

Compliance Program for Field Compliance Testing of Cabinet X-ray Equipment (CP 7386.004); Final Guidance for Industry and FDA Staff

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This document supersedes "Field Compliance Testing of Cabinet X-ray Equipment" (CP7386.004) dated September 30, 1996.



**U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Electronic Products Branch
Division of Enforcement III
Office of Compliance**

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, 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.

For questions regarding the use or interpretation of this guidance contact Daniel Kassiday at (301) 594-4654 or email at dfk@cdrh.fda.gov.

Additional Copies

Additional copies are available from the Internet at:
<http://www.fda.gov/cdrh/comp/guidance/57.pdf> or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 57 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Guidance on Field Compliance Testing of Cabinet X-ray Equipment (CP 7386.004)

This document is intended to provide guidance. It represents the Agency'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 the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

CHAPTER 82 - MEDICAL AND RADIOLOGICAL DEVICE MONITORING AND QUALITY
CONFORMANCE

SUBJECT: FIELD COMPLIANCE TESTING OF CABINET X-RAY EQUIPMENT Attachments A-E		IMPLEMENTATION DATE Upon Receipt of Final Document
		COMPLETION DATE September 30, 2005
DATA REPORTING		
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES	
94 IS-11 and 94 IS-21	86004	

FIELD REPORTING REQUIREMENTS

Hardcopy Reports to Headquarters

- Submit all OAI EIRs, attachments, exhibits, user location lists, airport baggage x-ray location lists, and field test records to the CDRH, Office of Compliance, Electronic Products Branch HFZ-342. Airport baggage x-ray systems are those located at airports.

Hardcopy Reports to Other Field Locations.

- Submit a copy of all user location lists, investigations, and field test records to the home district of the manufacturer, districts containing at least one user location, and the Regional Radiological Health Representative (RRHR) for State and/or Federal Aviation Administration (FAA) files.

FACTS

- The accomplishing district where the inspection was performed should enter all FACTS data.

PART I - BACKGROUND

The Performance Standard for Cabinet X-ray Systems (Title 21 CFR § 1020.40), which includes baggage x-ray systems, requires that the radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliRoentgen (mR) in one hour at any point 5 centimeters (cm) from the external surface. This exposure shall not be exceeded with the cabinet x-ray system operating under conditions which will maximize x-ray exposure at the external surface. These requirements apply to all cabinet x-ray systems manufactured or assembled on or after April 10, 1975. Requirements regarding x-ray systems designed primarily for the inspection of carry-on airline baggage, however, apply to systems manufactured or assembled on or after April 25, 1974.

PART II - PROGRAM

A. OBJECTIVES

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

1. Identify certified cabinet x-ray systems that fail to comply with applicable performance standard requirements through field testing.
2. Obtain correction of noncompliant cabinet x-ray systems identified in (1) above, or remove those systems from use.

B. PROGRAM MANAGEMENT INSTRUCTIONS

1. Planning Instructions

Updated lists of cabinet x-ray manufacturers will be provided to the RRHR's by CDRH bi-annually, during the first quarter of the fiscal year. A copy of the updated list of manufacturers can be requested from the RRHR or CDRH via e-mail. Each district must review the list of cabinet x-ray manufacturers to determine inspection obligation. During the first quarter of the fiscal year, each home District with an inspection obligation shall:

- a. Contact, via telephone, cabinet x-ray manufacturers in their district to determine if they have introduced cabinet x-ray systems into commerce within the last 12 months. Cabinet x-ray manufacturers are those firms engaged in the business of manufacture or importation of cabinet x-ray systems. If a firm is not active, proceed to paragraph 'd' of this section.
- b. Every two years, each district must either inspect all active firms or collect a user location listing through alternate means. The district should plan to conduct inspections or collect user location listings for approximately half of the assigned firms each year. Any inspections performed should be scheduled in advance. During the inspection, investigators should obtain user location listings for all systems sold within the U.S. to dealers, distributors, and users within the last 24 months or create a listing from the firm's distribution records. Further guidance on the conduct of the inspection, including the content of the user location listing, is found under Part III of this document, Section A - Operations, Paragraph 1 - Inspections.
- c. Distribute the user location list of cabinet x-ray systems not located at airports to the applicable testing districts and CDRH in accordance with the Field and HQ Reporting Requirements found on the cover page of this document. Distribute the user location list of airport baggage cabinet x-ray systems to CDRH only. If possible, send sorted lists

to each district containing only those user locations within the district. Otherwise, distribute the entire list to each district.

NOTE: Airport installations are to be inspected only if requested by CDRH, FAA, Customs, or Department of Agriculture (USDA). If requested, coordinate the test with the appropriate agency.

- c. Notify CDRH of firms that are not actively manufacturing cabinet x-ray systems in the United States. If possible, identify whether the firm is out of business (OOB), inactive (has not manufactured a system within the last 24 months) but may manufacture cabinet x-ray systems in the future, or inactive and does not plan to manufacture cabinet x-ray systems in the future. If a firm has gone OOB or inactive because its product lines were sold to another manufacturer, identify the name, address, telephone number, and e-mail address of the new manufacturer. Send this information via e-mail to the first contact under the General Contacts list (Attachment A).
- d. Notify CDRH of any new manufacturers or importers. Send information on these firms via e-mail to the first contact under the General Contacts list (Attachment A).

2. Field Test Priorities

- a. Review all user location lists received from home districts of cabinet x-ray manufacturers and schedule field tests in accordance with the ORA Workplan. Manufacturers designated as high priority will be identified in the manufacturer list sent by CDRH to the RRHR's. New manufacturers and firms with a history of noncompliances are always high priority.

This program should gather data on a variety of models and manufacturers of cabinet x-ray systems. Therefore, do not test more than one of any one model system in any one year unless you are verifying a noncompliance for that specific model.

Field tests performed at Federal facilities **DO NOT** count towards the completion of this program unless the system is tested within two calendar years of the system's installation. Please continue to forward Federal facility tests to CDRH and the system's manufacturer's home district.

NOTE: Test Airport Baggage X-ray Systems only if *requested by CDRH, FAA, Customs, or USDA*.

- b. When a cabinet x-ray system becomes damaged during a field test, the owner, investigator, and supervisor should complete the appropriate sections of the form FDA-2766 entitled, Claim for Damages to an Electronic Product. Instructions for completion are on the back of the form. The RRHR should review the form for completeness and accuracy before it is forwarded to CDRH.

The forms mentioned in this CPGM may be obtained by writing a letter or memo directly to:

Consolidated Forms and Publications Distribution Center
Washington Commerce Center
3222 Hubbard Road
Landover, MD 20785

Alternatively, forms may be ordered via intranet. See (internal web link)

3. RRHR Management Activities

The RRHR is the principal contact with the FAA, Customs, USDA, State and local agencies for issues relating to cabinet x-ray system radiation safety. The RRHR will:

- a. Arrange for and oversee the training of interested State and local personnel who have a comprehensive x-ray background.
- b. Monitor field test reports to assure that the reports submitted by the State or local agencies are accurate and complete prior to distribution and submission to headquarters.

NOTE: State participation must be in accordance with CDRH procedures for collecting cabinet x-ray field test data. Field tests done by State personnel do not count toward District workplans.

- c. For airport baggage systems tested on request from FAA, telephone the FAA if Class A or B violations are reported and request that FAA withdraw authorization for system usage until the system is brought into compliance. Also, request that FAA notify FDA when the suspension of operations has been accomplished and/or violations corrected. Confirm telephone contact with a written notification and copy of the Field Test Record (FDA-2903).
- d. Forward a copy of the Field Test Record (FDA-2903) to the appropriate FAA and state officials for all Airport Baggage X-Ray field tests completed under this program.

4. Personnel Radiation Monitors

Field personnel must wear personal radiation monitors, such as thermal luminescent dosimeter badges, when performing tests under this program. These monitors are available through the RRHR from the Health Physicist at WEAC. The current contact at WEAC is Ed Baratta, (781) 729-5700 ext. 728, e-mail ebaratta@orahq.ora.fda.gov.

5. Calibration of Radiation Meters

Field personnel are responsible for contacting OST to have their radiation meters re-calibrated annually. Any problems or malfunctions of radiation meters should be reported to OST (Attachment C) as soon as possible.

PART III - INSPECTIONAL

A. OPERATIONS

1. Inspections of Manufacturers and Acquiring User Location Lists

The following operations should be covered:

- a. Inspect pertinent records and files of the firm, and obtain the following user information from distribution (sales) records for the last 24 months:
 - 1) The name and address of each purchaser of record. If different from the purchaser, obtain the address and name of the user location where the system is installed. Where possible identify a contact person and telephone number. (see b. for further details).
 - 2) The model and serial number of each cabinet x-ray system sold.
 - 3) The purpose for which each model cabinet x-ray system is intended; i.e., baggage, security, food, electronics, etc.
 - 4) The date on which each cabinet x-ray system was manufactured.
 - 5) Identify any model cabinet x-ray system that only operates in a mode where the beam will not be on for at least 7 continuous seconds. The Victoreen 440 RF/C or 440 RF/D meter used to survey these systems does respond to radiation quickly. The 440 RF/C meter has a response time of 12 seconds and the 440 RF/D meter has a response time of 7 seconds. The meter must be placed in the radiation field for no less than the response time of the meter you are using to obtain an accurate measurement.
- b. Prepare user location lists, sorted by district, for all systems sold within the U.S. to dealers, distributors, and users within the last 24 months. A summary of the types of cabinet x-ray systems should be provided with the user location list to indicate the number of each type of system installed by the manufacturer. The type of system is based on its purpose as described in a.3 above.

If the manufacturer makes both airport baggage systems and other types of systems request that the manufacturer sort the user locations into two lists. One user location list will cover airport baggage systems and the other user location list will cover all other systems. Also, request that the other systems' user location list be sorted by zip code.

Encourage the manufacturer to provide sorted information during the next scheduled inspection if they can not do so during the current inspection.

NOTE:

1) If the manufacturer has provided an adequate user locations list via alternate means an inspection is not required.

2) If the manufacturer's user location list does not follow the suggested format, it **IS NOT** a violation of the regulations or law. We recommend that the user location list is requested and format discussed when the inspection is scheduled. This should enable the manufacturer to provide appropriate information while you are present. If a user location list is not provided, you should be able to assemble one during inspection of the manufacturer's records. Inadequate records are a violation of the regulations and indicate a need for closer examination of other records and the quality control and testing program.

- c. Check the calibration records to assure that all instrumentation for measuring leakage radiation is currently in calibration. Equipment that is out of calibration or uncalibrated might indicate that systems were falsely or inappropriately certified.

Note: There is no requirement that a "calibration sticker" be on each instrument. The establishment may keep a calibration history for their instruments at the supervisor's desk, or some other place readily available to test personnel.

- d. Document any failure to maintain the required records or failure to certify the manufactured systems, or evidence of noncompliant or defective units. If possible, request to see some of their test procedures performed (if there is a system present) for various requirements of the standard. Requirements to be tested include the leakage limit, door and access panel interlocks, "x-ray on" indicators, and for baggage systems a mechanism to assure operator presence. There should be complete test records for systems sold during the previous year.
- e. Request evidence that the firm submitted a report or supplement for its most recent cabinet x-ray system model and its latest annual report on cabinet x-ray systems. The annual report is due on September 1 of each year and covers July 1 of the previous year through June 30 of the current year. 21 CFR 1002.7 contains the address to which the report should have been sent.

NOTE: Records may be maintained at foreign manufacturing locations, in which case importers, who are considered to be manufacturers (as defined by Section 531 of the Act and by 21 CFR 1000.3(f)), may only possess user location lists.

- f. If the results of the inspection are NAI or VAI send a follow-up letter to the firm. Examples can be found in Attachment E. OAI inspections should be referred to CDRH.
2. Field testing at User Locations
- a. Schedule an appointment with the user prior to the field test. Tell the user that the purpose of the visit is to conduct a "survey of cabinet x-ray systems to determine compliance with the federal performance standard for cabinet x-ray systems."
- b. Request that persons familiar with the operation of the x-ray equipment be available to assist in the operation of the equipment.
- c. Collect data in accordance with the written procedures prescribed in Part VI. A. reference 3, "Routine Compliance Testing for Cabinet X-ray Systems to which 21 CFR Subchapter J is applicable, dated March 1985." If it is determined that the written procedures cannot be followed, describe in detail the variance from the prescribed procedure in the comments section of the test form.
- d. Classify test results in accordance with Attachment D. The specific reporting procedure and immediate follow up by the field is determined by classification of the noncompliance. Write the classification at the top of the first page of the field test record and in the comment section.
- e. Advise the owner and/or person responsible for the equipment of the test results in the following manner:
- 1) Class A Conditions - Advise the dealer or owner/operator of the field test results and that:
- a) The system could be hazardous to the operators, passengers, etc., in close proximity.
- b) Routine use should be discontinued until corrected by the manufacturer.
- (Note: The FDA does not have the authority to require the discontinued use of commercial or baggage x-ray systems; however, the State may have such authority. For airport baggage inspection systems, the FAA does have this authority as defined in Part VI.A.4)
- c) CDRH will contact the manufacturer immediately about the correction of defects or items of noncompliance.

- d) The appropriate RRHR will notify the responsible State officials (and local FAA, Customs, or USDA authorities if airport baggage inspection systems are involved).
- 2) Class B and C Conditions - Advise the dealer or owner/operator of the field test results and that:
 - a) The unit is not in compliance with the cabinet x-ray standard.
 - b) Further investigation may be required for the unit.
 - c) CDRH will contact the manufacturer regarding the correction of defects or items of noncompliance.
 - d) The appropriate RRHR will notify the responsible State officials (and local FAA, Customs, or USDA authorities if airport baggage inspection systems are involved).
 - 3) Class D Conditions - Advise the dealer or owner/operator of the test results and that the unit appears to be in compliance with the cabinet x-ray standard.

f. Reporting

(See Cover Sheet "Field Reporting Requirements" for field test record distribution)

- 1) Class A Conditions:
 - a) Contact CDRH (Attachment A) and the RRHR by telephone immediately.
 - b) Flag the Field Test Record (FDA-2903) by writing 'A' on the top of the form and mark it with a highlighter pen and distribute within 24 hours.
- 2) Class B Conditions:

Flag the Field Test Record (FDA-2903) by writing 'B' on the top of the form and mark it with a highlighter pen and distribute within 7 days.
- 3) Class C and D Conditions:

Distribute the Field Test Record (FDA-2903) as marked on a monthly basis.

g. Special Instructions

- 1) If there are questions about the test results, instrument error, potential risks to persons, etc., contact individuals listed in Attachment B or the RRHR.
- 2) When an owner claims x-ray equipment damage resulting from a field test performed by FDA personnel refer to Part II, B.2.b. Special Instructions.

3. Domestic Sample Collections

No physical samples will be collected under this program. Collect documentary samples as necessary to document conditions of noncompliance and violations of Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) of Chapter V, of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (See IOM 405).

4. Personnel Qualifications and Training

To prevent personal injury, and due to the complexity of the testing procedure, only personnel who have received scientific training specific to this program may perform the required testing of cabinet x-ray systems. This training will be coordinated by the RRHR and supervised by personnel experienced in x-ray testing and safety. The background knowledge is covered in diagnostic x-ray testing or mammography x-ray system testing training courses provided by CDRH. Specific training on the cabinet x-ray testing procedure is on the job training provided by experienced investigators.

PART IV - ANALYTICAL

No laboratory testing will be done under this program.

PART V - REGULATORY/ADMINISTRATIVE FOLLOW-UP

A. REGULATORY PHILOSOPHY

Cabinet X-ray equipment is subject to a performance standard and is regulated under Subchapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968) of Chapter V, of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Violations of the Electronic Product Radiation Control provisions include the introduction into commerce of any electronic product which is defective or does not comply with an applicable standard; failure to maintain or submit required reports; failure to maintain or make available distribution records; failure to certify; and false certification.

Occasionally cabinet x-ray systems will also be medical devices in which case medical device authorities may be used in addition to radiation control authorities. If this situation occurs, please contact CDRH to develop an appropriate strategy.

B. CDRH RESPONSIBILITIES

The CDRH is responsible for all administrative and regulatory actions, regulatory follow-up, and for the issuance of all notices of violations to factory-based manufacturers. CDRH actions against manufacturers may include untitled letters, Warning Letters (which includes declaration of noncompliance, mandatory recall, and disapproval of quality control program), civil penalties, and/or injunction.

C. DISTRICT RESPONSIBILITIES

Where a field inspection report documents record keeping violations or a field test record determines that a product is defective or noncompliant with the standard, the district should forward the report or test record to CDRH for regulatory action. The district may recommend issuance of Warning Letters for noncompliances with the performance standard or for first-time violations of Section 538 of the FD&C Act.

Districts will also monitor corrective action programs (recalls) approved by the CDRH in accordance with the Regulatory Procedures Manual, Chapter 7, Attachment F. The issuance of the declaration of noncompliance and the approval of a corrective action plan by the Center does not preclude the consideration of other regulatory or administrative actions for violations of the Electronic Product Radiation Control provisions of the FD&C Act based on the results of a field test or inspection, or where the corrective action plan is found to be ineffective.

Districts may recommend civil penalties for failure to correct products or other continuing or willful violations of Section 538 of the FD&C Act or injunction for serious hazards such as excessive radiation emission. Consult Compliance Policy Guide 390.300 and Regulatory Procedures Manual, Chapter 6 SUBCHAPTER Civil

Penalties – Electronic Product Radiation Control, for guidance on civil penalties. Informal consultation with the Center at an early stage in the development of a regulatory action is recommended in order to facilitate timely implementation of the action; contact the Chief, Electronics Products Branch, Division of Enforcement III, Office of Compliance, HFZ-342, (301) 594-4654. The Chief of the Electronic Products Branch is contact 2 on the general contacts list found in Attachment A.

PART VI - REFERENCES, ATTACHMENTS AND PROGRAM CONTACTS

A. REFERENCES

Note: Items 1, 2, and 3 can be obtained from FDA's web site at:
<http://www.fda.gov/cdrh/radhlth/index.html>

1. Title 21 Code of Federal Regulations, Subchapter J – Radiological Health. Relevant sections include Title 21 CFR 1002, 1003, 1004, 1005, 1010, and 1020.40.
2. Title 42 U.S. Code 263b, ET SEQ., Radiation Control for Health and Safety Act of 1968 (P.L. 90-602). Note: This act was incorporated into the Federal Food, Drug, and Cosmetic Act as Subchapter C – Electronic Product Radiation Control.
3. Routine Compliance Testing for Cabinet X-ray Systems to which 21 CFR Subchapter J is applicable, dated March 1985.
4. Title 14 Code of Federal Regulations, Section 108.17, Use of X-ray systems.

B. ATTACHMENTS

1. ATTACHMENT - A. General Communications List
2. ATTACHMENT - B. List of CDRH Personnel to Contact on Test Procedures and Instrument Usage
3. ATTACHMENT - C. List of CDRH Personnel to Contact on Procurement, Maintenance, and Repair of Instrumentation.
4. ATTACHMENT - D. Classification of Items of Noncompliance for Certified Systems.
5. ATTACHMENT - E. Location and Field Testing Priority List for Cabinet X-ray Equipment Manufacturers.

C. PROGRAM CONTACTS

1. CDRH Contact - Questions concerning this compliance program should be directed to Debra Adams, CDRH, Office of Compliance, Division of Program Operations, HFZ-306, 301-594-4695. Secondary contact may be made with individuals listed on Attachment A.

2. ORA Contact - The ORA Headquarters contact for this compliance program is CDR James Simpson, USPHS, Office of Regional Operations, Division of Emergency and Investigational Operations, HFC-130, (301) 827-1124, fax (301) 443-6919.

PART VII - CENTER RESPONSIBILITIES

A. THE CDRH SHALL:

1. Notify the region and the home district of the status of compliance actions within their jurisdictions.
2. Revise and update the directory of known cabinet x-ray system manufacturers as needed. Note: The source of this information is from product reports and reports from field contacts about OOB and inactive firms. The current manufacturer list can be obtained via email to contact 1 on the general communications list (Attachment A).
3. Notify manufacturers of defective and noncompliant cabinet x-ray systems.
4. Issue follow-up assignments to the field to document noncompliances.
5. Monitor first quarter distribution of cabinet x-ray user location lists to testing districts and assist districts in obtaining test locations.
6. Provide meters needed to accomplish the field testing activities (OST).

GENERAL COMMUNICATIONS LIST

<u>Who</u>	<u>Telephone number</u>	<u>E-mail address</u>	<u>Mail Code</u>
1. Daniel Kassiday	(301) 594-4654	dfk@cdrh.fda.gov	HFZ-342
2. Collin Figueroa	(301) 594-4654	cxm@cdrh.fda.gov	HFZ-342
3. Gladys Rodriguez	(301) 594-4646	gor@cdrh.fda.gov	HFZ-340

Regional Radiological Health Representatives

<u>Who</u>	<u>Telephone number</u>	<u>E-mail address</u>	<u>Mail Code</u>
1. Ronald Bernacki	(718) 662-5612	RBERNACK	HFR-NE19
2. Lynn Jenkins	(312) 353-9400 x129	LJENKINS	HFR-CE19
3. Tom Trout	(615) 781-5380 x171	RTROUT	HFR-SE19
4. Belinda Collins	(214) 655-8100 x148	BCOLLINS	HFR-SW19
5. Ken Miles	(510) 637-3960 x122	KMILES	HFR-PA19

Additionally it may be useful to contact the X-Ray Monitors and/or Auditors who are listed in the IOM distributed by ORA.

*LIST OF CDRH PERSONNEL TO CONTACT ON TEST PROCEDURES AND
INSTRUMENT USAGE*

<u>Who</u>	<u>Telephone number</u>	<u>E-mail address</u>
1. Daniel Kassiday	(301) 594-4654	dfk@cdrh.fda.gov
2. Frank Cerra	(301) 443-2536 ext. 123	fxc@cdrh.fda.gov

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

The following is a list of Office of Science and Technology staff to be contacted for questions regarding equipment used in field compliance testing of cabinet x-ray equipment.

Do not send instruments to headquarters for calibration or repairs until one of these individuals has been notified.

1. Frank Cerra 301-443-2536 ext. 123 fxc@cdrh.fda.gov

CLASSIFICATION OF ITEMS OF NONCOMPLIANCE
CERTIFIED CABINET X-RAY SYSTEMS

(Baggage inspection systems manufactured on or after April 25, 1974, and other cabinet systems manufactured on or after April 10, 1975.)

CLASS A

Conditions that pose an immediate radiation hazard to health and safety. The reporting of accidental radiation injuries is included in this category.

1. Failure of all safety interlocks on a door or access panel. System is capable of generating x-radiation with a door or access panel open.
2. X-ray leakage is greater than 10 mR in 1 hour at a distance of 5 cm from the external surface of the cabinet x-ray system.
3. Access to the primary beam is possible through a port. Please consider ergonomic factors when making this assessment.
4. Lack of, or failure of a means to prevent x-ray generation within the interior of a “walk-in” cabinet system.
5. X-ray generation may be initiated from the interior of a “walk-in” cabinet x-ray system.
6. The interior audible and visible warning indicators are absent or are inoperable for a “walk-in” cabinet x-ray system.
7. “Operator Presence” control is not provided or is not functional on a baggage inspection system in a public place such as an airport, train station, port of call, school, or court house. A failure of the operator presence control to function is only a violation if it is a manufacturing defect and not due to user abuse of the system. For example, many users bypass footpad interlocks. If the system’s user caused this failure, contact state regulators to address the issue.

CLASS B

Conditions including defects or major items of noncompliance with the standard.

1. X-ray leakage radiation is greater than 0.5 mR in 1 hour, at a distance of 5 cm from the external surface of the cabinet x-ray system.

2. Use of the "x-ray on" control is not necessary to resume x-ray generation following interlock operation.
3. Key switch with the key captured in the "on" position is not provided or is not functional. A non-functional key switch is a violation only if the manufacturer is responsible for the failure to function.
4. Two "x-ray on" indicators are not provided at x-ray controls or are not functional. Not functional is a violation only if the manufacturer is responsible for the failure to function.
5. An "x-ray on" indicator is not visible from each port, access panel and door, is not provided, or is not functional. A non-functional "x-ray on" indicator is a violation only if the manufacturer is responsible for the failure to function.
6. Warning label at a port is not provided.

Note: If a system shows signs of user abuse or neglect that leads to a noncompliance, contact state regulators to address the issue.

CLASS C

These are items of noncompliance or defects, other than those included under Classes A or B.

1. Certification label is not present, legible or visible.
2. Label stating name and address of manufacturer and date of manufacture is not present, legible, or visible.
3. Warning label at control panel is not present, legible, or visible.
4. Labels indicating the meaning of the interior warning system of walk-in cabinets are not provided, legible, or visible.
5. Instructions were not provided with system when it was installed. (This is difficult to verify. Just because the operator does not know the location of the instructions does not mean they were not provided. Respond to this only if you are assured the instructions were not provided.)

CLASS D

No items of noncompliance were discovered.

MODEL NAI POST-INSPECTION NOTIFICATION LETTER

[The following is an example of a letter intended to be issued in situations classified as NAI where no FDA-483 was issued, or only limited less significant violations were reported:]

Date:

Name:

Address:

Dear:

The Food and Drug Administration (FDA) conducted an inspection of your firm's [description] facility at [address] on [date]. The inspection covered the products described below.

[List of products]

The areas inspected appear to be in compliance with the applicable requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations.

[Include these paragraphs ONLY if the firm manufactures a medical device]{Based on these findings, the agency is prepared to endorse applicable pending pre-market (PMA/510(k)) submissions or Export Certificates for products manufactured at your facility that were specifically inspected. This information is available to Federal agencies when they consider awarding contracts. There may be other products and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address quality system/good manufacturing practices (QS/GMPs) in these areas.

Your firm has an ongoing responsibility to ensure you are continuing to maintain conformance with QS/GMPs. }

For further information, please contact the following individual at this office:

[Name and telephone number]

Sincerely yours,

MODEL VAI POST-INSPECTION NOTIFICATION LETTER

[The following is an example of a letter intended to be used in situations classified as VAI where an FDA-483 was issued, but all profile classes were found to be acceptable. This type of letter should be issued only when no regulatory action is contemplated, including issuing a Warning Letter:]

Date:

Name:

Address:

Dear:

The Food and Drug Administration (FDA) conducted an inspection of your firm's [description] facility at [address] on [date]. The inspection covered the products described below.

[List of products and their profile classes]

While some items of noncompliance/deficiencies were observed during the inspection, they do not appear to warrant regulatory follow-up at this time. These problems were reported to you on the FDA-483 (copy enclosed) issued at the conclusion of the inspection. The problems should be corrected and we encourage you to advise us as to your follow-up actions.

[Include these paragraphs ONLY if the firm manufactures a medical device]{Based on these findings, the agency is prepared to endorse applicable pending pre-market (PMA/510(k)) submissions or Export Certificates for the products manufactured at your facility that were specifically inspected. This information is available to Federal agencies when they consider awarding contracts. There may be other products and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address quality system/good manufacturing practices (QS/GMPs) in these areas.

Your firm has an ongoing responsibility to ensure you are continuing to maintain conformance with QS/GMPs. }

For further information, please contact the following individual at this office:

[Name and telephone number]

Sincerely yours,

Enclosures: FDA-483