These noncompliances also represent some of the most significant radiation hazards.

The highest rates of noncompliant systems (i.e., systems with one or more major noncompliances) have been for the more complex radiographic and fluoroscopic x-ray systems that require considerable calibration and adjustment by the assembler. Mobile and dental x-ray systems that require comparatively little adjustment by the assembler have had much lower rates of noncompliance and have been eliminated from routine testing. Testing of mammographic systems was discontinued in October 1994 when compliance testing under the Mammography Quality Standards Act was begun.

Where field testing has identified generic or design related noncompliances, CDRH has required component manufacturers to initiate recalls to correct violative products. Since 1974, more than 65 such recalls have been initiated based in whole, or in part, on field activities under this compliance program. The majority of the noncompliances identified through this program have been caused by incomplete or improper installations by x-ray assemblers. The initial reduction in noncompliance has come primarily from voluntary efforts by the x-ray industry to better train and equip assemblers and to require final system compliance testing. A stronger regulatory approach is necessary to prevent continued violative installations and to further reduce the noncompliance rate. *

Notification letters are issued to assemblers each time a noncompliance is discovered by routine compliance field testing. The notification letter advises the assembler about each noncompliance and requests corrections on a case-by-case basis without requiring any formal recall or corrective action

plan. When the assembler continues a pattern of violative assemblies, or refuses to correct cited violations, regulatory action (civil penalties and/or injunction) can be initiated. The documentation and inspections necessary for civil penalty/injunction action can be time consuming and resource intensive on FDA and, therefore, an optional strategy has been devised which may be used separately or in conjunction with civil penalties and/or injunction. This additional strategy is a warning letter of declaration of assembler noncompliance with district ordered assembler recall (NC/DOAR). By this process, the assembler's installation program is considered noncompliant by FDA. Since an assembler is considered a manufacturer under 21 CFR 1000.3(n), all regulations pertaining to noncompliance declarations pertain to assemblers, including formal corrective action plan (CAP) and recall (21 CFR parts 1003, 1004). Should the assembler fail to comply with the NC/DOAR provisions, additional civil penalties can be charged for failure to notify and correct (sections 538(a)(2) and 539 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Previously, civil penalties were only charged for systems for which FDA had field test data or documentation. The noncompliance declaration process, however, includes all assemblies during the specified time applicable to the data analysis and requests that the assembler provide a CAP for all of them.

Since this strategy is based on a sample of systems installed by the assembler, civil penalties will still be the preferred enforcement action for companies installing small numbers of systems.

PART II - IMPLEMENTATION

A. Objectives

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

1. To identify certified diagnostic x-ray systems that fail to comply with applicable performance standard requirements.
2. To obtain correction of noncompliant systems identified in (1) above.
3. To identify assemblers and manufacturers responsible for violative x-ray installations and take appropriate administrative/enforcement actions necessary to prevent further installations of noncompliant products.

This program is based primarily on monitoring of assembler certification reports (FDA 2579's) to identify installation sites, and on field testing (by FDA and State personnel) of x-ray systems at the user site. Inspections of assembler firms are intended primarily as follow-up to violations identified from field testing and FDA 2579 reviews to document reporting violations and to support legal action recommendations.

B. Program Management Instruction

1. Resource Instructions

District office interface with the automated data systems maintained by CDRH and the role of the x-ray auditor are critical factors for effective implementation of this program. All District Offices have direct entry capability of field test data into the CDRH data base and are responsible for timely data entry. Contact CDRH with any direct data entry problems (See Attachment B).

The accomplishing district auditor is responsible for maintaining the competence of personnel to perform work under this program. These and other x-ray auditor functions are described in Part III.A.2. Only personnel qualified under Field Management Directive No. 125 may perform the auditor functions (see Attachment O). Districts without a qualified auditor must arrange with the regional office for an auditor from another district to perform their audit functions until a local district auditor can be qualified. On-the-job training (OJT) may be used to assist in training for the auditor position.

- * All field tests of diagnostic x-ray equipment shall be performed in accordance with test procedures provided by CDRH in FDA's "Routine Compliance Testing for Diagnostic X-ray Systems or Components of Diagnostic X-ray Systems to which 21 CFR Subchapter J is Applicable" manual (Reference 4) with latest updates. Only field investigators with

specialized training may perform x-ray field tests. Such training may consist of a formal course in x-ray survey techniques or in-house training arranged by the RRHR, but must include OJT with a qualified auditor for a minimum of 3 above-table radiographic test procedures, 3 under-table fluoroscopic test procedures and 4 additional tests of other type systems. *

All FDA personnel performing or participating in field tests shall wear personnel dosimeters issued by the Field Health Physicist at WEAC. State personnel will utilize the personnel dosimeter provided by their State program.

CDRH requires direct field test data entry using XRAYAPSY and strongly supports on-line interactive computer access for all Districts. CDRH provides routine and/or special reports (on request) in support of this compliance program. Information concerning potential test locations, assembler noncompliance trends, and assembler reporting are accessible and should be requested through the x-ray auditor.

2. Planning Instructions

Each District shall develop a strategy:

- a. to concentrate proportionately more field testing and special monitoring for those assemblers with the highest volume of noncompliant installations and the highest rates of noncompliance (i.e., greatest negative public health impact) and those assemblers suspected of non-reporting installations and,
- b. where necessary, to develop legal action cases in accordance with CPG 7133.12, to bring these violative assemblers into compliance.

For assemblers that make installations outside their home district, the FDA home district and accomplishing district must establish a strong liaison to monitor the assembler and develop evidence. The FDA accomplishing district will prepare and issue all untitled letters, review responses to the untitled letters, and update the FCAR database for these responses. The FDA home district will prepare all warning letters and regulatory action recommendations. The FDA home district will review the responses to warning letters and update the FCAR database for these responses.

For Districts with state contract or partnership testing, the District office will work through the RRHR to have state testing concentrate on problem assemblers when appropriate (Refer to Part II, B.5. - RRHR Management Activities).

Field test priorities are:

- (1) Problem assemblers with the highest noncompliance rate as identified by routine reports from CDRH.

- (2) Other problem assemblers known to the district.
- (3) High volume assemblers of radiographic and fluoroscopic systems for whom very few systems have been tested.
- * (4) New assemblers of radiographic and fluoroscopic systems.
- (5) Routine testing of randomly selected radiographic and fluoroscopic systems (to include re-installed systems). *
- (6) Infrequent testing of dental and mobile x-ray systems, for training purposes or at the request of CDRH. Mammography equipment will not be tested under this program except under authorization from CDRH. The MQSA testing program will cover mammographic equipment.

3. Legal Action Case Development

- * The primary enforcement mechanism against x-ray assemblers is Civil Penalties with an alternative enforcement mechanism of noncompliance declaration with district or region ordered assembler recall (NC/DOAR). Compliance Policy Guides 7133.12 (with revised alternative enforcement) and 7133.23 and Regulatory Procedures Manual (RPM) Chapter 6 provide guidance for developing case recommendations. Although the RPM points out that a health hazard is implicit in all performance standard violations, at this time actions will be approved only for those field tests which demonstrate more than a low health hazard (see Attachment D). Should violations continue, following the assembler's NC/DOAR warning, or imposition of Civil Penalties, further action (i.e., injunction with further Civil Penalties) will be considered. *

Unlike some FDA programs where the need for legal action may be triggered by a single violative inspection report or sample, legal action against x-ray assemblers is most frequently triggered by a pattern of violative field tests. Such a pattern of violation cannot routinely be detected by monitoring individual field tests or Notification letters. Special district record-keeping or use of the CDRH computer data base by the x-ray auditor will be needed for monitoring assembler noncompliance trends.

Recommendations for NC/DOAR warning letters will be reviewed by CDRH (HFZ-240). For assemblers installing less than 16 systems in the cited time frame (not to exceed two (2) years) civil penalties will be the enforcement choice when the conditions of CPG 7133.12 are met. Table 1, listed below will be used as criteria for noncompliance declarations.

TABLE I

<u>No. Installed</u>	<u>No. Tested</u>	<u>No. Noncompliant</u>	<u>%NC</u>
Less than 16	(refer to CPG 7133.12 paragraph B)		
16 to 25	5	2 or more	40
26 to 50	8	3 or more	37.5

51 to 90	13	4 or more	30.8
91 to 150	20	6 or more	30
151 to 280	32	8 or more	25

If the number tested exceeds the numbers listed in Table I, then the noncompliance rate must equal or exceed the percent NC rate listed in the table above. Should the number tested exceed 50 percent of the number installed, Civil Penalties may be the more advantageous approach. Any questions concerning this guidance should be referred to the Diagnostic Devices Branch.

4. Inspection Priorities

Inspections of diagnostic x-ray assemblers shall be initiated for the following reasons:

- To document the number and location of systems requiring coverage under the firm's corrective action plan (CAP) when a noncompliance declaration has been issued.
- When preparing a civil penalty action against an assembler, to document responsibility for violations.
- To obtain a listing of recent installations of certified x-ray equipment for further testing when developing a civil penalty case.
- When investigating product defects or accidental radiation occurrences.
- When investigating a failure to file an assembler report, form FDA 2579.
- When assembler reports, forms FDA 2579, are repeatedly late or repeatedly contain critical errors.

5. RRHR Management Activities

The RRHR will coordinate and supervise voluntary working agreements and agency contracts with states performing diagnostic x-ray field testing including:

- Arrange for states to submit the test data to the district auditor for review, calculations, and classification in accordance with Part III A.1.f.
- Arrange for states to contact the auditor by phone for all Class A deficiencies as soon as possible.
- Review any problem reported on the "blue copy" of the test form by the auditor and refer to the affected state, as appropriate.
- Maintain the "blue copy" of the test form in the state file.

- Draft, renew, or provide changes to Partnership Agreements (PA) for Regional Food and Drug Director (RFDD) signature. Recommendations will be provided to Division of Federal State Relations HFC-150 and HFZ-240. Copies of final signed agreements will also be provided to HFC-150 and HFZ-240. Field tests that do not pass the FDA audit will not be credited toward the agreement number.
- On request from the District Office, arrange with contract or partnership states to emphasize testing of installations by problem assemblers identified to them by FDA and to expedite submission of test results for those assemblers to assure timely follow-up action by FDA.
- Arrange for State follow-up field testing where State field test reports have determined that violative x-ray systems require correction and the district is unable to perform the required follow-up.
- Arrange for State follow-up of noncompliant x-ray systems that are determined to be the user's responsibility. If a State is unable to have the user correct a Class A timer non-termination violation, the RRHR shall arrange for district follow-up to document the violation for possible detention/seizure consideration.
- Arrange for qualified auditors to train State and FDA personnel to perform routine field tests.
- Arrange with the auditor for periodic joint field test audits of State or FDA personnel by a qualified auditor to insure that proper procedures and techniques are used in the collection of test data.

PART III - INSPECTIONALA. OPERATIONS1. Field Testing

- * a. Test fully certified x-ray systems, preferably within 3 months of and not later than 1 year after installation in accordance with specified CDRH test procedures (Reference 4). If the system is not fully certified or it is later than 1 year after installation, contact the RRHR or CDRH for approval to test. *
- b. Select test sites (concentrating on problem assemblers) based on information from:
 - (1) CDRH computer data base
 - (2) Copies of FDA 2579s sent to the district or State agency.
 - (3) Fully certified systems encountered at user facilities.
- c. Schedule appointments in advance to insure availability of the x-ray system for testing. Arrange to have someone familiar with the x-ray system available to assist in its operation during the test.
- d. At the test site:
 - (1) Wear personnel dosimeters (TLD badges) when performing tests.
 - (2) Issue a FDA 482 only when requested by the user (Applies to FDA personnel only).
 - * (3) Visually verify that the system is fully certified. If not fully certified, testing should not be performed unless approved by the RRHR or CDRH. *
 - * (4) Conduct the field test and complete the appropriate field test record (FTR) as instructed in the "Routine Compliance Testing for Diagnostic X-ray Systems or Components of Diagnostic X-ray Systems to which 21 CFR Subchapter J is Applicable" manual. *
 - * (5) Go through the field test record edit checks list for the specific field test to verify test data.
 - (6) Document (FDA personnel only) any x-ray system damage (real or claimed) due to the field test on form FD 2766, Claim for Damage to an

Electronic Product (Refer to Attachment F). Forward this form immediately through the RRHR to Office of Communication, Education, and Radiation Programs HFZ-200 (do not delay submission or attempt to refute the claimed damages). A copy of this form should be kept in the field test kit.

NOTE: State survey personnel should immediately report damage to an x-ray system to their supervisor and the RRHR and follow state procedures. *

- (7) Review the field test record for obvious items of noncompliance prior to leaving the test site. Class A items should be easily detected since most represent observations by the surveyor:
- Primary barrier interlock failure
 - Timer non-termination
 - Excessive entrance exposure rate (in excess of 25 R/Min)
 - The primary beam extends beyond the edges of the primary protective barrier.

Attachment D provides the criteria for classifying items of noncompliance.

- (8) For suspected Class A violations:
- (a) Advise the user immediately of the results and that:
- Routine use of the system should be discontinued until the problem is corrected.
 - Operation of the system could be hazardous to the patient and/or operator.
 - FDA will determine responsibility, notify the responsible party and the State, and effect correction.
- (b) Telephone the auditor immediately and inform the auditor of the Class A condition.
- (9) For suspected Class B violations, advise the user of the results and that:
- (a) The system may not comply with the Federal performance standard.

(b) FDA will confirm the compliance status of the system via computer data analysis.

*

(c) FDA will determine the responsibility for any items of noncompliance, notify the responsible party to effect correction and provide copies of the notification to the state and user/owner.

*

(10) For suspected Class C results, advise the user that computer calculations need to be made to determine if the system is in compliance, and that:

(a) FDA will determine the compliance status of the system.

(b) If the system fails to comply, FDA will determine responsibility, notify the responsible party, and effect correction.

(11) For suspected Class D results, advise the user that while computer calculations need to be performed to determine compliance, the system appears to be compliant with the specific parameter (identify each parameter) tested.

(12) Attempt to determine responsibility for any noncompliances before leaving the facility. (See Attachment N for further guidance).

*

e. Flag suspected Class A and Class B test records. A sticker or tag with "SPECIAL" should be affixed to the upper left corner of Class A test records to alert the auditor that the record has a suspected Class A result. A route slip or other suitable identifier with the designation "Class B" will suffice for suspected Class B results.

*

f. Route suspected Class A test records to the FDA accomplishing district auditor immediately, route suspected Class B records within 2 working days to the FDA accomplishing district auditor, and route Class C or D records within 2 weeks after testing to the FDA accomplishing district auditor. Send the original, 1st copy, and blue copy to the accomplishing district auditor. Retain the yellow copy as a reference in the event the auditor has questions regarding the field test.

2. Auditor Activities

a. Quality Assurance Review

The accomplishing district auditor shall:

(1) Ensure test data integrity by verifying the field test edit checks as specified in the CDRH test procedures manual (Reference 4).

- (2) Be responsible for timely field test data entry utilizing the XRAYAPSY system for CDRH computer calculation of test results.
- (3) Review all calculated field test results from CDRH computer entry and,
 - Return rejected FDA tests to the investigator's supervisor for appropriate action.
 - Return rejected state tests through the RRHR to the state. The RRHR will work with the state to achieve acceptable tests. Rejected tests will not count toward the state's agreement numbers.
- (4) Classify all field test records in accordance with criteria in Attachment D, based on test results.
- (5) When the auditing of the record is completed and the FTR is Class A, FAX a copy of the FTR to the FDA home district auditor and notify the home district auditor of the Class A FTR by e-mail. The home district auditor will prepare and send a Warning Letter. If the FTR is Class B, the accomplishing district auditor will prepare and send an untitled letter to the assembler regardless of the assembler's home district. For Class B violations the accomplishing district auditor will follow-up and assure computer update of field corrective action reporting (FCAR).

b. Evidence Development

The home district auditor shall:

- (1) Make a thorough determination of responsibility for violations when a recommendation for regulatory follow-up involving an assembler is being considered. This determination shall include at a minimum, the evaluation of all of the following factors:
 - field test data and calculated results
 - responses to any Notification/user letters
 - type of repair made to correct the violation (adjustment vs. component replacement)
 - equipment maintenance schedule and maintenance history
 - all past service repair records
 - information gathered during assembler establishment inspections

Unless there is clear documentary evidence that demonstrates that violations are attributable to improper assembly, the assembler cannot be held responsible.

If the service report shows only adjustment of a component, there is presumed evidence of assembler error at installation. However, replacement of a defective component may indicate a manufacturer problem and is less convincing evidence of assembler responsibility. Additional evidence development by the auditor or by CDRH engineers may be necessary.

- (2) Ensure that all field corrective actions of the home district are added to the CDRH data base with proper responsible party determination.
- (3) Request assistance from the accomplishing district auditors in developing documentation and evidence needed for regulatory follow-up.
- (4) Monitor field testing results, responses to Notification or Warning Letters, assembler EI's, follow-up field test data, etc., and identify assemblers for whom recommendations for regulatory follow-up should be considered. The auditor will prepare a referral memo describing the violations, evidence, and recommendation for appropriate action of civil penalty and/or assembler recall based on criteria specified in Part II.B.3 and CPG 7133.12.
- (5) Assist District to insure all Notification or Warning letters are complete and accurate prior to issuance. *

c. Quality Assurance Audits

Perform on-site quality assurance audits of FDA and State personnel to assure their proficiency in conducting field tests of diagnostic x-ray units.

Each fiscal year, conduct at least two joint audits per person. Personnel conducting at least 10 field tests per year shall be audited (See Field Management Directive No. 76 for further guidance). Personnel conducting less than 10 field tests per year shall be audited on an as needed basis. Audits shall be:

- Joint field tests with the person being audited, or
- Follow-up retest of the same unit within 30 days of the initial test by the person being audited.

d. Training

Provide OJT for all new FDA and State surveyors consisting of the following number of x-ray field tests:

NOTE: More than one person's name may appear on the field test record, however, the first name is the lead surveyor receiving credit for the survey.

Above-table X-ray Source Radiographic and kVp (at least 3).

Under-table X-ray Source Fluoroscopic and Spot Film (at least 3).

C-Arm Fluoroscopic (at least 1).

Mobile (at least 1).

Prior to conducting the OJT, ensure that the trainee has viewed the CDRH videotapes on field test procedures or completed the CDRH surveyor training course.

e. Public Liaison

Deliver presentations, when requested, on aspects of the Diagnostic X-ray Standard before groups of radiation professionals such as radiologists, technologists, and physicists.

3. Review/Maintenance of FDA 2579, Report of Assembly of a Diagnostic (Medical) X-ray System

The home district of the assembler shall:

- a. Maintain all originals of forms FDA 2579 for at least 3 years after installation after which they can be transferred to the National Archives in accordance with the FDA's Records Schedule. The approved FDA Records Schedule may be found at http://intranet.fda.gov/omp/records/fdarcs_html/titlepage.htm.
- b. When there is evidence of a problematic assembler, in preparation for assembler inspection for cause, review FDA 2579 reports for errors. Items requiring correction should be indicated for discussion upon inspection.
 - (1) Minor Corrections involve items not affecting compliance (e.g., missing or incorrect date of assembly (block 3e) or incorrect identification of component model numbers) and can be corrected directly on the form after verification by assembler.
 - Make the correction in red ink.

- Date and initial the form in the upper right hand corner.
- (2) Major corrections involve:
- Failure of assembler to sign the form.
 - Failure to enter the facility name, city, or state (block 1);
 - No indication of what components were installed (blocks 4g and 4h).
- c. For major corrections to the assembler form, have the assembler fill out a new form with instructions to:
- Complete the entire form.
 - Return the white original to the district.
 - Distribute the other copies as usual within 15 days.
 - Indicate in the comments the form is a replacement for corrections to the original assembler form with number xxxx.
- d. Upon receipt of a replacement original form from the assembler, review the white original. If it is correct:
- Initial and date the form in the upper right hand corner.
 - Place a red sticker at the top of the white original, indicating the accession number of the old duplicate form. (This step is crucial in order for CDRH to locate and delete old duplicate information from the database.)
 - Send the original to CDRH, HFZ-307 (CDRH will update the computer database and send the white original on to the appropriate installation district.)
- e. For minor assembler form corrections:
- forward a copy of the form to CDRH HFZ-307
 - indicate the corrections in red
 - place a note or sticker to indicate the form has corrections.

The installation (accomplishing) district shall:

- a. Maintain all originals of forms FDA 2579 for 1 year from date of installation for the purpose of selecting testing sites. After 1 year the form should be mailed to

the assembler home district if it differs from the installation district, where it will be kept for 3 years after installation.

- b. When a field test is conducted at an installation, attach the original copy of FDA 2579 to the home district copy of all field test records. After the field test record has passed the audit/edit criteria distribute the field test record with attached FDA 2579 to the appropriate home district office. For Class B field tests, the documents are forwarded to the home district auditor after the FCAR has resolved all violations.

NOTE: For assembler reports of Dental x-ray equipment, the assembler shall mail the original white copy of the assembler report directly to the FDA district responsible for the installation site.

Any dental forms erroneously mailed by the assembler to CDRH will be forwarded to the installation district. Likewise, districts should forward to the correct installation district any forms erroneously received in their office. CDRH does not maintain assembler forms for dental systems in the centralized data base.

All x-ray assembly reports will continue to be maintained by the responsible home district office for at least 3 years.

4. Assembler Inspections

Conduct inspections in accordance with Chapter 5 of the Investigations Operations Manual (IOM) and investigate these specific aspects of the assembler's operation:

- a. Assembly and sales records - full review to determine if all installations have been reported.
- b. Complaint files - look for evidence of accidental radiation occurrences, radiation defects, and noncompliances with the standard.
- * c. Repair records - determine if the assembler is charging users to correct items of noncompliance identified by FDA testing. In addition look for patterns of repairs or problems, which would indicate a design problem. *
- d. Test equipment and calibration - assembly of noncompliant systems may be due to use of improper test equipment or equipment, which is out of calibration.
- e. If the inspection is a follow-up to errors or non-submission of forms FDA 2579:
 - discuss the reporting requirements with the assembler.
 - explain how to complete the forms correctly.

- point out discrepancies encountered on the forms and leave copies for correction.
 - instruct the assembler to resubmit corrected forms to the district within 10 days.
- f. Determine responsibility for field test noncompliances by the review of installation and repair records.
5. Sample Collection - Collect documentary samples when noncompliance is suspected and documentary evidence is needed to support regulatory action (see IOM 405.02). No physical samples will be collected under this program.

B. REPORTING BY THE ACCOMPLISHING DISTRICT AUDITOR

1. Suspected Class A Violative Field Tests
- a. Confirm the suspected noncompliance is a Class A violation by consulting Attachment D of this compliance program.
 - b. Verify proper user notification by the surveyor, and if not done, immediately warn the user against use of the hazardous system.
 - c. If the assembler is suspected to be responsible for the violation, inform the assembler of the noncompliance by telephone and request correction. Document the assembler notification.
 - d. Notify CDRH (see Part VI and Attachment C), the home district auditor, and the RRHR within 2 working days.
 - e. When the above information is obtained by telephone response, follow-up to insure that receipt of the field test record is provided as soon as possible.
2. Review the CDRH Field Correction Action Report (FCAR) and ensure that all updates are added to the CDRH data base.

CAUTION: Unless responsibility has been clearly determined, responsibility should be reported as "Not Determined." CDRH generally will not include in a legal action any test record for which the auditor determines the responsible party is other than the assembler.

* Forward assembler responses which allege manufacturer responsibility for noncompliances to the home district auditor and HFZ-240 for Center follow-up. Include all documentation necessary to support this conclusion. *

C. REPORTING BY THE HOME DISTRICT AUDITOR

Review the CDRH Field Correction Action Report (FCAR) and ensure that all updates are added to the CDRH data base.

CAUTION: Unless responsibility has been clearly determined, responsibility should be reported as "Not Determined." CDRH generally will not include in a legal action any test record for which the auditor determines the responsible party is other than the assembler.

Forward assembler responses which allege manufacturer responsibility for noncompliances to HFZ-240 for Center follow-up. Include all documentation necessary to support this conclusion.

D. AUDITING ASSEMBLER CORRECTIVE ACTIONS

* The accomplishing district auditor shall arrange the following field testing follow-up:

1. Within 10 working days following reported correction of all Class A violations by the home district auditor to verify that the Class A violation has been corrected.
2. Within 30 days following reported correction conduct a follow-up field test for at least 10 percent of the systems with Class B violations to verify corrections have been accomplished. *

Concentrate follow-up field tests more heavily for:

1. Assemblers who in the past have reported violative products to be corrected when in fact they were not, and
2. New assemblers with no established record of properly correcting violative products.

PART IV

No laboratory testing will be done under this program.

PART V - REGULATORY/ADMINISTRATIVE STRATEGYA. REGULATORY PHILOSOPHY AND STRATEGY

Diagnostic x-ray equipment is regulated under both Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) and Subchapter A - Drugs and Devices of Chapter V of the Federal Food, Drug, and Cosmetic Act (FFDCA). Subchapter C provides authority to require product recalls for noncompliant or defective radiation-emitting electronic products. In addition, Subchapter A (as amended by the Safe Medical Devices Act) provides authority to require product recalls for medical devices that may cause a serious risk to health. (All diagnostic (medical) x-ray products are medical devices.) When there is a choice, regulatory/administrative action is preferred under Subchapter C, but both portions of the FFDCA may be used in conjunction for maximum effectiveness.

The primary enforcement approach for generic/design related violations caused by the x-ray component manufacturer is recall (refer to RPM Chapter 7, Attachment E for details). CDRH is responsible for initiating recalls by x-ray manufacturers and importers. For violations which are attributable to the assembler, the field maintains responsibility for enforcement.

Since x-ray assembly is more of a customized operation in which widely varying random violations may occur, when a single system is discovered noncompliant (as with our routine compliance testing program), a product-wide recall or civil penalty action is not generally applicable. The primary assembler enforcement approach is issuance of a Notification letter requiring correction of the cited violations on the unit tested, followed by increased surveillance to establish a pattern of violation. Once a pattern of violations is determined (see TABLE I Part II and CPG 7133.12) then the district should either issue a noncompliance declaration with district ordered assembler recall (NC/DOAR) or pursue civil penalties to dissuade further violations.

When a pattern of performance standard violations has been documented, or the responses to Notification letters are unsatisfactory, or the firm fails to file form FD 2579 after being previously advised in writing of the consequences of continued failure to file, recommend appropriate action against the assembler as described in CPG 7133.12.

In the absence of evidence to the contrary, for violative x-ray systems found during field testing:

- the assembler is generally viewed as responsible if the unit was tested within one year of installation
- the user is generally viewed as responsible if the unit was tested more than one year after installation

Other relevant compliance policies, and mandatory recall, detention/seizure and civil penalty procedures are contained in:

- CPG 7133.12 (Regulatory Actions Against Assemblers Who Install Noncompliant Diagnostic X-ray Equipment)
- CPG 7133.23 (Assessment of Civil Penalties Against Manufacturers and Importers of Electronic Products)
- CPG 7133.25 (Detention/Seizure - Hazardous Diagnostic X-ray Systems, July 1, 1983)
- CPG 7133.27 (Corrective Actions - Obligations of Factory-Based Manufacturers and Assemblers of Diagnostic X-ray Equipment Under the Performance Standard for Diagnostic X-ray Equipment)
- CPG 7133.28 (Regulatory Actions Against Assemblers of X-ray Equipment That Fail to File Reports of Assembly)
- RPM Chapter 6 (Civil Penalties - Electronic Product Radiation Control)
- RPM Chapter 7, Attachment E (Recalls of Radiation-Emitting Electronic Products under Subchapter C Electronic Product Radiation Control)

B. CASE GUIDANCE

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 the Chief, Diagnostic Devices Branch, HFZ-240, Phone: 240-276-3332. All necessary samples and other supporting documentation should be tabbed and their location cross-referenced in the recommendation in order to assist in a timely review.

1. Assembler Violations

Recommend radiation control civil penalties (see CPG 7133.12 for appropriateness) for:

- a pattern of violative field tests in accordance with Table I Part II B.3. and CPG 7133.12.
- a pattern of failure to provide FDA with required assembler reports meeting the criteria in CPG 7133.28.
- unsatisfactory responses to Notification letters or failure to correct noncompliant products.
- deliberate and willful violations.

- violations occurring when NC/DOAR action is not appropriate or adequate (see section D. below and Table I, Part II, B.3).
- the violation has resulted in serious injury or death.

* Recommend medical device civil penalties as appropriate. Charges from the FFDCA can be used if the field test shows one or more assembler related noncompliance for each unit.

*

2. Manufacturer Violations

Refer all Class A or Class B noncompliant test records attributable to the x-ray system or component manufacturer to CDRH (HFZ-240) for evaluation and follow-up action. The referral memo should include:

- A description of the noncompliance.
- Identity of the manufacturer(s) and model(s) involved.
- Reason for suspecting a manufacturer problem.
- Identity and date of any previous telephone contact with CDRH on the problem.
- Whether the unit has been corrected.

If the unit has not been corrected, CDRH will request correction by the manufacturer. If evaluation confirms a generic or design problem, CDRH will declare noncompliance and require correction/recall in accordance with RPM Chapter 7, Attachment E.

The home district will monitor approved corrective action programs (recalls). It may be appropriate to recommend civil penalties for failure to correct noncompliant products or for continuing or willful violations.

3. Detention/Seizure

Recommend detention/seizure for serious radiation hazards if the responsible firm (manufacturer or assembler) refuses to correct or is unable (e.g., out of business) to correct the hazard. Serious radiation hazards include the following or similar situations (see CPG 7133.25):

- Non-termination of the x-ray timer,
- Excessive entrance exposure rate on fluoroscopic units (Class A, see attachment D).

*

Direct reference authority is provided for seizure actions when an administrative detention action has previously been approved.

C. ISSUANCE OF NOTIFICATION LETTERS FOR NONCOMPLIANCE WITH THE STANDARD WHERE THE ASSEMBLER IS SUSPECTED TO BE RESPONSIBLE.

NOTE: All untitled letters should be reviewed by the accomplishing district auditor prior to issuance. Class A violations are issued as Warning Letters by the home district and should be reviewed by the home district auditor.

1. Assembly of Noncompliant Diagnostic X-ray Systems

- a. Issue a Notification letter (see Attachment K) to the responsible assembler for Class A and Class B field test results obtained within one year of installation. Notification letters shall issue:
 - Addressed to the most responsible individual at the local assembler firm.
 - Warning of civil penalties in accordance with Chapter 6 of the Regulatory Procedures Manual.
 - Within 45 days of the field test (60 days for state tests).
 - Within 2 working days after receipt of results showing Class A violations.
 - Within 10 working days after receipt of results showing Class B violations.
 - Requesting assembler response within 15 working days after receipt for all Class A or within 30 working days for all Class B violations.
 - Requesting a copy of the assembler service report (to help determine the cause of the violation and to assure correction at no cost to the user).
 - With copies of the Notification letter in every case sent to:
 - a) the user
 - b) the x-ray or medical systems headquarters official responsible for the local assembler firm
 - c) the x-ray control manufacturer's corporate headquarters officials identified in Attachment G. If the violative product is a beam limiting device (BLD), the BLD manufacturer's corporate headquarters official identified in Attachment G will receive a copy if different from the x-ray control manufacturer's firm.

- d) the home district auditor (auditor will review all warning letters prior to being issued)
- e) the accomplishing district auditor (auditor will review all untitled letters prior to being issued)
- * f) CDRH, HFZ-240 *
- g) The State Radiological Health Agency of the facility

- b. Evaluate the assembler's response and route a copy to the home district x-ray auditor for confirmation of responsibility, assessment of qualification for civil penalties recommendation, and completion of CDRH Field Correction Status Report.
- c. Respond to refutations or exemption requests when the assembler exercises his rights under 21 CFR 1003.30. Obtain technical assistance from the auditor or CDRH personnel listed in Attachment B, if necessary.
- d. Disapprove unsatisfactory corrective actions proposed or performed by assemblers.
- e. If the assembler fails to provide a satisfactory or timely response, issue an assignment for follow-up field testing. If the violation is not corrected, consider regulatory action.

NOTE: When an assembler disagrees with Agency action, he may request a hearing under 21 CFR part 16. If such a request is received by the district, contact HFZ-200 so that arrangements may be made to designate a hearing officer in accordance with FDA Staff Manual Guide 1410.29 (http://www.fda.gov/smg/1410_29.html).

2. Failure to Submit, Late Submission of, or Errors in the Submission of FDA 2579, Report of Assembly of Diagnostic X-ray Systems

Issue a Notification letter to the most responsible person at the local assembler's office (see Attachments H through J).

NOTE: Submission of a 2579 more than 30 days after assembly is considered late.

D. ISSUANCE OF WARNING LETTER, NONCOMPLIANCE DECLARATION AND DISTRICT ORDERED ASSEMBLER RECALL (NC/DOAR WARNING LETTER) FOR ASSEMBLER RESPONSIBLE NONCOMPLIANCES WITH THE STANDARD. (NOTE: All NC/DOAR letters should be reviewed by the home district auditor prior to issuance.)

1. Assembly of Noncompliant Diagnostic X-ray Systems

- a. Issue a NC/DOAR warning letter (see Attachment P) to the responsible assembler in accordance with CPG 7133.12 and Table I of Part II. Address the letter to the most responsible individual at the local assembler firm. Copies of the NC/DOAR letter should be sent to the home district auditor, installation district auditor, the RRHR and HFZ-240.
- b. Evaluate the assembler response using the guidance of Attachment Q. Full use of the home district auditor and contacts with the Diagnostic Devices Branch are advised to assist in the technical aspects of determining acceptable responses.

2. Monitoring Assembler Corrective Action Plans

When Notification letters are issued as follow-up to a violative routine field test, the assembler is not required to submit a corrective action plan (CAP) for the correction of the one individual unit.

Under the NC/DOAR action, FDA Districts will issue noncompliance declarations to specific assemblers, covering all assemblies of fully certified diagnostic x-ray systems assembled over a prescribed time period. Thus, it is essential that a CAP be submitted to, and monitored by, the assembler's home district. Monitoring begins when it is determined that the assembler has elected to submit a CAP in lieu of a refutation or exemption request. Review of the technical aspects of the CAP should be the responsibility of the home district x-ray auditor. If assistance is needed, the auditor should contact the Diagnostic Devices Branch (HFZ-240) at (301)-594-3332. Guidance for evaluating assembler responses can be found in Attachment Q.

Assembler CAPs are to be handled as recalls. The procedures for handling recalls are detailed in the Regulatory Procedures Manual (RPM), Chapter 7. Attachment E of the RPM provides specific guidance for x-ray assemblers.

The home district should incorporate the following steps as part of the CAP monitoring:

- a. Upon receipt of a CAP, prepare the Recall Alert described in the RPM.
- b. Schedule an establishment inspection of the assembler to obtain additional details of the CAP. During this inspection, the investigator should obtain the information necessary for submitting a Recall Recommendation.

NOTE: The district should allow the assembler up to 30 days to formulate a complete CAP and to submit it in writing. Delay submitting the Recall Recommendation until this information is received.

- c. If there will be a delay in obtaining complete details of a CAP, advise the assembler that he must provide interim purchaser notification pursuant to 21 CFR 1003.21. A model letter to purchasers is included as Attachment R.
- d. Once a complete CAP is received, the district x-ray auditor should review the CAP, and if acceptable, prepare a CAP approval letter (Attachment S) for the signature of the District Director.
- e. Copies of the CAP approval letter should be sent to the Diagnostic Devices Branch (HFZ-240).
- * f. The Diagnostic Devices Branch, DMQRP, OCER, CDRH will assign the recall number, recall strategy, and recall classification as directed in the RPM.
- g. The district will also, upon receipt of the recall information from CDRH, prepare a notification letter to the recalling firm setting forth the Agency's position regarding the recall. Include instructions for submitting monthly progress reports, if not included in the CAP approval letter. *
- h. Once the assembler reports completion of the CAP, the district can begin to schedule audit checks at purchaser locations as assigned by CDRH in the Recall Strategy Statement. Audit checks should be performed within six months of the date of correction by the assembler and should consist of a complete field test of the system utilizing the appropriate field test method. The focus of the audit checks should be on the noncompliances cited in the original Warning Letter. Under some circumstances when the recall takes longer than 6 months, an audit check can begin before the completion of the CAP on all locations (see RPM Chapter 7 Attachment E). Generally audit checks are performed on 10% of the product under recall.
- i. The recall should be declared effective if all audit checks demonstrate full compliance with the elements of the Performance Standard cited in the original Warning Letter. Prepare a Recall Termination Recommendation at that time.

NOTE: Since the number of audit checks will normally be small, a decision regarding the effectiveness will not be made if only one of the audited units fails to comply. A second series of audit checks should be conducted at purchaser locations, using the sampling criteria of ANSI/ASQ Z1.4. An identical number of units should be audited in both the first series and second series of audit checks. If the second series of the audit checks reveals no noncompliances, then the recall is effective. The recall shall be considered ineffective if during the first series of audit checks, more than one unit fails to comply with the Performance Standard as cited in the original Warning Letter, or, if during the second series of audit checks, one or more units fail to comply.

- j. Whenever an audit check detects an item of noncompliance (covered by the CAP) that has not been corrected, issue a Notification letter to the assembler. If two or more such noncompliant systems are encountered which are assembler related (not caused by user abuse or failed component), prepare a recommendation for civil penalty.

NOTE: CDRH will not consider for inclusion in a civil penalty case any noncompliance for which the responsible party is identified as other than the assembler. The Field Corrective Action Report must identify the assembler as the responsible party.

* 3. Preparing the Recall Alert and Recall recommendation

In preparing the 24-hour recall alert and recommendation (Attachment A & B of RPM Chapter 7), follow the guidance at the internet address http://www.fda.gov/ora/compliance_ref/rpm_new2/ch7.html . *

E. ISSUANCE OF INFORMATION LETTERS FOR USER CAUSED VIOLATIONS AND REFERRAL TO STATE AUTHORITIES

1. Issue information letters to users when field test results are obtained more than one year after installation and/or violations cannot be determined to be the fault of the manufacturer or assembler (see Attachment M). Send copies to the appropriate state radiation control authorities, the assembler, the component manufacturer, the RRHR for State coordination, the home district auditor, the installation district auditor, and HFZ-240.
2. If the user fails to respond, notify state authorities and the RRHR and request their assistance in obtaining correction. Also request state assistance to prevent use of a Class A violative product until it is corrected. If the state is unable or unwilling to gain compliance:
 - For non-termination of the x-ray timer only, consider detention/seizure in accordance with CPG 7133.25.
 - For all other Class A violations, contact HFZ-240.
 - For Class B violations, do not pursue the matter further.
3. Advise the home district auditor of all final actions or failures to obtain correction so that the Field Corrective Action Report (FCAR) may be completed.

F. FEDERAL/STATE RELATIONS

The RRHR will coordinate and supervise voluntary working agreements, agency contracts and/or Partnership Agreements (PA) with states performing diagnostic x-ray field testing.

PART VI - REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

A. REFERENCES

1. Title 21 Code of Federal Regulations, Subchapter J. Radiological Health.
2. Subchapter C Electronic Product Radiation Control of Chapter V of the Federal Food, Drug, and Cosmetic Act.
3. FDA Regulatory Procedures Manual, Chapter 7, Attachment E and Chapter 6.
- * 4. FDA "Routine Compliance Testing for Diagnostic X-ray Systems or Components of Diagnostic X-ray Systems to which 21 CFR Subchapter J is Applicable," Updated February 2005. *
5. Office of Radiological Health, Division of Compliance, Assemblers Guide to Diagnostic X-ray Equipment. (Rockville, Maryland).
6. United States Code, Title 21, Federal Food, Drug, and Cosmetic Act, As Amended
7. Compliance Policy Guide 7133.12, Regulatory Actions Against Assemblers Who Install Noncompliant diagnostic x-ray equipment.
8. "Calculation Programs for Routine Compliance Testing of Diagnostic X-ray Systems."
9. Compliance Policy Guide 7133.23, Assessment of Civil Penalties Against Manufacturers and Importers of Electronic Products.
10. Compliance Policy Guide 7133.25, Hazardous Diagnostic X-ray Systems.
11. Investigations Operations Manual (IOM).
12. Compliance Policy Guide 7133.27, Obligations of Factory-based Manufacturers and Assemblers of Diagnostic X-Ray Equipment Under the Performance Standard for Diagnostic X-Ray Equipment.
13. Compliance Policy Guide 7133.28, Regulatory Actions Against Assemblers of X-Ray Equipment that Fail to File Reports of Assembly.

B. ATTACHMENTS

1. Attachment A - List of CDRH Personnel to Contact on Procurement, Maintenance and Repair of Instrumentation.

2. Attachment B - List of CDRH Personnel to Contact on Test Procedures, Use of Instrumentation, and Data Entry Problems.
3. Attachment C - General Communications List.
4. Attachment D - Classification of Items of Noncompliance and Defects.
5. Attachment E - Sample Report of Assembly of a Diagnostic X-ray System (FDA-2579).
6. Attachment F - Form FD-2766 Claim for Damages to Electronic Products.
7. Attachment G - Contacts for Manufacturers of Diagnostic X-ray Systems Controls.
8. Attachment H - Notification letter to the Assembler (Incomplete or incorrect FDA-2579 Report of Assembly).
9. Attachment I - Notification letter to Assembler - Standards Violation Found During Review of FDA-2579's or Records Review at the Assembler.
10. Attachment J - Notification letter to the Assembler (Failure to File FDA-2579 Report of Assembly).
11. Attachment K - Notification letter to the Assembler (Notification of Defect or Noncompliance on FD-2786 Field Test).
12. Attachment L - Field Correction Status Report.
13. Attachment M - Notification Letter to the User (Notification of Noncompliance Attributable to User Actions or Inaction).
14. Attachment N - Responsibility for Defects or Noncompliances.
15. Attachment O - Listing of Qualified X-ray Auditors.
16. Attachment P - Sample Warning letter-Noncompliance Declaration With District Ordered Assembler Recall Letter to X-ray Assemblers.
17. Attachment Q - Guidance for Evaluating an Assembler Response to a Noncompliance Declaration With District Ordered Assembler Recall Letter.
18. Attachment R - Sample User Notification Letter for District Ordered Assembler Recall and CAPs.
19. Attachment S - Sample CAP Approval Letter to X-ray Assemblers.

C. PROGRAM CONTACTS

1. CDRH Contact - Questions concerning this compliance program should be directed to the Diagnostic Devices Branch, Division of Mammography and Radiation Programs, Office of Communication, Education, and Radiation Programs, CDRH, telephone number (301) 594-3332. Secondary contact may be made with individuals listed on Attachment C.
2. ORA Contact - The ORA Headquarters contact for this compliance program is ORO/DFI (HFC-130), telephone number (301) 827-5649.

PART VII - CENTER RESPONSIBILITIESA. CDRH INTENDS TO:

1. Monitor nationwide noncompliance trends for different types of x-ray systems and for various plant based x-ray manufacturers.
2. Declare noncompliance and require product recall by manufacturers where nationwide field test data indicates a noncompliance rate well above the national average, or where design related generic violations are identified.
3. Provide calibrated test equipment for use by FDA and state inspectors.
4. Develop computer listings of all certified models of diagnostic x-ray components and systems (Manufacturers Model List) and provide these to each Region and District.
5. Routinely provide listings of problem assemblers for concentrated field testing and enforcement action.
6. Provide periodic status reports on assembler noncompliance trends, and special reports on request by the District.
7. Maintain/develop computer software for direct access to CDRH computer data by Auditors and District DPU's.
8. Date-stamp assembler reports (FDA-2579) as received, enter the data into the data base, and mail forms to the appropriate accomplishing district investigations branch weekly for review for testing selections.
- * 9. Recommend specific sites for special tests when necessary. Survey forms and special test procedures will be provided by the Office of Communication, Education, and Radiation Programs. Portable test equipment will be supplied if needed by the Office of Science and Engineering Laboratories. *
10. Provide the field with information concerning system and component manufacturers corrective action plans. This information will include procedures for monitoring these plans. Advise the field of legal opinions, including those compliance cases, and advisory opinions which impact on their responsibilities in dealing with assemblers.
11. Provide the field with a listing of unresolved noncompliances on a routine basis (Field Correction Status Report) and provide a procedure for each district to monitor their status of unresolved noncompliances.
12. Provide originals of all FD 2579 reports of assembly to the installation district.

13. Monitor and evaluate all test records, assignments, and correspondence relating to this program to identify trends or problems with the program.
14. Resolve specific program problems with the district office or ORA as soon as they are identified.

*B. PROGRAM EVALUATION - Within 3 months after receipt of all documentation for the fiscal year, an informal evaluation will be conducted to review the results of this program and any needed improvements to increase program effectiveness. No formal written evaluation report will be prepared unless requested by the Director, Office of Communication, Education, and Radiation Programs. *

**LIST OF CDRH PERSONNEL TO CONTACT ON PROCUREMENT, MAINTENANCE, AND
REPAIR OF INSTRUMENTATION**

- * All requests for repair or replacement of instrumentation should be made through the instrumentation "HOT LINE" (301) 443-1736. This phone will be answered 24 hours a day by either CDRH personnel or a recorder. If answered by the recorder, the call will be returned if you leave your name and telephone number. Mary Walker HFZ-143, telephone (301) 443-2536 ext 137, is coordinator of field support activities and is the primary contact for questions which cannot be resolved on the "HOT LINE".

The following is a list of individuals most familiar and able to answer questions regarding equipment.

CONTACTS:

Calibration Laboratory Shipping Address:

X-ray Calibration Laboratory
Twinbrook Building 2
12720 Twinbrook Parkway
Rockville, Maryland 20857
Attn: Jannita Ridgell

Calibration Laboratory Mailing Address:

X-ray Calibration Laboratory
HFZ- 143
12720 Twinbrook Parkway
Rockville, Maryland 20852

Supply & Logistics Contact

Jannita Ridgell

Phone: 301 443-1736

Email: jzr@cdrh.fda.gov

Technical Support Contacts

Mary Walker

Phone: 301 443-2536 ext. 137

Email: mdw@cdrh.fda.gov

*

DO NOT return instruments to headquarters for calibration or repairs until calling the "HOT LINE" or the appropriate individual and thus obtaining instructions for return.

CDRH, OCER PERSONNEL TO CONTACT ON TEST PROCEDURES AND USE OF INSTRUMENTATION

*

COMMERCIAL TELEPHONE**FAX NUMBER**

- | | | |
|----------------|--------------|--------------|
| 1. Larry Rourk | 240-276-3283 | 240-276-3272 |
| 2. Tom Jakub | 240-276-3332 | 240-276-3272 |

CDRH PERSONNEL TO CONTACT FOR COMPUTER DATA ENTRY PROBLEMS

- | | | |
|----------------|--------------|--------------|
| 1. Larry Rourk | 240-276-3283 | 240-276-3272 |
|----------------|--------------|--------------|

ORA PERSONNEL TO CONTACT FOR M204 ACCOUNT AND PASSWORD

- | | |
|------------------|--------------|
| 1. Michele Bacum | 301-827-1573 |
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GENERAL COMMUNICATIONS LIST

	<u>COMMERCIAL TELEPHONE</u>	<u>FAX NUMBER</u>
* 1. Larry Rourk	240-276-3283	240-276-3272
2. Thomas Jakub	240-276-3332	240-276-3272
3. Division of Mammography Quality and Radiation Programs	240-276-3332	240-276-3272

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CLASSIFICATION OF ITEMS OF NONCOMPLIANCE AND DEFECTSClass A

Conditions which may pose a serious radiation hazard to the public health and safety.

1. An x-ray system having a malfunction such that inadvertent exposures could occur, e.g., when the exposure switch is activated, not one but repeated exposures occur, or the timer fails to terminate exposure, or exposure initiated without utilizing the exposure switch.
2. A fluoroscopic x-ray system with an entrance exposure rate of greater than or equal to 25 R/min., except:
 - (a) During recording of fluoroscopic images, or
 - (b) When an optional high level control is activated. If the control was manufactured after May 1995, the high level entrance exposure rate is limited to 20 R/min and any reading exceeding 25 R/min is also a Class A violation.
3. A fluoroscopic system where the entire cross section of the useful beam at any SID is not intercepted by the primary protective barrier.
4. A fluoroscopic system such that x-ray production is possible when the primary protective barrier is not in position to intercept the beam.

Class BCertified Systems and Components Only

These are conditions that (1) would result in a large amount of unnecessary radiation exposure during a routine diagnostic x-ray examination, or (2) indicate other clearly defined items of noncompliance (certified systems and components only). These conditions may be determined in the field and calculated as in Reference 4 (the Routine Compliance Test Manual). For purposes of regulatory follow up, Class B conditions are divided into four groups according to the degree of health hazard presented by the conditions. The groupings are: Substantial Hazard, Moderate Hazard, Low Hazard, and Minimal Hazard (as compared to a fully compliant x-ray system).

Substantial Hazard

1. An exposure rate beyond the plane of the image receptor, due to transmission through the primary protective barrier of a fluoroscopic x-ray system (with the attenuation block in the useful

beam) of greater than or equal to 10 mR/hr for each R/min of entrance exposure rate at 10 cm from any accessible surface of the fluoroscopic imaging assembly.

2. An image-intensified fluoroscopic x-ray system such that the total misalignment of the edges of the x-ray field with the respective edges of the visible area of the visually defined field in the plane of the image receptor is greater than 10 percent of the SID.
3. A spot film device such that the total misalignment of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, exceeds 10 percent of the SID.
4. A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by greater than 10 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.
5. Mobile radiographic systems where the illuminance of the light localizer is less than 96 lux at a 100 centimeter measurement distance.

Moderate Hazard

1. For radiographic x-ray systems:
 - a. A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by greater than 5 percent of the SID and that the sum of the length and width differences without regard to sign is greater than 7 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.
 - b. A radiographic x-ray system providing means to align the center of the x-ray field with respect to the center of the image receptor and the misalignment is greater than or equal to 5 percent of the SID.
 - c. A radiographic x-ray system providing means for visually defining the perimeter of the x-ray field and the total misalignment of the edges of the visually defined field is greater than 5 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is indicated to be perpendicular to the axis of the x-ray beam.

- d. A coefficient of variation greater than or equal to 0.10 for a sample set of ten exposures as described in Reference 4.
- e. A half-value layer more than 1/2 mm aluminum below the appropriate value listed in 21 CFR 1020.30, Table I.
- f. Systems equipped with positive beam limitation where at SIDs for which the device is designed to operate, it does not either cause automatic adjustment of the x-ray field to the image receptor size in the plane of the image receptor within 5 seconds after insertion of the image receptor; or if adjustment is accomplished automatically in a time interval greater than 5 seconds, or manually, does not prevent the production of x-rays until such adjustment is made.
- g. An average light localizer illuminance of less than 96 lux for stationary systems and between 96 and 144 lux for mobile systems, as measured with a Digiphot at a measurement distance of 100 centimeters or the maximum SID, whichever is greater.
- h. A capacitor storage system such that the standby radiation is greater than or equal to 25 mR/hr.
- i. A measured kilovoltage greater or less than the manufacturer's upper or lower accuracy limits:
 - (1) Measured kilovoltage greater than the indicated kilovoltage A measured kilovoltage more than 105 percent of the manufacturer's upper accuracy limit for indicated kilovoltage.
 - (2) Measured kilovoltage less than the indicated kilovoltage A measured kilovoltage that is less than 95 percent of the manufacturer's lower limit for indicated kilovoltage.
- j. Intraoral dental systems capable of operation in the above 50 kVp range, which exhibit a minimum source to skin distance less than 16 centimeters.
- k. Intraoral dental systems capable of operation in the above 50 kVp range for which the field size at the cone tip is greater than or equal to 9 centimeters.
- l. Dental radiographic systems in which it is possible to produce x-rays with the timer in the zero or off position.
- m. Mammographic x-ray systems in which the edge of the x-ray field at the chest wall extends beyond the edges of the image receptor by more than 5 percent of the source to image receptor distance.

2. For fluoroscopic x-ray systems:
- a. An image-intensified fluoroscopic x-ray system such that the total misalignment of the edges of the x-ray field with the respective edges of the visually defined field in the plane of the image receptor is equal to or greater than 6 percent, but less than 10 percent of the SID, and the sum, without regard to sign, of the misalignment along any two orthogonal dimensions intersecting at the center of the visible area of the image receptor is equal to or greater than 8 percent of the SID.
 - b. A nonimage-intensified fluoroscopic system such that any dimension of the x-ray field extends beyond the visible portion of the image receptor by greater than 8 percent of the SID.
 - c. For conditions described in 21 CFR 1020.32(d), if the maximum allowable entrance exposure rate is 5 R/min., test values of greater than or equal to 5.6 R/min., but less than 25 R/min. Correspondingly, for a maximum allowable rate of 10 R/min., test values of greater than or equal to 11.5 R/min. but less than 25 R/min. are included.
 - d. Half-value layer values that are more than 1/2 mm below the value specified in 21 CFR 1020.30 Table I.
 - e. An exposure rate due to transmission through the primary protective barrier of a fluoroscopic system with the attenuation block in the useful beam of greater than or equal to 4 mR/hr but less than 10 mR/hr for each R/min of entrance exposure rate at 10 cm beyond the plane of the image receptor.
 - f. A spot film device such that the total misalignment of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, exceeds 6 percent, but is less than 10 percent of the SID. The sum without regard to sign of the misalignment along any two orthogonal dimensions exceeds 7 percent of the SID.
 - g. Stationary fluoroscopes with a minimum source-to-skin distance of less than 35.2 centimeters.
 - h. Mobile fluoroscopes with a minimum source-to-skin distance of less than 27.2 centimeters or 18.1 centimeters when configured for surgical use (e.g. spacer removed).
 - i. For controls manufactured after May 1995, which have high level controls limited to 20 R/min, test values of greater than 21.5 R/min but less than 25 R/min.
 - j. Other similar situations.

Low Hazard

1. For radiographic x-ray systems:
 - a. A coefficient of variation greater than or equal to 0.084 for a sample set of four exposures, or between 0.06 and 0.10 for a sample set of ten exposures as described in Reference 4.
 - b. A linearity value of greater than or equal to 0.153. This value is based upon two sample sets of at least four exposures each, as described in Reference 4.
 - c. A radiographic x-ray system having indicated field size dimensions such that aperture adjustments result in x-ray field dimensions that differ from those of the image receptor by equal to or greater than 5 percent of the SID when the beam axis is intended to be perpendicular to the plane of the image receptor.
 - d. A stationary general purpose radiographic x-ray system (i.e., one equipped with stepless adjustment of the size of the x-ray field) such that the actual SID differs from the indicated SID by more than 5 percent of the indicated SID. These values are based on a test procedure using a direct measurement of the distance from the focal spot to the tabletop and from the tabletop to the film plane as described in Reference 4.
 - e. For stationary systems only, an average light localizer illuminance of between 96 and 144 lux as measured with a Digiphot.
 - f. A capacitor storage radiographic system such that the standby radiation is greater than 3.0 mR/hr, but less than 25 mR/hr.
 - g. Systems equipped with positive beam limitation devices that do not allow the field size to be reduced to a size less than that of the image receptor.
 - h. Systems equipped with positive beam limiting devices that do not provide for an automatic return to PBL from a reduced field size.
 - i. Mobile radiographic systems for which the minimum source to skin distance is less than 27.5 centimeters.
 - j. Mammographic systems for which the edges of the x-ray field on any side extend beyond the edge of the image receptor by more than 5 percent of the SID.
 - k. (1) When the maximum operating range is above 70 kVp; a half-value layer (HVL) between $(0.15 + 0.04 \times \text{HVL})$ mm and 0.5 mm aluminum below the appropriate value listed in 21 CFR 1020.30 Table I.

- (2) When the maximum operating range is 50 to 70 kVp: a half-value layer (HVL) between $(0.08 + 0.04 \times \text{HVL})$ mm and 0.5 mm aluminum below the appropriate value listed in 21 CFR 1020.30 Table I.
 - (3) When the maximum operating range is less than 50 kVp: a half-value layer (HVL) between 0.1 mm and 0.5 mm aluminum below the appropriate value listed in 21 CFR 1020.30 Table I.
1. Systems equipped with positive beam limitation, which do not prevent the production of x-rays at SID's greater than 36 inches where the PBL device is not intended to operate.
2. For fluoroscopic x-ray systems:
 - a. Fluoroscopic systems equipped with high level control that do not provide an audible indication of the activation of the high level control.
 - b. Half-value layer (see item k(1) under radiographic systems).
 - c. Systems which do not provide either continuous audible signal or termination of x-rays at the completion of a previously selected time interval.

Class B

Uncertified Systems and Components Only

Other situations similar to those of Class B certified systems and components, which in the judgement of the auditor constitute a defect as defined in 21 CFR 1003.2(b).

Class C

Certified Systems and Components Only

These are conditions that indicate test results exceeding the requirements of the standard but less than the values for Class B noncompliances for certified systems and components only. These may be determined in the field and calculated as in Reference 4.

1. For radiographic x-ray systems:
 - a. A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by

- 3.00 to 4.99 percent of the SID and that the sum of the length and width differences without regard to sign is between 4.00 and 6.99 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.
- b. A radiographic x-ray system providing means to align the center of the x-ray field with respect to the center of the image receptor and misalignment is between 2.00 and 4.99 percent of the SID.
 - c. A radiographic x-ray system providing means for visually defining the perimeter of the x-ray field and the total misalignment of the edges of the visually defined field is between 2.00 and 4.99 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is indicated to be perpendicular to the axis of the x-ray beam.
 - d. A radiographic x-ray system having indicated field size dimensions such that aperture adjustments result in x-ray field dimensions that differ from those of the image receptor by between 2.00 and 4.99 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.
 - e. A stationary radiographic x-ray system providing means for stepless adjustment of the size of the x-ray field such that the actual SID is either larger or smaller than the indicated SID by between 2.00 and 4.99 percent. These values are based on a test procedure using direct measurement of the distance from the focal spot to the tabletop and from the tabletop to the film plane as described in Reference 4.
 - f. A coefficient of variation greater than 0.050 but less than 0.084. This value is based upon a sample set of four exposures. When a set of ten exposure values is made, the upper limit is reduced from 0.084 to 0.06 (see Reference 4).
 - g. Linearity value of greater than 0.100 but less than 0.152. This value is based upon two sample sets of at least four exposures each, as described in Reference 4.
 - h.
 - (1) When the maximum operating range is above 70 kVp: A half-value layer (HVL) below the appropriate value listed in 21 CFR 1020.30, Table I, but less than $(0.15 + 0.04 \times \text{HVL})$ mm Al below the listed value.
 - (2) When the maximum operating range is 50 to 70 kVp: A half-value layer below the appropriate value listed in 21 CFR 1020.30, Table I, but less than $(0.08 + 0.04 \times \text{HVL})$ below the listed values.
 - (3) When the maximum operating range is less than 50 kVp: A half-value layer (HVL) below the appropriate value listed in 21 CFR 1020.30 Table I but less than 0.1 mm Al below the listed value.

- i. An average light localizer illumination greater than 144 but less than 160 lux as measured with a Digiphot.
- j. A capacitor energy storage radiographic system such that the standby radiation is greater than 2.0 mR/hr but less than 3.0 mR/hr.
- k. A measurable kilovoltage greater or less than the manufacturer's upper or lower accuracy limits.
 - (1) Measured kilovoltage greater than indicated kilovoltage A measured kilovoltage ranging from the manufacturer's upper accuracy limit to a measured kilovoltage such that 95 percent of this value is greater than the upper accuracy limit.

Example: The indicated kilovoltage on the x-ray control is 100 kVp. If the manufacturer states an accuracy of ± 10 percent, the upper and lower accuracy limits would be 110 kVp and 90 kVp, respectively. In this case, a measured kilovoltage ranging from 110 kVp to 115.8 kVp would be a Class C noncompliance.

- (2) Measured kilovoltage less than indicated kilovoltage A measured kilovoltage ranging from the manufacturer's lower accuracy limit to a measured kilovoltage such that 105 percent of this value is less than the lower accuracy limit.

Example: The indicated kilovoltage on the x-ray control is 100 kVp. If the manufacturer states an accuracy of ± 10 percent, the upper and lower accuracy limits would be 110 kVp and 90 kVp, respectively. In this case, a measured kilovoltage ranging from 90 kVp to 85.7 kVp would be a Class C noncompliance.

2. For fluoroscopic x-ray systems:

- a. An image-intensified fluoroscopic x-ray system such that the total misalignment of the edges of the x-ray field with the respective edges of the visible area of the visually defined field in the plane of the image receptor is greater than 3 percent but less than 6 percent of the SID, and the sum, without regard to sign, of the misalignment along any two orthogonal dimensions intersecting at the center of the visible area of the image receptor is greater than 4 percent but less than 8 percent of the SID.
- b. A nonimage-intensified fluoroscopic system such that any dimension of the x-ray field extends beyond the visible portion of the image receptor but by less than 8 percent of the SID.
- c. For conditions described in 21 CFR 1020.32(d), if the maximum allowable entrance exposure rate is 5 R/min., test values of greater than 5.0 R/min., but less than 5.6 R/min. Correspondingly, if the maximum allowable entrance exposure rate is 10 R/min., test values of greater than 10.0 R/min. but less than 11.5 R/min. are included.

- d. Half-value layer (see h(1) under radiographic x-ray systems this section).
- e. An exposure rate due to transmission through the primary protective barrier of a fluoroscopic system with the attenuation block in the useful beam of greater than 2.0 mR/hr but less than 4.0 mR/hr for each R/min. of entrance exposure rate at 10 cm beyond the plane of the image receptor.
- f. A spot film device such that total misalignment of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, is greater than 3 percent but less than 6 percent of the SID. The sum without regard to sign of the misalignment along any two orthogonal dimensions is greater than 4 percent but less than 7 percent of the SID.
- g. For controls manufactured after May 1995 that contain high level controls, where the maximum allowable entrance exposure rate is 20 R/min, test values greater than 20 R/min, but less than 21.5 R/min.
- h. Stationary fluoroscopes with a minimum source-to-skin distance between 35.2 centimeters and 38 centimeters.
- i. Mobile fluoroscopes with a minimum source-to-skin distance between 27.2 centimeters and 30 centimeters or between 18.1 centimeters and 20 centimeters when configured for surgical use (e.g. spacer removed).
- j. Other similar situations.

Class C

Uncertified Systems and Components Only

Other situations similar to those of Class C certified systems and components which in the judgment of the auditor meet the definition of 21 CFR 1003.2(b).

Class D

All items that indicate a system in compliance.

Class E

These items are minor functional noncompliances which may not be assembler related. They do not warrant a Notification letter by themselves, but may be included in a Notification letter issued because of other violations (similar to notification of Class C violations).

Minimal Hazard

1. For radiographic systems:
 - a. Stationary systems where there are no means to indicate when the beam axis is perpendicular to the plane of the image receptor.
 - b. Stationary systems where means are not provided to center the diagnostic source assembly over the image receptor.
 - c. Systems where technique factors are not indicated at the operator's position.
 - d. Systems which lack a warning label.
2. For fluoroscopic systems:
 - a. No warning label present on the master x-ray control panel.
 - b. Systems where the tube potential and tube current are not continuously indicated during x-ray exposure.

SAMPLE REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM (FDA-2579)

FOR FDA USE ONLY	DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service FOOD AND DRUG ADMINISTRATION REPORT OF ASSEMBLY OF A DIAGNOSTIC X-RAY SYSTEM	Form Approved: OMB No. 0910-0213. Expiration Date: March 31, 1998 See Reverse for OMB statement <div style="text-align: center; font-size: 2em; font-weight: bold;">D</div>
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1. EQUIPMENT LOCATION a. NAME OF HOSPITAL, DOCTOR OR OFFICE WHERE INSTALLED b. STREET ADDRESS c. CITY d. STATE e. ZIP CODE f. TELEPHONE NUMBER ()	2. ASSEMBLER INFORMATION a. COMPANY NAME b. STREET ADDRESS c. CITY d. STATE e. ZIP CODE f. TELEPHONE NUMBER ()
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3. GENERAL INFORMATION			
a. THIS REPORT IS FOR ASSEMBLY OF CERTIFIED COMPONENTS WHICH ARE (Check appropriate box(es)) <div style="display: flex; justify-content: space-between;"><div><input type="checkbox"/> NEW ASSEMBLY-FULLY CERTIFIED SYSTEM <input type="checkbox"/> REASSEMBLY-FULLY CERTIFIED SYSTEM</div><div><input type="checkbox"/> REASSEMBLY-MIXED SYSTEM (Both certified and non-certified components) <input type="checkbox"/> REPLACEMENT COMPONENTS IN AN EXISTING SYSTEM <input type="checkbox"/> AN ADDITION TO AN EXISTING SYSTEM</div></div>			
b. INTENDED USE(S) (Check appropriate box(es)) <div style="display: flex; flex-wrap: wrap;"><div style="width: 50%;"><input type="checkbox"/> GENERAL PURPOSE RADIOGRAPHY <input type="checkbox"/> GENERAL PURPOSE FLUOROSCOPY <input type="checkbox"/> TOMOGRAPHY (Other than CT) <input type="checkbox"/> ANGIOGRAPHY <input type="checkbox"/> PODIATRY</div><div style="width: 50%;"><input type="checkbox"/> UROLOGY <input type="checkbox"/> MAMMOGRAPHY <input type="checkbox"/> CHEST <input type="checkbox"/> CHIROPRACTIC <input type="checkbox"/> CT HEADSCANNER</div><div style="width: 50%;"><input type="checkbox"/> CT WHOLE BODY SCANNER <input type="checkbox"/> HEAD-NECK (Medical) <input type="checkbox"/> DENTAL-INTRAORAL <input type="checkbox"/> DENTAL-CEPHALOMETRIC <input type="checkbox"/> DENTAL PANORAMIC</div><div style="width: 50%;"><input type="checkbox"/> RADIATION THERAPY SIMULATOR <input type="checkbox"/> C-ARM FLUOROSCOPIC <input type="checkbox"/> DIGITAL <input type="checkbox"/> BONE MINERAL ANALYSIS <input type="checkbox"/> OTHER (Specify in comments)</div></div>			
c. THE X-RAY SYSTEM IS (Check one) <input type="checkbox"/> STATIONARY <input type="checkbox"/> MOBILE		d. THE MASTER CONTROL IS IN ROOM e. DATE OF ASSEMBLY ____/____/____ (mo.) (day) (yr.)	

4. COMPONENT INFORMATION (If additional space is needed for this section use another form, replacing the preprinted number with this Form Number, and complete Items 1, 4, and 5 only)

a. THE MASTER CONTROL IS <input type="checkbox"/> A NEW INSTALLATION <input type="checkbox"/> EXISTING (Certified) <input type="checkbox"/> EXISTING (Non-certified)	b. CONTROL MANUFACTURER c. CONTROL MODEL NUMBER	d. CONTROL SERIAL NUMBER e. SYSTEM MODEL NAME (CT Systems Only)	f. DATE MANUFACTURED
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Complete the following information for the certified components listed below which you installed. For beam limiting devices, tables and CT gantries enter the manufacturer and Model number in the indicated spaces. For other certified components, enter in the appropriate blocks how many of each you installed in this system.

g. SELECTED COMPONENTS				h. OTHER CERTIFIED COMPONENTS (Enter number of each installed in appropriate blocks.)	
BEAM LIMITING DEVICE	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED	<input type="checkbox"/> X-RAY CONTROL	<input type="checkbox"/> GRADLE
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED	<input type="checkbox"/> HIGH VOLTAGE GENERATOR	<input type="checkbox"/> FILM CHANGER
TABLES	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED	<input type="checkbox"/> VERTICAL CASSETTE HOLDER	<input type="checkbox"/> IMAGE INTENSIFIER
	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED	<input type="checkbox"/> TUBE HOUSING ASSEMBLY	<input type="checkbox"/> SPOT FILM DEVICE
CT GANTRY	MANUFACTURER	MODEL NUMBER	DATE MANUFACTURED	<input type="checkbox"/> DENTAL TUBE HEAD	<input type="checkbox"/> OTHER (Specify)

5. ASSEMBLER CERTIFICATION		
I affirm that all certified components assembled or installed by me, for which this report is being made, were adjusted and tested by me according to the instructions provided by the manufacture(s), were of the type required by the manufacturer(s), were of the type required by the diagnostic x-ray performance standard (21 CFR Part 1020), were not modified to adversely affect performance, and were installed in accordance with provisions of 21 CFR Part 1020. I also affirm that all instruction manuals and other information required by 21 CFR Part 1020 for this assembly have been furnished to the purchaser and, within 15 days from the date of assembly, each copy of this report will be distributed as indicated at the bottom of each copy.		
a. PRINTED NAME	b. SIGNATURE	c. DATE

6. COMMENTS

FORM FDA 2579 (10/97) PREVIOUS EDITION IS OBSOLETE

White Copy - FDA, HFZ-307.2098 Gaither Road, Rockville, MD 20850

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CONTACTS FOR MANUFACTURERS OF DIAGNOSTIC X-RAY SYSTEMS CONTROLS

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When a noncompliance is discovered through routine diagnostic x-ray field testing under this program, a courtesy copy of the findings should be sent to the component manufacturer associated with the violation. Generally systems are tracked by the master control. The name and address of the component manufacturer should be provided on a tag/label permanently affixed or inscribed on the component.

To obtain the most recent address for the manufacturers of diagnostic x-ray components search the FDA web site for medical devices databases under establishment registration. The site may be found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/registration.cfm> . The courtesy copy should be sent to the address that is listed for the official correspondent or the US Agent. Additionally, FACTS may be searched (Navigate/Firms/Firms Search) to obtain the current address for the component manufacturer. FACTS searches to locate a domestic manufacturer require you provide the manufacturer's state. FACTS searches to locate a foreign manufacturer require you provide the manufacturer's country and the first three letters of the city.

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**NOTIFICATION LETTER TO THE ASSEMBLER (INCOMPLETE OR INCORRECT FDA-
2579 REPORT OF ASSEMBLY)**

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE

FIRM NAME

FIRM'S COMPLETE ADDRESS

Dear (Addressee):

On (date) your firm was inspected/contacted by (investigator) from our (Location) District office. At that time, he (she or they) explained to you (or name & title of agent) your firm's responsibility as an assembler to submit complete and accurate Reports of Assembly of a Diagnostic X-ray System, Form FDA 2579, for each certified diagnostic x-ray component (system) installed by your firm.

Accurate and complete Reports of Assembly of a Diagnostic X-ray System, Form FDA 2579, are required to be submitted to FDA within 15 days following the completion of assembly pursuant to 21 CFR 1020.30 (copy enclosed).

We are requesting that you provide us with a corrected Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, within 30 working days of the receipt of this letter for (FDA 2579 number), which is for equipment assembled at (location). A copy of the report you previously submitted is enclosed.

Along with a corrected FDA 2579, you should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. Your response should be sent to (name), Compliance Officer, Food and Drug Administration, (street address), (city), (state & zip code). If you have any questions, (name) can be contacted at (telephone #).

Sincerely,

District Director

**NOTIFICATION LETTER TO ASSEMBLER - STANDARDS VIOLATIONS FOUND DURING
REVIEW OF FDA-2579's OR RECORDS REVIEW AT THE ASSEMBLER**

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (Addressee):

During an inspection of your firm located at (address), conducted on (date), our investigator(s) determined that your firm is an assembler of diagnostic x-ray equipment. At that time, he (she or they) specifically discussed your assembly of a (type of x-ray system i.e. general purpose radiographic) unit at (location) and explained to you that your installation of a (x-ray system component, e.g., beam limiting device which does not provide variable beam limitation on such a unit) was in violation of (identify regulation, e.g., 21 CFR 1020.31(d)(1)).

At that time you agreed to replace (component, e.g., the beam limiting device) with the type called for by the standard (e.g., required standard i.e. variable x-ray field limitation), and submit a corrected Report of Assembly of a Diagnostic X-ray System, Form FDA 2579 to the Food and Drug Administration, the State Radiation Control Program, and the purchaser by (date). Please use the enclosed forms for this purpose. We have enclosed an envelope for your use in returning the original (white) copy directly to this office.

Subsequent to (date agreed upon), a representative of the Food and Drug Administration may investigate your assembly at (location) to verify your correction.

Failure to correct a defect or noncompliance or failure to file a Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, is a violation of the Federal Food, Drug, and Cosmetic Act (the Act), section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

Accurate and complete Reports of Assembly of a Diagnostic X-ray System, Form FDA 2579, are required to be submitted to FDA within 15 days following the completion of assembly pursuant to 21 CFR 1020.30.

Along with a revised FDA 2579, you should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation(s), including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the

corrections will be completed. Your response should be sent to (name), Compliance Officer, Food and Drug Administration, (street address), (city), (state & zip code). If you have any questions, (name) can be contacted at (telephone #).

Sincerely,

District Director

Enclosures

NOTIFICATION LETTER TO ASSEMBLERS (FAILURE TO FILE FDA 2579 REPORTS OF ASSEMBLY)

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (Addressee):

During an inspection of your firm located at (address), conducted on (date), our Investigator(s) determined that your firm is an assembler of diagnostic x-ray equipment. At that time, he (she or they) explained to you (or to your agent) your responsibility to file a Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, for each certified diagnostic x-ray component (system) you assemble (see attached copy of applicable regulations). We have identified the following facility(s) for which your assembly was not reported to FDA in accordance with 21 CFR 1020.30:

1. (name and location)
2. (name and location)

etc.

Accurate and complete Reports of Assembly of a Diagnostic X-ray System, Form FDA 2579, are required to be submitted to FDA, the appropriate State Radiation Control Program, and the purchaser within 15 days following the completion of assembly pursuant to 21 CFR 1020.30.

Failure to file a Report of Assembly of a Diagnostic X-ray System, Form FDA 2579, is a violation of the Federal Food, Drug, and Cosmetic Act (the Act), section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

Along with a FDA 2579 for each of the above listed installations, you should notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. Your response should be sent to (name), Compliance Officer, Food and Drug Administration, (street address), (city), (state & zip code). If you have any questions, (name) can be contacted at (telephone #).

Sincerely yours,

District Director

Enclosures

**NOTIFICATION LETTER TO THE ASSEMBLER (NOTIFICATION OF DEFECT OR
NONCOMPLIANCE AS THE RESULT OF FIELD TESTING)**

NOTE: This letter is a model letter for use under the audit review program [See Regulatory Procedures Manual, Chapter 4, Exhibit 4-1, Section 6.4] and is located at ORA's Office of Enforcement "Warning Letters and Untitled Letters Main Page" (<http://web.ora.fda.gov/oe/tempdoc.htm>).

[When letter contains Class A violations: WARNING LETTER]

[DATE]

Via Federal Express—Next Day

Most Responsible Individual at Company, Title
Company
Address
City, State Zip

Re: Field Test Number GI-_____

Dear _____:

On _____, 200X, a representative from the Food and Drug Administration (FDA) conducted a field test of the certified diagnostic x-ray system at the following facility:

Name of Facility:

Address:

City, State Zip:

X-Ray Control Manufacturer:

X-Ray Control Model/ Serial No.:

Room No.:

Our records indicate that your firm assembled this system (FDA-2579; _____) on _____, and we tested this system to determine its compliance with portions of the Performance Standard for Diagnostic X-Ray Equipment (21 C.F.R. §§ 1020.30-32). Diagnostic x-ray equipment is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

[WHEN YOU HAVE A CLASS A VIOLATION INSERT THE FOLLOWING:]

This letter confirms our telephone notification on _____ to Mr./Ms. [Most Responsible Individual] of

your firm. During this telephone call, we requested that you immediately correct the following serious non-compliance(s) with the performance standard:

[Indent and list Class A violations in numbered or bullet-pointed paragraphs]

[WHEN YOU HAVE A CLASS B VIOLATION INSERT THE FOLLOWING:]

Our analysis of the field test data indicates that the system does not comply with the following items of the performance standard:

[Indent and list Class B violations in numbered or bullet-pointed paragraphs]

[WHEN YOU HAVE A DEFECT, ADD THE FOLLOWING:]

While conducting our field test, we also determined that the system was defective in the following manner:

[Indent and list defects, as defined in 21 CFR § 1003.2, in numbered or bullet-pointed paragraphs]

WHEN YOU HAVE A CLASS C VIOLATION AND YOU ARE ALSO DECLARING CLASS A AND/OR B VIOLATIONS OR A DEFECT, ADD THE FOLLOWING:

In addition to the above problems, we consider the compliance status of the following items to be suspect. Please verify the compliance status of these items when you correct the previously cited problems.

[Indent and list Class C violations in numbered or bullet-pointed paragraphs]

We request that you, as the responsible assembler, investigate the deviation(s) from the performance standard and/or the defects listed above in accordance with 21 C.F.R. §§ 1003 and 1004, as follows:

1. If you determine that the deviation and/or defect is caused by improper assembly or installation, you should correct the deviation and/or defect *at no charge* to the user by either repairing the system, replacing it, or refunding the cost.
2. If you determine that the deviation and/or defect is caused by the factory-based manufacturer, you should notify the manufacturer of the deviation and/or defect and send documentation of such notification to this office.
3. If you can establish that the system is compliant, that the alleged deviation and/or defect does not exist or does not relate to the safety of the product, or is directly attributable to user abuse or lack of maintenance, you may submit such evidence to

this office in accordance with 21 C.F.R. § 1003.11(a)(3) within **[if letter includes Class A violations: fifteen (15); if letter does not include Class A violations thirty (30)]** working days of receipt of this letter.

You are requested to report the results of your investigation and follow-up action to this office within **[if letter includes Class A violations: fifteen (15); if letter does not include Class A violations thirty (30)]** working days of the receipt of this letter. Your response should include the date that the corrective actions were completed, and a copy of the service record and/or other supportive documents. **[if letter does not include Class A violations, insert the following:]** Failure to respond may constitute a violation of the Act, Sections 538(a)(2) and 538(a)(4) of Sub-chapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

[Include the following only when letter contains Class A violations:]

Failure to respond constitutes a violation of the Act, Sections 538(a)(2) and 538(a)(4) of Sub-chapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968). Failure to promptly correct this violation can result in regulatory action being initiated by FDA without further notice. These actions include seizure, injunction, and the imposition of civil penalties as provided for in Section 539 of the Act. Persons violating Section 538 of the Act are subject to civil penalties of up to \$1,000 per violation and up to a maximum of \$300,000.

Your response should be sent to _____, Compliance Officer, Food and Drug Administration, Address. If you have any questions, please contact _____, telephone number, extension.

Sincerely,

Director of Compliance
District Office

cc: **Facility Representative**
Facility
Address
City, State Zip

FIELD CORRECTION STATUS REPORT

X-RAY FIELD TEST NON-COMPLIANCES THAT ARE UNRESOLVED IN ATLANTA HOME DISTRICT

TEST ID	TEST DATE	ACCOMP DISTRICT	FACILITY/ZIP ASSEMBLER/ZIP	NONCOMPLIANCES
-----	----	-----	-----	-----
AR56175R	19961009	LOS	MOBILE LITHOTRIPTERS/92630	
			DORNIER MEDICAL SYSTEMS INC./30144	Q07 Q08 Q71
AR54497A	19961018	ATL	NORTHSIDE HOSPITAL/30342	
			PICKER INTERNATIONAL/30071	9
UF55410B	19961029	NOL	VICKSBURG MEDICAL CENTER/39180	
			GENERAL ELECTRIC COMPANY/30071	10
UF55415B	19970123	NOL	MONFORT JONES MEMORIAL HOSPITAL/39090	
			PICKER INTERNATIONAL/30071	8 9
AR64877A	19970127	ATL	PROMINA PRIMARY CARE CENTER/30060	
			RAMSEY ENTERPRISES INC./30188	Q54
AR56372A	19970130	ATL	THE PAPP CLINIC/30265	
			X-RAY OF GEORGIA, INC./30071	2
UF56357B	19970214	ATL	KAISER PERMANENTE, SPMO/28210	
			GENERAL ELECTRIC COMPANY/30071	16
AR37356A	19970305	NOL	HUEY P. LONG REGIONAL MED CNT/71360	
			GENERAL ELECTRIC COMPANY/30071	3
AR55416	19970312	NOL	BAPTIST MEMORIAL HOSPITAL/38671	
			UNKNOWN (CFN: 1043749)	3 5
AR57378A	19970318	ATL	CANDLER HOSPITAL/31405	
			GENERAL ELECTRIC COMPANY/30071	3
AR58973A	19970319	ATL	CANDLER HOSPITAL/31405	
			GENERAL ELECTRIC COMPANY/30071	3
AR58972A	19970320	ATL	MEDICAL CENTER LLP/31021	
			X-RAY OF GEORGIA, INC./30071	9
AR50490A	19970509	NSV	ST. CLAIRE REGIONAL HOSPITAL/35125	
			UNKNOWN (CFN: 1056430)	Q54 Q69 Q70
AR57884A	19970515	ORL	MORTON PLANT MEASE HOSPITAL/34698	
			GENERAL ELECTRIC COMPANY/30071	Q71
UF57943B	19970611	ORL	MIAMI CHILDRENS HOSPITAL/33155	
			GENERAL ELECTRIC COMPANY/30071	12
AR43600A	19970616	NSV	QUANTUM IMAGING/37203	
			GENERAL ELECTRIC COMPANY/30071	9 33 35
UF64654C	19970909	ORL	CEDARS MEDICAL CENTER/33136	
			GENERAL ELECTRIC COMPANY/30071	10
AR64057A	19971030	NOL	FOREST GENERAL HOSPITAL/30401	
			GENERAL ELECTRIC COMPANY/30071	35
AR57336A	19971112	ATL	OCONEE MEMORIAL HOSPITAL/29679	
			PHILIPS MEDICAL SYSTEMS, INC./28217	29 31
AR57337A	19971112	ATL	OCONEE MEMORIAL HOSPITAL/29672	
			PHILIPS MEDICAL SYSTEMS, INC./28217	17 19 21

TOTAL FIELD TEST RECORDS FOR ATLANTA HOME DISTRICT IS: 21

**NOTIFICATION LETTER TO THE USER (NOTIFICATION OF NONCOMPLIANCE
ATTRIBUTABLE TO USER ACTIONS OR INACTION)**

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (Addressee):

On (date), a field test was performed on the (name of mfr.) diagnostic x-ray system, control model number (model number), located in room (number) of your facility. We tested this system to determine its compliance with portions of the Performance Standard for Diagnostic X-ray Equipment (Title 21, Code of Federal Regulations (CFR), sections 1020.30-32).

Analysis of the data obtained from the field test shows the system fails to comply with the following requirements of the Federal performance standard for diagnostic x-ray systems:

(Describe Each Item of Noncompliance)

Our investigation indicates that neither the manufacturer nor the assembler is likely to be responsible for these noncompliances under the regulations. The use of a noncompliant x-ray system may result in unnecessary radiation exposure to the patient or operator. Therefore, we encourage you to arrange for correction of the noncompliance.

(If Class A Conditions are Involved, Substitute the Following)

Our investigation indicates that neither the manufacturer nor the assembler is likely to be responsible for the noncompliances under the regulations. These problems may pose a serious health hazard to the patient or operator. We strongly encourage you to discontinue use of the system and arrange for its repair immediately.

You are hereby requested to notify this office in writing, within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted noncompliance. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to (name), Compliance Officer, Food and Drug Administration, (street address), (city), (state & zip code). If you have any questions, (name) can be contacted at (telephone #).

Sincerely yours,
District Director

NOTE: Indicate at the bottom of the original letter that the state radiation control program has received a copy of this letter.

RESPONSIBILITY FOR DEFECTS AND NONCOMPLIANCES

The Diagnostic X-ray Performance Standard specifies certain limits of responsibility for manufacturers and assemblers of x-ray equipment. Assemblers are responsible for noncompliances that are attributed solely to improper assembly or installation or caused by improperly following the instructions provided by the manufacturer. Manufacturers are responsible for noncompliances caused by improper assembly if adequate instructions were not provided to the assembler (21 CFR 1020.30(c)). The performance standard does not specifically address the limits of responsibility regarding equipment age or user responsibility.

Manufacturers are required by the performance standard to provide purchasers with a schedule of maintenance necessary to keep the x-ray equipment in compliance with the performance standard (21 CFR 1020.30(h)(1)(ii)). The regulations require manufacturers to provide a maintenance schedule because it is unreasonable to expect x-ray equipment to meet certain performance requirements if proper maintenance is not performed. After the first maintenance is performed or after the time it should have been performed, the assembler may no longer be responsible for requirements affected by proper adherence to the maintenance schedule. Some assemblers of older certified equipment will correct the noncompliance and bill the owner rather than attempting to refute responsibility for the noncompliance. This practice frequently upsets the x-ray system owner since he believes this work should have been performed free of charge.

Evidence that would exempt manufacturers/assemblers from responsibility includes:

1. Failure by the user to follow the manufacturer's prescribed maintenance schedule for those items requiring periodic adjustment.
2. Photographs or other documentation (written description) of physical damage to the x-ray system, which was due to abuse.

The manufacturer/assembler may be held responsible if the user has failed to follow the maintenance schedule but the facility has documented continued compliance problems with the system beginning in the warranty period.

Items that may require periodic adjustment under a manufacturer's maintenance schedule include:

- a) linearity
- b) x-ray field/light field alignment
- c) PBL sizing
- d) illuminance
- e) entrance exposure rate
- f) fluoroscopic alignment
- g) spot film alignment

- h) indication of technique factors
- i) signal and warning lights

Some items require adjustment on a time basis while others require adjustment at time of a tube reloading or bulb change in the collimator lamp. The individual maintenance schedule must be checked to determine the applicable situation and time interval.

LIST OF QUALIFIED X-RAY AUDITORS

		PHONE NUMBER/ FAX NUMBER
New England District	Michael J. Leal	508-793-0422
	George Allen	508-793-0422
		508-793-0456
New York District	James Wormuth	518-453-2314x30
		513-453-2443
Baltimore District	Jeffrey Sincek*	614-487-1273x16
		614-487-9658
Cincinnati District	Terry R. Bolen	513-679-2700x138
	Jeffrey Sincek*	614-487-1273x16
New Jersey District	Jeffrey Sincek*	614-487-1273x16
		614-487-9658
Philadelphia District	Robert E. Davis	412-644-3394x13
		412-644-5496
Atlanta District	Thomas D. Clarida	704-344-6116
		704-344-6402
Florida District	Janneth Caycedo	561-338-5236x23
		407-367-8685
New Orleans District	Karen Smallwood	615-781-5380x144
	Carl Huffman	615-781-5391
San Juan District	Jorge Martinez*	787-474-9533
		787-729-6747
Chicago District	Dennis E. Swartz*	313-393-8156
		313-393-8139
Detroit District	Dennis E. Swartz	313-393-8156
		313-393-8139
Minneapolis District	Thomas W. Garvin	414-771-7167x12
		414-771-7512
Dallas District	John D. Mays	214 253-4935
	Deborah McGee	214 253-4935
	Scotty L. Hargrave	214 253-4935
		214-253-4960
Kansas City	Reggie Cope	913-752-2403
		913-752-2413
Denver District	Robert G. Antonsen	303-236-3025
		303-236-3551
Los Angeles District	Suzie Kent*	208-334-1054
		208-334-1053
San Francisco District	Suzie Kent*	208-334-1054
		208-334-1053
Seattle District	Suzie Kent*	208-334-1054
		208-334-1053

*Providing auditor functions for district

**SAMPLE WARNING LETTER-NONCOMPLIANCE DECLARATION WITH DISTRICT
ORDERED ASSEMBLER RECALL LETTER TO X-RAY ASEMBLERS**

WARNING LETTER

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE

FIRM NAME

FIRM'S COMPLETE ADDRESS

Dear (Addressee) :

Field compliance testing of fully certified diagnostic x-ray systems assembled by (firm name) since (date) has shown that (number, e.g., 43) percent of the x-ray systems tested failed to comply with the Performance Standard for Diagnostic X-ray Systems and Their Major Components (Performance Standard). Diagnostic x-ray equipment are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The Food and Drug Administration (FDA) has issued (number, e.g., 12) letters to you addressing your firm's noncompliant assemblies, yet you continue to install diagnostic x-ray systems that fail to comply with the Performance Standard. Based on this high rate of noncompliance with the Performance Standard and your inability to provide assurance that x-ray systems which you assemble will comply with the Performance Standard, the FDA has determined that you fail to comply with Title 21, Code of Federal Regulations (21 CFR), section 1020.30(d). Therefore, the FDA declares your assemblies since (date) as noncompliant. As noted below, you are required to provide user notification and corrective action plan (CAP) for the recall of your assemblies.

You are advised that it is a prohibited act under the Federal Food, Drug, and Cosmetic Act, section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968), to fail to correct electronic products that do not comply with an applicable standard, or that have a defect which relates to the safe use of such products. Additionally, under the Act, it is a prohibited act to adulterate a medical device after receipt in interstate commerce. Your installations are in violation of 21 U.S.C. 351(c) because they fail to have the quality that they purport or are represented to possess in that they do not comply with the Performance Standard for Diagnostic X-ray Systems and Their Major Components, 21 CFR 1020.30.

You must respond in writing within 15 working days of receipt of this letter and provide the number of x-ray assemblies you have completed since (date). In responding, you have the following options:

1. Refutation - You may submit your views and evidence in accordance with 21 CFR 1003.11(a)(3) to establish that the alleged noncompliances do not exist, do not relate to the safety of the product, or are directly attributable to user abuse or lack of maintenance. Should you choose to refute the allegation of noncompliance, you will have an opportunity to request a hearing under 21 CFR part 16.

2. Exemption Request - If you do not refute the alleged noncompliance, in accordance with 21 CFR 1003.30, you may request an exemption from the requirements of user and dealer/distributor notification found in 21 CFR 1003.10(b) and from the obligation to correct the violative products found in 21 CFR 1004.1. You must include the grounds upon which such exemption is requested. Please see 21 CFR 1003.31 for further information on what constitutes reasonable grounds for an exemption.
3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you will be required to (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost at no charge to the user.
 - a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to this office. It is recommended that you submit a draft of any letters to us for review and concurrence prior to mailing. Please submit such drafts with your response to this letter, because, under 21 CFR 1003.11(c), you will have only 14 days to furnish the notification to purchasers and dealers/distributors once we direct you to begin notification.
 - b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, and 1004.4. Such a plan must expeditiously correct the noncompliance and must be approved by FDA. (See 21 CFR 1004.6)

If you require additional time to prepare your refutation, notification, CAP, or evidence to support an exemption request, you must submit within 15 working days of the receipt of this letter a written request to this office, which outlines the reasons for any delays and a reasonable target date for submission of your response. If you do not respond within 15 working days, the agency may consider you to be in violation of section 538(a)(2) and 538(a)(4) of the Act.

Please be advised that if your refutation or exemption request is not accepted by the FDA, you must submit a CAP for all certified diagnostic x-ray systems you have assembled since (date). An acceptable CAP submission must include:

1. An agreement to test all assemblies of certified components installed since (date), to ensure that all assemblies comply fully with the Performance Standard.
2. A statement of the testing to be performed, and a copy of the test method.
3. An agreement to correct any items of noncompliance detected by the above testing, at no cost to the user. If you can document that the noncompliance is directly attributed to user abuse or attributable to servicing by another party, you may submit this evidence in lieu of correcting the noncompliance.

4. A listing of all equipment to be used in the testing and calibration of diagnostic x-ray systems.
5. An agreement that all equipment that will be used in testing and calibration will be within current calibration.
6. The number of certified systems assembled since (date).
7. A timetable for the correction of all affected systems.
8. An agreement to submit copies of all test data for FDA review.
9. A copy of the notification letter to be sent to affected purchasers or a draft of said letter.
10. Provisions to ensure that all future assemblies of certified diagnostic x-ray systems comply with all aspects of the Performance Standard.

Failure to promptly correct this violation(s) can result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include seizure and/or injunction and/or the imposition of civil penalties as provided for in section 539 of the Act. Persons violating section 538 of the Act are subject to civil penalties of up to \$1,000 per violation and up to a maximum of \$300,000.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violation(s), including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to (Name), Compliance Officer, Food and Drug Administration, (street address), (City, State & zip code). If you have any questions, (name) can be contacted at (telephone #).

Sincerely yours,

District Director

Enclosures

**GUIDANCE FOR EVALUATING AN ASSEMBLER RESPONSE TO A NONCOMPLIANCE
DECLARATION WITH DISTRICT ORDERED ASSEMBLER RECALL LETTER**

The Federal Food, Drug, and Cosmetic Act (the Act), section 538 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) affords manufacturers the opportunity to respond to a declaration of defect or noncompliance in one of three ways:

1. Submit evidence to refute the alleged defect or noncompliance.
2. Submit an exemption request.
3. Submit a corrective action plan (CAP).

Generally, noncompliance declarations are prepared with the expectation that the manufacturer will submit a CAP. However, some manufacturers may choose to first attempt to refute the cited noncompliance, then seek an exemption, and if not successful, submit a CAP; as noted above, these are all available options.

Evaluating Refutations

If an assembler can demonstrate that more than one individual noncompliant system was not attributable to improper assembly or calibration, the assembler may have a valid refutation for the declaration of noncompliance. The statistics involved in identifying assemblers for coverage in this program are such that a shift of one or two violations greatly affects the decision to pursue a District Ordered Assembler Recall (DOAR). Because of this, we do not include any field tests that are reported to be of manufacturer origin, or are reported as being in dispute.

The refutation needs to have a sound basis. The assembler should submit copies of test data and the test method to demonstrate the system fully complied with the Performance Standard at the time of assembly. Unless such evidence is presented, there is generally no basis for the assembler certification of the respective system.

If you would like assistance in evaluating a refutation, please contact the Diagnostic Devices Branch (HFZ-240) at (301) 594-3332.

Exemption Requests

Exemption requests are permitted by FDA regulations, 21 CFR 1003.30. The regulations require the manufacturer (assembler) to submit his exemption request in writing, within 15 days of receiving a declaration of defect or noncompliance. In the case where refutation has been denied, the exemption request must be submitted within 15 days of receiving written denial of the refutation.

Exemption requests may be granted only if the assembler submits evidence to demonstrate the failure to comply with the Performance Standard does not create a significant risk of injury, including genetic injury, to any person. Since the capability to evaluate such submission does not exist in most FDA District offices, all exemption requests should be forwarded to the Diagnostic Devices Branch (HFZ-240) for evaluation. The Diagnostic Devices Branch will provide the district with their evaluation and a determination as to the acceptability of the exemption request.

Please note that an assembler who has his exemption request denied may contest the denial in a part 16 hearing (21 CFR part 16). It is essential therefore, that all exemption requests be submitted to HFZ-240 for proper evaluation.

If an exemption is granted, no further action is required. Since granting an exemption implies no significant hazard to the user, the violative systems cited may not be used for future legal action (civil penalty or injunction) for the same specific violation.

Please note that the Center does not expect to approve many exemption requests, due to the implied health hazard presented by violative field test results.

When the Center's evaluation of the exemption request is received in the district, it will contain either a draft denial letter, or draft approval letter. If the exemption request is denied, the assembler is required to submit a CAP within 15 working days of receiving the denial letter. The return receipt should be maintained as evidence of receipt by the assembler.

Corrective Action Plan

Corrective action plans (CAPs) must include one of the following options:

1. Repair the noncompliant products.
2. Refund the purchase price of noncompliant product.
3. Replace the noncompliant products with compliant products.

Of the three options, most assemblers elect to repair the noncompliant components. Since the other two options do not require explanation, only the repair option will be discussed further.

The underlying philosophy of declaring as noncompliant all diagnostic x-ray systems installed over certain time period presupposes that combined FDA/State testing has not tested all systems installed by a particular assembler. This implies that there exist other assemblies (not tested by FDA or the State) of diagnostic x-ray equipment, which also fail to comply. The purpose of the noncompliance declaration is to obtain a CAP, which will require the testing (and correction) of previously untested system.

An acceptable CAP will contain the following elements:

1. The assembler's proposed method of re-testing all assemblies of certified components installed within the specified time period. (CDRH will help the district with the time frame to be cited in the noncompliance declaration.)

2. A statement of the testing to be performed and a copy of the test method.
3. A listing of all equipment to be used in the testing.
4. Documentation that all equipment used in the testing will be properly calibrated.
5. The number of certified systems assembled during the period covered by the noncompliance declaration.
6. A timetable for the correction of all affected systems.
7. Provisions to submit copies of all test data for FDA view.
8. A draft notification letter to affected purchasers or a copy of the letter that was sent.

Assemblers generally will not submit such detailed information in their initial response to the district. Once a CAP is received, the district should perform a review, and if further guidance is required, contact the Diagnostic Devices Branch (HFZ-240) at (301) 594-3332. Since submission of a CAP represents a commitment to correct the violative products, an establishment inspection should be scheduled to collect the recall information.

During this inspection the investigator may obtain the above commitments regarding the CAP. If an inspection cannot be conducted in a timely manner, a letter to the assembler requesting the required information may be sent in lieu of an establishment inspection.

An establishment inspection at this point may check that all items enumerated above can be provided. The investigator should confirm the following:

- The assembler has the test equipment to perform the required testing.
- Measurement equipment is properly calibrated.
- The adequacy of any test method to be used in compliance testing.
- The assembler has maintained records for tracing assemblies of diagnostic x-ray systems.
- The assembler has adequate personnel to perform the testing.
- The assembler is capable of meeting specified timetables for correction of all systems.

You should consider granting a 30-day grace period for submitting the above information. Assemblers may require this much time to prepare an adequate CAP. If additional time is required, advise the assembler in writing that he must provide the user notification to affected purchasers within 15 working days of receiving this letter or he will be in violation of The Federal Food, Drug, and Cosmetic Act (the

Act), section 538(a)(2) of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

Please note: Exemptions usually only apply to products already introduced into commerce, not to future or ongoing installations. A variance may be requested and granted for an assembler to continue the introduction of products into commerce which do not comply with a part of the Performance Standard in accordance with 21 CFR 1010.4.

**SAMPLE USER NOTIFICATION LETTER FOR DISTRICT ORDERED
ASSEMBLER RECALL AND CAPS**

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

DOCTOR'S NAME
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (Addressee) :

(Firm name, e.g., ABC X-ray Company) has been advised by the Food and Drug Administration (FDA) that diagnostic x-ray systems assembled by ABC X-ray Company since January 1, 1985, may fail to comply with the Performance Standard for Diagnostic X-ray Systems and Their Major Components (Performance Standard). The FDA advised that (number, e.g., 43) percent of the (number, e.g., 27) systems they tested failed to comply with the Performance Standard for Diagnostic X-ray Systems and Their Major Components, Title 21, Code of Federal Regulations, Section 1020.30.

We are working with the FDA to develop a plan for testing all diagnostic x-ray systems we have installed since (date, e.g., June 1, 1985). Any system we test that fails to comply with the Performance Standard will be adjusted and re-calibrated as necessary to correct the noncompliance. This will be done at no cost to you, the purchaser/ user.

Correction of noncompliant diagnostic x-ray systems is a requirement of the Federal Food, Drug, and Cosmetic Act, section 535 of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

We shall contact you shortly to test your diagnostic x-ray system, and make the necessary adjustments.

Sincerely,

John Doe
ABC X-ray Company

SAMPLE CAP APPROVAL LETTER TO X-RAY ASSEMBLERS

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

RESPONSIBLE INDIVIDUAL, TITLE
FIRM NAME
FIRM'S COMPLETE ADDRESS

Dear (Addressee):

On (date), the FDA sent you a letter advising that between (mo./day/yr.) and (mo./day/yr.), (number, e.g., 43) percent of your assemblies of certified diagnostic x-ray systems that were tested for compliance with the Performance Standard for Diagnostic X-ray Systems and Their Major Components (Performance Standard) failed to comply. Of the three options outlined in our letter, you elected to submit a corrective action plan (CAP). A partial CAP was submitted in your letter of (mo./day/yr.).

On (date), FDA Investigator(s) from this office visited your firm to obtain further information concerning the details of your proposed CAP. On (date), you submitted additional information which resulted in your CAP submission being complete.

We understand that you intend to conduct your CAP as follows:

1. You will identify all installations of fully certified diagnostic x-ray systems that you assembled between (mo./day/yr.) and (mo./day/yr.).
2. You will notify all affected purchasers (via certified mail) concerning your CAP.
3. You will retest all assemblies of fully certified diagnostic x-ray systems (which have not previously been tested by FDA) reported in 1. to determine if each system is in full compliance with the Performance Standard.
4. You will correct all items of noncompliance which you encounter during your retests. You will also notify this FDA office of each of the noncompliances you encounter.
5. _____.
6. _____.

We are approving your CAP contingent upon the following:

1. You will submit monthly status reports which include: (1) the number of systems to be corrected, (2) the number of purchaser notification letters sent, (3) the number of letters returned as undeliverable, (4) the number of systems tested, (5) the number of systems which were noncompliant, and (6) the number of noncompliant systems which were corrected, including details of each noncompliance

Purchaser notification will be made in accordance with all requirements of 21 CFR 1003.21.
This office is to be included in the notification process as if it were a purchaser.

2. _____.

You may commence implementation of your CAP upon receipt of this letter.

Please note that the ABC X-ray Company is responsible for the correction of all certified x-ray systems that you have assembled between (mo./day/yr.) and (mo./day/yr.). Should your CAP prove ineffective, we reserve the right to require you to take more stringent measures.

The Food and Drug Administration classifies corrective action plans for diagnostic x-ray products as recalls. We will notify you of the classification of this recall and the FDA recall number. When making monthly reports or in any future correspondence relating to this CAP, please reference the recall number. Monthly status reports should be sent to:

(Name)
Recall and Emergency Coordinator, HFR-
Food and Drug Administration
(Street address)
(City, State and zip code)

Please be advised that it is FDA policy to report facts surrounding all noncompliances with the Performance Standard in the FDA Enforcement Report. This publication is available to the public.

If you have any questions concerning this matter, please contact (name) at (address), (telephone number).

Sincerely yours,

District Director