Specific Instructions for Cabinet X-Ray Product Inspections and Tests

Purpose

The Radiation Safety Performance Standard for Cabinet X-ray Systems [Title 21 CFR § 1020.40] (performance standard) was designed to protect the public and system operators from unnecessary radiation hazards associated with the use of cabinet x-ray systems. The performance standard sets an exposure emission limit of 0.5 milliRoentgen (mR) in one hour for radiation emitted from a cabinet x-ray system. Additional required safety features include interlocks, indicator lights, and warning labels. The performance standard applies 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 apply to systems manufactured or assembled on or after April 25, 1974.

Specific Instructions

The potential risk from a cabinet x-ray system is dependent on the maximum power that can be delivered to the x-ray tube and the environment in which the system is used. A cabinet x-ray system that can operate at higher peak tube potential and tube current will present a greater potential risk when compared with a lower power cabinet x-ray system. The following is an example of how the use environment affects the potential risk: a cabinet x-ray system used for checking circuit board quality is integrated into an automated production line and very rarely approached by anyone poses a lower potential risk than a carry on baggage security x-ray system which is loaded by members of the public and always has an operator present in close proximity.

Follow the general guidance on inspection, investigation, and field test priorities provided in section II.B.3 above and use your discretion based on the preceding discussion of potential risk. An example inspection checklist of cabinet x-ray specific issues has been included. For further guidance on compliance with specific requirements of the performance standard see the Cabinet X-Ray Compliance Guide (see reference below).

Radiological Health Specialists have been specifically trained in general EPRC requirements and also have specialized training in the cabinet x-ray product performance standards. These specialists should perform cabinet x-ray inspections and field tests, and may train additional field staff or accompany a medical device investigator to conduct joint EPRC/medical device inspections.

When conducting a cabinet x-ray system manufacturer inspection or field test all FDA personnel are required to wear a personal radiation monitor. If you do not have a personal radiation monitor badge, follow the instructions as noted in Part II of this program.

CDRH is responsible for all administrative/regulatory action, regulatory follow-up, and for the issuance of all notices of violations to manufacturers of cabinet x-ray systems.

Field Test Instructions

Generally cabinet x-ray field tests should be performed when requested by CDRH, in response to requests from other federal agencies, to check the validity of a trade or consumer complaint, or when it is necessary for confirmation that a manufacturer's testing program or corrective action plan is adequate.

When performing a cabinet x-ray field test collect data in accordance with the written procedures prescribed in "Routine Compliance Testing for Cabinet X-ray Systems to which 21 CFR Subchapter J is

applicable, Dated March 1985" (see reference below). 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.

Field Test Equipment: MDH meters are not sufficiently sensitive to detect radiation emissions from a cabinet x-ray system. Use only the meters identified in the field test procedure identified below.

NOTE: Cabinet X-Ray Systems installed at airports are not to be field tested except as requested by CDRH, Transportation Security Administration (TSA), Customs and Border Protection (CBP), or Department of Agriculture (USDA). Usually there will be a manager from the relevant agency at the facility containing the system to be tested. Coordinate the test with the appropriate agency on-site manager. Where the national radiation safety contacts are known they should also be contacted. The national contacts for TSA and CBP are included below:

Contacts for Radiation Safety at other Federal Agencies

Name	Phone	Email	Position
Jill Segraves	(571) 227-2292	Jill.Segraves@dhs.gov	Radiation Safety Program Manager, Transportation Security Administration
Richard Whitman	(317)614-4843	richard.t.whitman@dhs.gov	Radiation Safety Officer, Customs and Border Protection

Results for all field tests of TSA or CBP cabinet x-ray systems should be sent CDRH, the appropriate contact listed above, and the on-site manager.

References

Frequently Asked Questions on Cabinet X-ray Systems (March 24, 2003)
http://www.fda.gov/cdrh/radhealth/products/cabinetxrayfaq.html

Compliance Guide for Cabinet X-Ray Systems: Coming soon to the web

Routine Compliance Testing for Cabinet X-ray Systems to which 21 CFR Subchapter J is applicable, Dated March 1985
http://www.fda.gov/cdrh/radhlth/pdf/cabgdeft.pdf

Refer to the Cabinet X-Ray Systems main page for additional information:
http://www.fda.gov/cdrh/radhealth/products/cabinetxray.html

Cabinet X-Ray Product Codes

Translation of 2-Digit Code	Product Name	Product Code		CFR	Definition
Cabinet X-Ray Systems, Non-Medical	Cabinet X-Ray, Industrial, Non-Medical	94	RCE	1020.40	A cabinet x-ray system used for quality control, non-destructive testing, or some other industrial purpose.
Cabinet X-Ray Systems, Non-Medical	Explosive Detection Systems, Cabinet X-Ray Systems, Non-Medical	94	RCF	1020.40	A cabinet x-ray system used for detection of explosives in closed containers such as airline baggage. Usually these systems use a non-standard x-ray mode to perform this function such as computed tomography.
Cabinet X-Ray Systems, Non-Medical	Security X-Ray (includes Baggage X-Ray), Cabinet X-Ray Systems, Non-Medical	94	RCG	1020.40	A cabinet x-ray system used to examine the contents of containers such as airline baggage, brief cases, and purses to detect weapons or other contraband.
Cabinet X-Ray Systems, Non-Medical	Cargo X-Ray, Cabinet X-Ray Systems, Non-Medical	94	RCH	1020.40	A large cabinet x-ray system used to examine pallets full of cargo to find weapons or other contraband.
Cabinet X-Ray Systems, Non-Medical	Other	94	RZZ	1020.40	A cabinet x-ray system used for an unlisted specific purpose.

Classification of Non-compliant Items

Emission Limit			
1020.40(c)(1)(i)	**Exceeds emission limit**		
1020.40(c)(1)(i)	Radiation emission > 10mR in one hour	Major	Class A
1020.40(c)(1)(i)	Radiation emission rate ≤ 10 mR in one hour and > 0.5 mR in one hour	Major	Class B
1020.40(c)(1)(ii)	Emission limit requirements – measurement inadequate	Major	See (c)(1)(i)
Floors			
1020.40(c)(2)	Floor fails to adequately attenuate radiation emission into occupied area underneath x-ray system	Major	See (c)(1)(i)
Ports and Apertures			
1020.40(c)(3)(i)	**It is possible to reach the primary beam through a port**		
	Primary beam greater than 10 R per hour and beam is easy to access	Major	Class A
	Primary beam greater than 10 R per hour and beam is possible but difficult to access inadvertently	Major	Class B
	Primary beam less than 10 R per hour and greater than 5 R per hour	Minor	Class B
	Primary beam less than 5 R per hour	Concern	Class C
1020.40(c)(3)(ii)	**Aperture allows human access to interior of cabinet**		
	Radiation exposure rate in accessed area greater than 5 R per hour	Major	Class B
	Radiation exposure rate in accessed area less than 5 R per hour	Minor	Class C
Safety Interlocks			
1020.40(c)(4)(i)	Safety interlock - door does not have any interlock and emission rate with door open is > 10mR in one hour	Major	Class A
1020.40(c)(4)(i)	Safety interlock - door does not have multiple interlocks	Major	Class B
1020.40(c)(4)(i)	**Neither door safety interlock causes physical disconnect**		
1020.40(c)(4)(i)	Radiation emission rate with interlock failure and door open > 2 mR per hour	Major	Class B
1020.40(c)(4)(i)	Radiation emission rate with interlock failure and door open ≤ 2 mR per hour and > 0.5 mR in any one hour	Minor	Class B
1020.40(c)(4)(i)	**Safety interlocks - disconnect based on movement other than door**		
1020.40(c)(4)(i)	Radiation emission rate with interlock failure and door open > 2 mR per hour	Major	Class B
1020.40(c)(4)(i)	Radiation emission rate with interlock failure and door open ≤ 2 mR per hour and > 0.5 mR in any one hour	Minor	Class B
1020.40(c)(4)(ii)	Lack of safety interlock - access panel and emission rate with access panel open is > 10 mR in one	Major	Class B
1020.40(c)(4)(iii)	Safety interlocks - after an interruption reset of the interlock results in resumption of x-ray production	Major	Class B
1020.40(c)(4)(iv)	Safety interlocks - single component failure disables more than one interlock	Major	Class B
Ground fault			
1020.40(c)(5)	Ground fault can result in x-ray initiation	Major	Class A
Controls and Indicators			
1020.40(c)(6)(i)	Key control - not provided	Major	Class B
1020.40(c)(6)(i)	Key control - not functional	Major	Class B
1020.40(c)(6)(ii)	Controls to initiate and terminate x-rays other than interlocks or power control are not present	Major	Class B

1020.40(c)(6)(iii)	Two independent means of Exposure indication at initiation are not present	Major	Class B
1020.40(c)(6)(iii)	Exposure indication - other than milliammeter is not present	Major	Class B
1020.40(c)(6)(iii)	Exposure indication at initiation – is not visible from control	Major	Class B
1020.40(c)(6)(iii)	Multiple failures of exposure indication caused by a single failure	Major	Class B
1020.40(c)(6)(iii)	Exposure indication - labeling - X-RAY ON is not present	Concern	Class C
1020.40(c)(6)(iii)	Exposure indication - labeling - x-ray tube current is not present	Concern	Class C
1020.40(c)(6)(iv)	Exposure indication required to be visible from a door, panel, or port and is not present	Major	Class B
1020.40(c)(6)(iv)	Exposure indication not visible from each door, panel, or port	Major	Class B
1020.40(c)(6)(iv)	Exposure indication at door, panel, or port is not labeled - X-RAY ON	Concern	Class C
Additional controls and indicators for systems designed to admit humans			
1020.40(c)(7)(i)	No means for preventing and terminating x-rays from within	Major	Class A
1020.40(c)(7)(ii)	X-rays can be initiated from within the cabinet	Major	Class A
1020.40(c)(7)(iii)	No Pre-exposure warning within cabinet	Major	Class A
1020.40(c)(7)(iii)	Pre-exposure warning within cabinet – Warning did not activate at least 10 seconds prior to exposure	Major	Class A
1020.40(c)(7)(iii)	Pre-exposure warning within cabinet - a single failure causes both audible and visual warnings to fail	Major	Class A
1020.40(c)(7)(iv)	No exposure warning within cabinet	Major	Class A
1020.40(c)(7)(v)	Lack of signs giving meaning of warning signals	Major	Class B
1020.40(c)(7)(v)	Lack of signs giving instructions for use of controls to terminate	Major	Class B
1020.40(c)(7)(v)	Signs are not legible, accessible, illuminated	Major	Class B
Warning Labels			
1020.40(c)(8)(i)	Lack of Warning labels - X-rays Produced	Concern	Class C
1020.40(c)(8)(ii)	Lack of Warning labels - Human Access	Concern	Class C
Information to be provided			
1020.40(c)(9)(i)	Instruction manuals - not provided	Minor	Class C
1020.40(c)(9)(i)	Instruction manuals - inadequate technical & safety information	Minor	Class C
1020.40(c)(9)(i)	Assembly instructions - required and not provided	Major	Class B
1020.40(c)(9)(i)	Assembly instructions - not adequate for compliance	Major	Class B
Additional requirements for systems loaded by the public (e.g. Baggage inspection)			
1020.40(c)(10)	X-ray baggage inspection systems (public area) - No means to assure operator presence	Major	Class A
1020.40(c)(10)(i)	No means to terminate exposure	Major	Class B
1020.40(c)(10)(ii)	No means to terminate an exposure sequence	Major	Class B
Modification of a certified system			
1020.40(d)	Modification – failure to re-certify and re-identify	Major	Class B

Cabinet X-Ray Product Inspection Guidance and Field Test Form

Cabinet X-ray inspection checklist.

This guidance is in addition to the instruction provided in Part III.A.2 of this program. Refer to the *Compliance Guide for Cabinet X-Ray Systems* (referenced above) for a detailed discussion of the cabinet x-ray system performance standard.

I. Record Firm Identification, Location, and Contact information

II. Models
   a. What models does the manufacturer produce?
   b. What models are available for observation of certification testing?

III. Performance Requirements
   a. Radiation Emission Limit
      Unlike lasers, the "characterization" of the radiation emitted from a cabinet x-ray system is not relevant. The amount of x radiation emitted is critical. **Note:** The emission limit in the cabinet x-ray standard is for the amount of exposure (less than 0.5 mR) in one hour. It is not a limit on the instantaneous rate of radiation emission.
      i. Is there a written procedure for emission testing?
      ii. Are numerical values recorded for the worst case emission from each system?
      iii. What instruments are used during emission testing? (Record the model and manufacturer of each radiation meter)
         1. Identify the type of each meter (ideally the mfr. should know the type). A few possible types are: ion chamber, Geiger-Mueller (GM), plastic scintillators.
         2. What is the response time for each meter?
         3. Can the x-ray system produce a beam for longer than the meter's response time? Does the procedure specify that x-ray will be produced for longer than the meter's response time?
         4. Is the meter held still at various positions around the x-ray system or is it moved slowly around the system?
            a. If the meter is in motion during an exposure is there a maximum scan speed noted in the procedure?
            b. During the test, is the meter moved slowly enough so that its response time is not a factor?
            c. Is the scan speed limit adhered to by the person performing the test?
            d. Are all the likely points of excess emission checked? If there are emission issues they usually occur at the ports, seems, corners, access panels, and doors.
         5. If the x-ray beam can not be produced continuously can the radiation meter measure an integrated dose?
         6. Does the meter used for the quantitative measurement have a current calibration? What energy was the meter calibrated at? What is the peak tube potential of the cabinet x-ray system?
         7. Does the meter produce a linear response for the expected energy range of emission from the product?
         8. Is the meter sufficiently sensitive in the relevant energy range that it

responds to radiation emission from the product?

iv. If there are calculations involved in determining the total amount of exposure in anyone hour are all the steps clearly identified and justified?
v. What is the rejection limit set by the manufacturer for emissions? If the rejection limit is the same as the limit in the performance standard how is the inherent experimental error in measuring radiation emission from the system accounted for? If less than the limit in the performance standard is it sufficiently restrictive to account for experimental error?
vi. Based on the answers above and observation of the emission test procedure, is the emission testing conducted by the manufacturer sufficient to assure that the product will comply with the performance standard?

b. Are items placed into the cabinet through a port or through a door?
   i. If items are placed into the cabinet through a port is it necessary for someone to hold the item while it is being exposed to radiation? If so can any part of the body reach the primary beam through the port?
   ii. If items are moved into the system on a conveyor belt will any part of the body reach the primary beam during normal operation? (Crawling into the system is not considered normal operations)
   iii. If it appears that it is possible to reach the primary beam inadvertently ask the manufacturer for the exposure rate in the primary beam per hour.
c. If the system has a door does it have a minimum of two interlocks? **Note:** A door is used to put a sample into the cabinet. If a part of the shielding is opened for maintenance it is an access panel not a door.
   i. Is at least one of the interlocks designed so that door opening results in <u>physical</u> disconnection of the energy supply circuit to the high-voltage generator? Occasionally a system may have a "shutter" so that when either the shutter or the door is closed energy continues to be supplied to the high-voltage generator and if both were to open simultaneously then the power would be cut.
   ii. Is the disconnection <u>dependent upon any moving part</u> other than the door? In most cases the secondary physical disconnect interlock will be visible when the door is open. Relays and magnetic switches contain moving parts and do not meet this requirement.
   iii. Will closing the door cause the automatic resumption of x-ray production or is it necessary for an operator to re-initiate x-ray production by taking some action?
d. Does the system have an access panel?
   i. Do all access panels that allow access to the interior of the cabinet require a tool to open?
   ii. Do all access panels have an interlock that prevents production of x-ray when the panel is open?
   iii. Will closing an access panel cause the automatic resumption of x-ray production or is it necessary for an operator to re-initiate x-ray production by taking some action?
e. Has the manufacturer performed a ground fault analysis? Can the product fail via a ground fault in such a way that x-ray production is initiated?
f. Is there a capture key control? Can the key be removed when in a position that allows the production of x-ray?

g. Is there a control to initiate and stop x-ray production other than the power key?
h. Are there at least 2 independent means that indicate when and only when x-ray is being produced? Are they labeled "x-ray on"?
i. Can an x-ray on indicator be seen from any position that a port, access panel, or door can be operated? Is the indicator labeled "x-ray on"?
j. Is the system designed to admit humans? Is the system so large that it would be easy for a human to walk into the cabinet?
    i. Is there a control inside the cabinet for terminating x-ray generation?
    ii. Can x-ray generation be initiated from within the cabinet?
    iii. Are there audible and visible warning signals within the cabinet that are actuated for at least 10 seconds prior to the first x-ray generation after closing any door designed to admit humans?
    iv. Visible warning signal within the cabinet that is illuminated when and only when x-rays are being generated?
    v. Signs that indicate the meaning of the warning signals provided to meet the other requirements of this section?
k. Warning labels
    i. At the location of any controls that can be used to initiate x-rays is there a label that says: **Caution: X-Rays Produced When Energized**
    ii. Is there a label at every port that says: Caution: **Do Not Insert Any Part of the Body When System is Energized--X-ray Hazard**
l. Are user instructions provided to purchasers?
    i. Do the instructions include: Potential, current, and duty cycle ratings of the x-ray generation equipment; and adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the system?
    ii. Do the instructions include a schedule of maintenance necessary to keep the system in compliance with this section?
m. Does the product require the customer or a third party to be assembled? If so are there adequate assembly instructions provided by the manufacturer?
n. Is the product used for security screening of items placed on it by members of the public?
    i. Are there means provided to assure that the operator is present at the control area and in a position that permits surveillance of the ports and doors during generation of x-radiation?
    ii. Are there means provided to assure that the operator can terminate an exposure?
o. Is the manufacturer modifying a previously certified system? If so have they re-labeled the system and re-identified and recertified that the modified product meets the requirements of the performance standard?

Field Test Form

The cabinet x-ray field test procedure uses an official form to record the data. This form, FDA 2903 entitled, Cabinet X-Ray Systems Field Test Record can be found at the FDA Forms Catalog (see the FDA intranet home page under Medical Devices).