SUBJECT:	IMPLEMENTATION DATE
Field Compliance Testing of Diagnostic (Medical) X-ray Equipment	October 1, 2000
	COMPLETION DATE
	September 30, 2003

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
90IZF 90IZL 90KPR 90IZG 90 JAA 90IZH 90JAB 90IZI 90 JAC 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 Radological Health Representative (RRHR) for State file

The following field test records shall be handled in the above manner with order of priority as listed below:

FDA 3071 General Information
FDA 2784 Abovetable X-ray Source Radiographic Systems
FDA 2786 Undertable X-ray Source Fluoroscopic and Spot Film Systems
FDA 3068 Peak Kilovoltage Determination
FDA 3260 C-Arm Fluoroscopic and Spot Film Systems
FDA 3069 Abovetable 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

- Beginning October 1, 1994, routine compliance testing of mammographic equipment will not be conducted by this compliance program unless approved under special consideration by the RRHR. The RRHR will contact the Center for Devices and Radiological Health (CDRH) to receive authorization for such tests. In addition testing of dental units will not be conducted routinely. The RRHR must be contacted to approve special testing for dental units.

- The Home 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 Home 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.

  Submit all violative assembler inspection reports to the District Compliance Branch for review, evaluation, and classification prior to referral to CDRH, Division of Program Operations, HFZ-305. Do not send non-actionable inspection reports to HFZ-305.

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.2. 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.

  Report all time spent in preparation, arranging the test, and on-site conducting of field tests under Operation Code 53 (Field Examination/Test) in the FACTS "Maintain Field Examination/Tests" screen since the test is an inspection of the assembler's performance. Enter the number of tests performed for the assembler on that date and also reference the field test record (FTR) number(s) in the description field.

  SPECIAL AUDITOR INSTRUCTIONS: When performing an on-site audit of an x-ray surveyor, a special entry must be made in FACTS. 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 which was

  conducted.

  Example: Joint Test NJ GI12344
  Joint Test DET GI12345

* Also, report as Operation Code 92, (Coordination/Technical Review) 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-322) will be provided by CDRH on assignment.

* Report newly identified assembler firms to CDRH, HFZ-307 by returning photo copies of assembler forms or submitting inspection reports and indicating in large red letters, in the upper left corner, the words "NEW ASSEMBLER" with their FEI number.

Send copies of all correspondence generated under this program to HFZ-322. 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. *

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 65,000 field tests of certified diagnostic x-ray systems for compliance with the standard.

The most prevalent items of major noncompliance identified under this program have been:

- Inoperable radiographic positive beam limitation (PBL) collimation systems.
- 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.
- Failure of the primary protective barrier interlock for fluoroscopic systems.
- 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.

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 60 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 Subchapter J Part 1000.3(n), all regulations pertaining to noncompliance declarations pertain to assemblers. This process will require the assembler to submit a formal corrective action plan (CAP) and initiate a recall. Should the assembler fail to comply with the NC/DOAR provisions, additional civil penalties can be charged for failure to notify and correct, (Section 538(a)(2).

Previously civil penalties could only be charged for systems for which FDA had field test data or documentation. The noncompliance declaration process includes all assemblies during the specified time applicable to the data analysis and will require the assembler to provide a CAP for all of them. Thus for failure to respond or inadequate response to the NC/DOAR, the assembler faces a greater number of violative charges than initially using the direct civil penalty approach.

Since this strategy is based on a sample of systems installed by the assembler, civil penalties will still be the choice of enforcement strategy 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, and 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. 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 the CDRH in FDA publication number 81-8161 (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 approximately two weeks of OJT with a qualified auditor.

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 normally 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 above an untitled letter. 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.

(6) Infrequent testing of dental and mobile x-ray systems, for training purposes or at the request of CDRH. Mammographic 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 minimal 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-322). 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

No. Installed	No. Tested	No. Noncompliant	%NC
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 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-322. Copies of final signed agreements will also be provided to HFC-150 and HFZ-322. 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 - INSPECTIONAL

A. OPERATIONS

1. Field Testing

a. Test new 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).

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 may only be performed if a major component is certified.

(4) Conduct the field test and complete the appropriate field test record (FTR) as instructed in FDA 81-8161.

(5) Document 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 Compliance HFZ-300 (Do not delay submission or attempt to refute the claimed damages).

NOTE: State survey personnel should immediately report damage to an x-ray system to the RRHR. The RRHR will determine what follow-up is required.

(6) 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.

(7) 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.

(8) 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, and effect correction.

(9) For suspected Class C results, advise the user that computer calculations must 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.

(c) FDA will send the facility a copy of any Notification letter which it issues.

(10) For suspected Class D results, advise the user that while computer calculations must be performed to determine compliance, the system appears to be fully compliant.

(11) 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 "SPECIAL" sticker 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 recommendations 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 which may be pertinent:

- 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 which 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.3 and CPG 7133.12.

(5) Review all Notification or Warning letters for completeness and accuracy 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. Only personnel conducting at least 10 field tests per year will be joint audited. (See Field Management Directive No. 76 for further guidance). 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 on-the-job training (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.

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

Undertable 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.

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 3 years.

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 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.

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 405.2). 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 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-300 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-300 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 testing:

* 1. Within 10 working days following reported correction of all Class A violations by the home district auditor. *

2. Within 30 days following reported correction for at least 10 percent of the Class B violations.

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 STRATEGY

A. 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 mandatory recall (refer to RPM Chapter 7, Attachment F for details). The 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 responsible if the unit was tested within one year of installation
- the user is 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 F (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-322, Phone: 301-594-4591. All necessary samples and other supporting documentation must 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. Section 501(c) charges 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-322) 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 F.

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.

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 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-300.

  g) The State Radiological Health Agency

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 16. If such a request is received by the district, contact HFZ-300 so that arrangements may be made to designate a hearing officer in accordance with 21 CFR 5.30(c).

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-300.

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. To require submission of a CAP for individual violations would prolong indefinitely the correction of violative products.

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 assemblers 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-322) at (301)-594-4591. 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 F 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. Although the Regulations do not require FDA to provide the assembler with this 30-day grace period, additional time should be permitted to prepare a complete CAP since the CAP submission by an assembler has not normally been required.

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-322).

f. The Diagnostic Devices Branch, DOE I, OC, CDRH will assign the recall number, recall strategy, and recall classification as directed in the RPM.

g. Upon receipt of the recall number, strategy, and classification by CDRH, the district will prepare the recall notification.

h. 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.

i. 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 F). Generally audit checks are performed on 10% of the product under recall.

j. 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.

k. 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

In preparing the 24-hour recall alert (Attachment A of RPM Chapter 7), the following standard responses should be used:

a. Product - All assemblies of certified diagnostic x-ray systems performed between _____and _____.

b. Code - All makes and models, including _____ and _____.

c. Recalling Firm - List the names and address of the assembler.

d. Reason for Recall - Field test data collected by the FDA establishes that the recalling firm was routinely assembling certified diagnostic x-ray systems which failed to comply with the Performance Standard. The district issued a noncompliance declaration letter dated _____. The assembler responded with a CAP dated _____.

e. District Follow-Up - Include plans for any follow-up establishment inspection and whether or nor the CAP appears complete.

f. Date district learned of recall - Date of CAP letter from the assembler.

g. Recall initiation date - the date the CAP is received in the home district.

4. Preparing the Recall Recommendation

a. Product - Certified diagnostic x-ray systems assembled by _____ between _____ and _____. The products are used on a daily basis for diagnostic radiology. All units are involved in this corrective action plan.

b. Code - Various

c. Recalled By & How - The assembler, _____, will test all systems for compliance with the Performance Standard, making the necessary corrections to bring each system into compliance.

d. Manufacturer - Products are assembled by the recalling firm using certified diagnostic x-ray components from a variety of manufacturers.

e. Date of recall - The date of the CAP. Since the CAP approval letter has not been issued, this is the date of the assembler response to the noncompliance declaration.

f. Reason - As described in Attachment A.

g. Distribution - Self explanatory.

h. Quantity - The number of certified x-ray systems covered by the CAP.

i. Current Status - Recall not started; Cap must be approved.

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-300.

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-300.

   - 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 F and Chapter 6.
4. BRH "Routine Compliance Testing for Diagnostic X-ray Systems or Components of Diagnostic X-ray Systems to which 21 CFR Subchapter J is Applicable", Revised December 1980, DHEW Publication (FDA) 81-8161.
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, MEB, 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 Assembler Noncompliances 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 Field Programs Branch, Division of Program Operations, Office of Compliance, CDRH, telephone number (301) 594-4695. Secondary contact may be made with individuals listed on Attachment C.

2. ORA Contact - The ORA Headquarters contact for this compliance program is ORO/DEIO (HFC-130), Cdr. James M. Simpson, USPHS, telephone number (301) 827-1124.

PART VII - CENTER RESPONSIBILITIES

A. The CDRH shall:

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 Compliance. Portable test equipment will be supplied if needed by the Office of Science and Technology.

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 Compliance.