ROUTINE COMPLIANCE TESTING FOR CABINET X-RAY SYSTEMS TO WHICH 21 CFR SUBCHAPTER J IS APPLICABLE

March 1985

X-Ray Products Branch
Division of Radiological Products
Office of Compliance
Center for Devices and Radiological Health

CONTENTS

ROUTINE COMPLIANCE TESTING PROCEDURES FOR CABINET X-RAY SYSTEMS

ROUTINE COMPLIANCE TESTING
PROCEDURES FOR CABINET X-RAY SYSTEMS
(use Form FD 2903)

GENERAL GUIDANCE

This procedure is applicable to all Cabinet X-ray Systems including x-ray systems designed primarily for the inspection of carry-on baggage at airports and similar facilities. A Cabinet X-ray System is defined as an x-ray system with the x-ray tube installed in an enclosure which, independently of existing architectural structures, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x-radiation.

The purpose of the Routine Compliance Testing Procedures for Cabinet X-ray Systems is to provide the field inspection data needed to assure compliance of all models of Cabinet X-ray Systems with 21 CFR Subchapter J Part 1020.40, Performance Standard for Cabinet X-ray Systems. Sections of Part 1020.40 are referenced throughout the procedures following the test item for which determination of compliance is intended.

The Routine Compliance Testing procedures for Cabinet X-ray Systems is composed of two parts. Part I contains a general procedure applicable to all cabinet x-ray systems and should be completed in its entirety for each system tested. Part II contains two specific procedures, one for continuously activated systems and one for noncontinuously activated systems or pulsed systems.

When a step or entire section of the procedure does not apply to the system being tested, simply pass over that step or section and continue. If passing over a step or section means that some portion of the data form (FD 2903) will not be completed, draw a large "X" across that entire portion of the form.

The Routine Compliance Testing Procedures for Cabinet X-ray Systems is designed with the assumption that those persons performing the tests are training in radiological health. Because of this no reference is made to the use of precautions. Those persons not thoroughly trained in radiological health should not attempt to perform the Routine Compliance Testing Procedures for Cabinet X-ray Systems.

PART I

ROUTINE COMPLIANCE TESTING

FOR

CABINET X-RAY SYSTEM

PART I

(To be completed for all cabinet x-ray systems)

1.0 PRETEST CHECKLIST

1.1 Complete the general information items of the Field Test Record

A. On page 2 FD 2093 and on FD 2782 (continuation sheet), if attached, copy the preprinted FIELD TEST SERIAL NO. shown on page 1.

IMPORTANT!

The FIELD TEST SERIAL NO. must be shown on each page.

B. Leave "blank" the following items:

REGIONAL REVIEW (NAME and DATE)
HOME DISTRICT
CENTRAL FILE NUMBER
ACCOMPLISHING DISTRICT

C. From the TABLE OF AGENCY CODES, (see Appendix A), select the appropriate FDA REGION number corresponding to the State (or territory) in which the "x-ray system" is located. For example, if the x-ray system being tested is located in Illinois, the corresponding FDA region number is 05.

D. Complete each of the items under NAME AND ADDRESS OF FACILITY AND SPECIFIC LOCATION OF X-RAY SYSTEM.

IMPORTANT!

For each item, limit the sum of letters, spaces, etc., to the number allotted for that item. For example, NAME OF FACILITY (18-80) is limited to a sum of 63 letters, spaces, etc.

1. Use the name of the airport for NAME OF FACILITY if the cabinet system is located at an airport.

2. Use the name of the individual owner for NAME OF FACILITY if the x-ray system is located in a private individual's facility.

3. Use the name of an airport terminal (e.g., North, International) and airline for STREET NUMBER AND NAME if the cabinet x-ray system is located at an airport.

4. For ROOM NUMBER OR OTHER LOCATION OF SYSTEM, use the floor number, description of area, boarding gate, etc. For systems which are movable and not limited to a specific room state the general location where it is used (e.g., a wing, third floor, concourse 23).

5. For PERSONS INTERVIEWED write the initials, last name and abbreviation (e.g., A.B. Jones, Ph.D.; C.D. Smith, M.S.; or E.F. Johnson).

6. Include a TELEPHONE Number if available.

7. For CERTIFICATION LABELS: Indicate Y for "YES" only if the system has a certification label. Indicate N for "NO" if there is no certification label.

8. For Instruments (TYPE AND SERIAL NUMBER), list each instrument type and serial number used for the procedure (e.g., Electrometer Number 85367, Chamber Number, etc.). Use the REMARKS section if additional space is required.

E. Complete each of the items under SURVEYOR INFORMATION - Page 2

1. For SURVEYING AGENCY CODE, use the appropriate code for your agency from the TABLE OF AGENCY CODES. Use State Code only if representing the State government.

2. Use FORM FD 2782 if additional REMARKS space is required.

1.2 Record at items A, B, C, D, E, and F of the Field Test Record the name of the manufacturer, manufacturer code (if known), the model designation, unique I.D. (assigned by CDRH), the system serial number, and the date of manufacture (month, year) from the IDENTIFICATION LABEL. If the manufacturer's address does not appear on the label indicate in the remarks section.

1.3 Place the appropriate letter in item 1.3 to indicate the type of cabinet x-ray systems tested. Classifications of the different types are as follows:

B. Baggage Inspection System - Cabinet x-ray systems designed primarily for inspection of carry-on baggage at airports or other similar facilities.

S. Special Purpose System - All cabinet systems that are designed for radiography or fluoroscopy of one type of object (e.g., aircraft or tractor tires).

G. General Purpose System - All cabinet x-ray systems that are not baggage inspection systems or special purpose systems.

U. Other - Any system which is questionable in regard to the Cabinet X-ray System Performance Standard applicability.

1.4 Indicate if operating instructions are available by completing item 1.4.

(c)(9)(i)

1.5 Indicate if a maintenance schedule is available by completing item 1.5.

(c)(9)(i)

1.6 Indicate if the system was designed to admit humans in item number 1.6. If there is any question regarding the intended design indicate that it is for admission of humans.

(c)(7)

1.7 Turn on the main power of the system if it is not already on.

2.0 WARNING LABELS AND INDICATORS

2.1 Check to see if a warning label is present and permanently affixed at the controls containing the statement: "CAUTION: X-RAYS PRODUCED WHEN ENERGIZED." Record in item 2.1.

(c)(8)(i)

2.2 Verify that the warning labels bearing the statement: "CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED ---- X-RAY HAZARD" are visible and permanently affixed adjacent to all ports. Record in item 2.2. If the answer is NO indicate the specific port(s) in the remarks section. If there are no ports enter a "u".

(c)(8)(ii)

2.3 Two labeled indicators must be present at the control. Both indicators must be labeled "X-RAY ON" unless one, but not both, is a milliammeter labeled to indicate x-ray tube current. All indicators must indicate only when x-rays are produced. The status of the indicators should be recorded in item 2.3.

(c)(6)(iii)

2.4 Check to see if one indicator marked "X-RAY ON" is visible from each port, door, and access panel. Fill in item 2.4 on the Field Test Record. If any port, door, or access panel does not have a visible indicator, report the location(s) in the remarks section.

(c)(6)(iv)

3.0 INTERLOCKS

3.1 Make sure that the key of the key-actuated control cannot be removed in any mode that allows x-ray generation. Do NOT turn the unit OFF. Some units take as long as an hour to warm up and stabilize. Record results in item 3.1.

(c)(6)(i)

3.2 If there are no doors to the system (see definition of a door (b)(3)) draw a large "X" across the entire 3.2 section of the Field Test Record. All doors must be such that the door opening results in physical disconnection of the energy supply circuit to the high-voltage generator and dependent on no moving part other than the door. Open each door to see if the two interlocks are visible around the door seal. It may not always be apparent how many interlocks are present. Some interlocks may be concealed. Fill in the minimum number of interlocks observed on any one door in item 3.2A. Try to determine if any interlock is dependent on no moving part other than the door. Complete item 3.2B. If the response is anything but the two (2) required interlocks on all doors, make comments in the remarks section. More information may be obtained by checking the characteristics of the unit in the information provided in Part II for for each specific unit.

(c)(4)(i)

3.3 Generation of x-radiation must be prevented when any door or access panel is open. Where possible all doors and access panels will be tested to assure prevention of x radiation. X-radiation is considered prevented if at any position of the door or access panel the radiation level is less than 0.5 mR in one hour at 5 cm from the opening. It will be up to the discretion of the inspector as to which access panel will be tested. It may not be possible to test all access panels because of time considerations, lack of necessary tools or keys to open panels, and non-cooperative operators. When possible, initiate x-ray generation and without manually defeating the interlocks, slightly open each door and access panel. This is not possible with pulsed systems or units with relatively short exposure times. In this case, slightly open each door and access panel separately and then attempt to initiate x-ray generation. Fill in the appropriate response for Part A of item 3.3.

WARNING!!!!

Do not attempt to open any access panel of a compartment containing an image intensifier because room light may severely damage the intensifier. If the access panels are sealed do not break the seals in an attempt to open the panels.

(c)(4)(i)
(c)(4)(ii)

While checking prevention of x-ray generation, make sure the use of the "ON" control is necessary to resume operation following interruption of generation by opening the door or access panel. A hand operated dead-man switch fulfills this requirement. Complete Part B of item 3.3. Use the remarks section for any response except Yes.

(c)(4)(iii)

4.0 PORTS AND/OR APERTURES

4.1 Determine if any part of the body can be inserted through a port into the primary beam. Respond in item 4.1. If the response is Yes include a statement in the remarks section giving the port(s) and the circumstances involved.

(c)(3)(i)

4.2 Determine if any part of the body can be inserted through any aperture. Respond in item 4.2. If the response is Yes include a statement in the remarks section giving the specific aperture(s) and the circumstances involved.

(c)(3)(ii)

5.0 SYSTEMS DESIGNED TO ADMIT HUMANS

If the system is not intended to admit humans draw a large "X" across the entire section (items 5.1 to 5.4) in the Field Test Record. Skip Section 5 and continue to the next section.

5.1 Determine if a control is located within the cabinet for preventing and terminating x-ray generation. Fill in the appropriate response in item 5.1A. If possible, activate the inside control, proceed to the outside and determine if the control can be overridden, reset, or bypassed from the outside of the cabinet. Complete the rest of item 5.1.

(c)(7)(i)

5.2 Indicate if there are any means to initiate x-ray generation from within the cabinet in item 5.2.

(c)(7)(ii)

5.3 Determine if audible and visible signals are contained within the cabinet which are activated for at least 10 seconds immediately prior to the initiation of x-ray generation after closing any door designed to admit humans. Determination should be accomplished by closing the door and waiting approximately half a minute before initiating an exposure with the "X-RAY ON" control. This is to insure that the closing of the door does <u>not</u> activate the signals.

NOTE: It may not always be determinable from outside the cabinet whether or not the signals have been activated. Do not remain within the cabinet for this test. Record the appropriate response in item 5.3.

(c)(7)(iii)

5.4 A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated must be provided. If the x-ray generation period is less than one-half second the indicators will be on for one-half second. Note: This may not be possible to determine from the outside of the cabinet. Respond to item 5.4.

(c)(7)(iv)

5.5 Determine if signs indicating the meaning of the warning signals and the use of the inside control are provided within the cabinet and illuminated when the main power switch is in the "ON" position. If all are present and illuminated indicate Yes in item 5.5. If the response is No, comment in the remarks section.

(c)(7)(v)

6.0 BAGGAGE INSPECTION SYSTEMS

If the system is designed primarily for the inspection of carry-on baggage at airline, railroad, bus terminals, and at other similar public facilities draw a large "X" across the entire section (items 6.1 to 6.2) in Field Test Record. Skip Section 6.0 and continue to Part II.

6.1 Determine if means are provided to assure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x radiation. The means may be, but is not limited to, a dead-man switch on the control panel or cord, a foot switch, or possibly a floor mat. Make sure that the provision has not been bypassed (e.g., chair or table placed on floor mat). Results are to be recorded in item 6.1 and any remarks placed in the comments section.

(c)(10)

6.2 Determine if means are provided to the operator for terminating exposures of greater than one-half second or preventing additional exposures of less than one-half second. A dead-man type switch fulfills this requirement. Item 6.2 should be completed with the appropriate response.

(c)(10(i)
(c)(10)(ii)

PART II

ROUTINE COMPLIANCE TESTING

FOR

CABINET X-RAY SYSTEMS

SPECIFIC PROCEDURES - 01

PROCEDURE: Continuously activated system (01)

APPLICABILITY: All models of cabinet x-ray systems that have the capabilities of exposure greater than 15 seconds.

7.0 Leakage Radiation

Test Setup

A. For horizontal beam orientation with manual inspection area, place the scatter object in the path of the primary beam of the unit flat against the image receptor as shown in Figure 1.

B. For horizontal beam orientation with a conveyor system, place the scatter object in an upright position on the conveyor belt as shown in Figure 2.

C. For vertical beam orientation with a manual system, place the scatter object in a flat position at the approximate center of the inspection area.

D. For vertical beam orientation with a conveyor system, place the scatter object in a flat position on the conveyor belt as shown in Figure 3.

7.1 Fill in 7.1 with a description of the scatter block used. Consult Appendix B for scatter block selection.

7.2 If the kVp and mA are given or can be selected, record the factors used during leakage testing in item 7.2. Attempt to use the worst case conditions of highest kVp and highest mA at that kVp.

(c)(1)(ii)

CAUTION: Consult the operator instructions to make sure that the x-ray tube is not overloaded.

7.3 Do not attempt to adjust the leaded drapes after the insertion of a scatter object, just let them hang freely in any position they fall.

7.4 Stop the conveyor when the scatter object is in the approximate center of the inspection area as the object appears in the center of the image screen.

NOTE: If it is not possible to stop the conveyor during the leakage testing, the scatter object must be continuously reinserted and run through the unit to create worst case scatter conditions.

7.5 Initiate continuous exposure and scan the external surface of the cabinet with the CDRH-wide area Survey Meter (Stoms Meter) to determine locations of high leakage radiation. Up to ten locations emitting high leakage radiation may be selected for further compliance measurements. If no leakage is detected with the Stoms Meter place an asterisk (*) in the first space of item 7.3 for the exposure level and no further leakage testing is required.

After determining the locations for further testing, use the Victoreen 440 RF/C to test for compliance. Place the center of the chamber 5 centimeters from the surface of the cabinet at each of the positions selected for leakage measurements. When measuring at the inspection well or the port openings at the end of the tunnels, masking tape placed across the opening makes the plane of the cabinet surface easily determinable.

Record the highest mR/hr meter reading obtained during at least a 15 second exposure at each of the locations in item 7.3. Draw a diagram of the system indicating locations of measurements or give a description of the locations tested in the remarks section.

(c)(1)(i)

For horizontal beam orientations with a manual inspection area, test at least eight locations for leakage; four on the operator side and four on the passenger side.

Place a large "X" across the entire section on Initiated Number of Exposures and Time at 7.3. Record the duty cycle of the system, if available.

8.0 ADDITIONAL INFORMATION

8.1 If the system is the conveyor type check the condition of the lead drapes at each port. Record the condition of the drapes in item 8.2 (e.g., TORN, MISSING STRIPS, GOOD CONDITION, and so forth).

8.2 Determine if there is a manual mode which is operational. This may be done by turning the key switch to the manual setting, if available, and activating the dead-man switch.

8.3 Record any additional information in items 8.1 to 8.5 and include any problems encountered during survey of the unit in the remarks section.

SCATTER BLOCK PLACEMENT

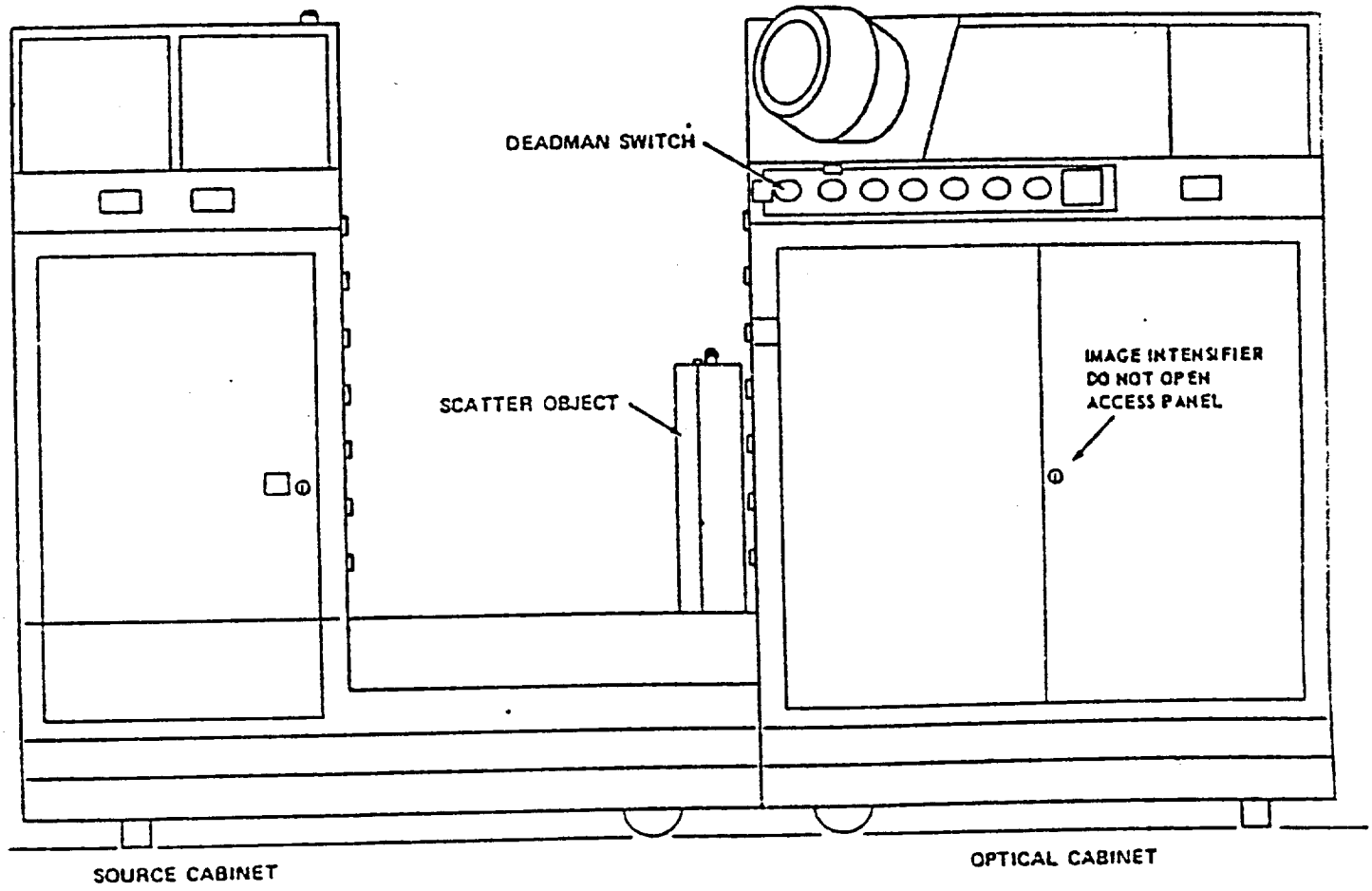

FIGURE 1

SCATTER BLOCK PLACEMENT

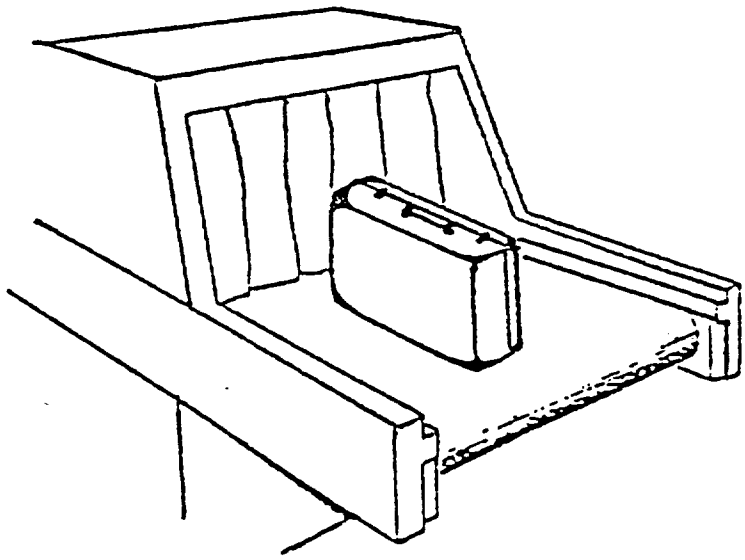

Figure 2

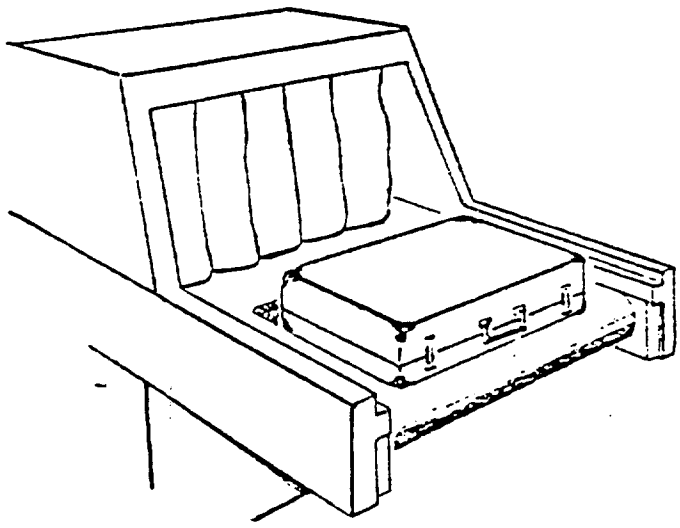

Figure 3

SPECIFIC PROCEDURE - 02

PROCEDURE: Noncontinuously Activated Systems

APPLICABILITY: All models of Cabinet X-ray Systems that have the Capabilities of exposures less than 15 seconds

7.0 Leakage Radiation

Test Setup

A. For horizontal beam orientation with manual inspection area, place the scatter object in the path of the primary beam of the unit flat against the image receptor as shown in Figure 1.

B. For horizontal beam orientation with a conveyor system, place the scatter object in an upright position on the conveyor belt as shown in Figure 2.

C. For vertical beam orientation with a manual system, place the scatter object in a flat position at the approximate center of the inspection area.

D. For vertical beam orientation with a conveyor system, place the scatter object in a flat position on the conveyor belt as shown in Figure 3.

7.1 Fill in 7.1 with a description of the scatter block used. Consult Appendix B for scatter block selection.

7.2 If the kVp and mA are indicated or can be selected, record the factors to be used during leakage testing in Item 7.2. Attempt to use the worst case conditions of highest kVp and the highest mA at the kVp.

(e)(1)(ii)

CAUTION: Consult the operator instructions to make sure that the x-ray tube is not overloaded.

7.3 Select five or six positions at the cabinet surface that would appear to have the more significant leakage (e.g., around doors, ports, apertures or joints). A survey meter with an integrate mode should be placed 5 centimeters from each of the positions selected. Initiate a reasonable number of exposures or until the meter reads half scale. Record the highest mR meter reading at each location tested. Do not correct for duty cycle or correct to mR/pulse. Record the number of exposures initiated at each location and the

length of each exposure if known. Complete item 7.3 with an estimate of the number of exposures that may reasonably be taken as the maximum workload in one hour. Draw a diagram of the system indicating locations of measurements or give a description of the locations tested in the remarks section.

(c)(1)(i)

8.0 ADDITIONAL INFORMATION

8.1 Check the condition of the sets of leaded drapes at each tunnel. Record the condition of the drapes in item 8.1, (e.g., TORN, MISSING STRIPS, GOOD CONDITION, and so forth.

8.2 Record any additional information in Items 8.2 to 8.5 and include any problems encountered during survey of the unit in the remarks section.

SCATTER BLOCK PLACEMENT

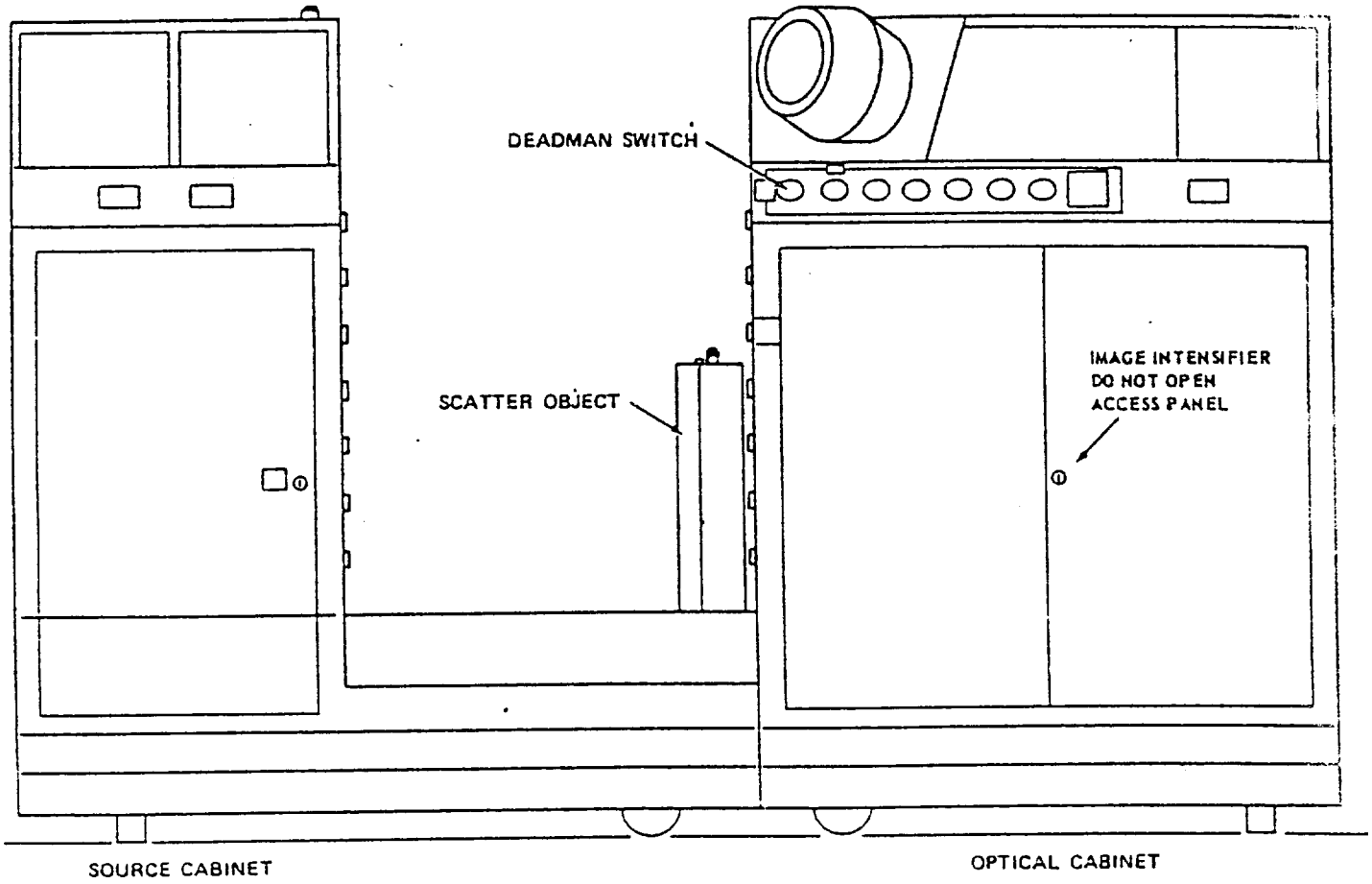

FIGURE 1

SCATTER BLOCK PLACEMENT

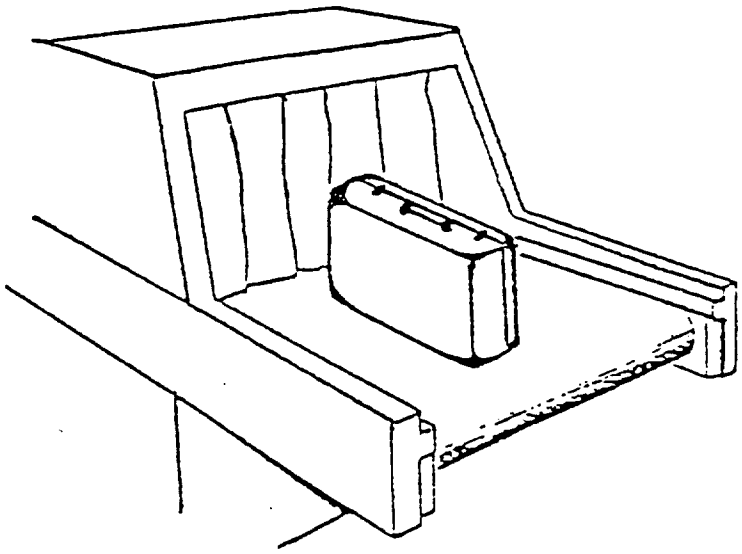

Figure 2

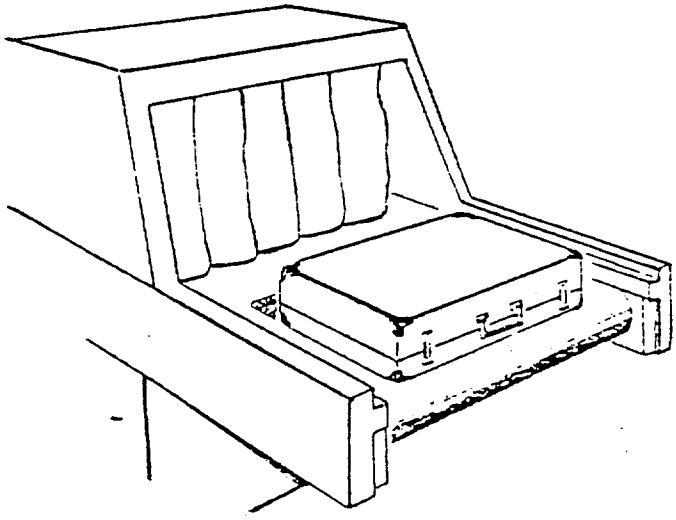

Figure 3

APPENDIX A

TABLE OF AGENCY CODE AND FIELD TEST RECORD FORM

TABLE OF AGENCY CODES

State or Other Agency	Agency Code	FDA Region Code
Alabama	AL	04
Alaska	AK	10
Arizona	AZ	09
Arkansas	AR	06
California	CA	09
Colorado	CO	08
Connecticut	CT	01
Delaware	DE	03
District of Columbia	DC	03
Florida	FL	04
Georgia	GA	04
Hawaii	HI	09
Idaho	ID	10
Illinois	IL	05
Indiana	IN	05
Iowa	IA	07
Kansas	KS	07
Kentucky	KY	04
Louisiana	LA	06
Maine	ME	01
Maryland	MD	03
Massachusetts	MA	01
Michigan	MI	05
Minnesota	MN	05
Mississippi	MS	04
Missouri	MO	07
Montana	MT	08
Nebraska	NE	07
Nevada	NV	09
New Hampshire	NH	01
New Jersey	NJ	02
New Mexico	NM	06
New York (State)	NY	02
North Carolina	NC	04
North Dakota	ND	08
Ohio	OH	05
Oklahoma	OK	06
Oregon	OR	10
Pennsylvania	PA	03
Rhode Island	RI	01
South Carolina	SC	04
South Dakota	SD	08
Tennessee	TN	04
Texas	TX	06
Utah	UT	08
Vermont	VT	01
Virginia	VA	03
Washington	WA	10

West Virginia	WV	03
Wisconsin	WI	05
Wyoming	WY	08
Canal Zone	CZ	02
Guam	GU	09
Puerto Rico	PR	02
Virgin Islands	VI	02
New York City	NX	02
New York State Department of Health	NY	02
New York State Department of Labor	NZ	02
Philadelphia	PD	03
Bureau of Prisons	BP	
U.S. Air Force	AF	
U.S. Army	AY	
U.S. Coast Guard	CG	
U.S. Navy	NA	
U.S. Public Health Service Center for Devices and Radiological Health	HQ	
Federal Aviation Administration	FA	
Private Consultant	PC	
Airline-Commercial	AC	
FDA Region I	01	
FDA Region II	02	
FDA Region III	03	
FDA Region IV	04	
FDA Region V	05	
FDA Region VI	06	
FDA Region VII	07	
FDA Region VIII	08	
FDA Region IX	09	
FDA Region X	10	

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CABINET X-RAY SYSTEMS
FIELD TEST RECORD
(Use Form FD 2962, Field Test Record Continuation, if more space is needed.)

Print Legibly, Use Black Ball Point Pen. Enter One Character Per Box.

FIELD TEST SERIAL NO. (1-7)

REGIONAL REVIEW (Name and Date)

CARD NO.

PART I – GENERAL PROCEDURE

1.0 PRETEST CHECKLIST

AA

HOME DISTRICT (10-12) | CENTRAL FILE NO. | ACCOMPLISHING DISTRICT (13-15) | FDA REGION (16-17)

1.1 NAME AND ADDRESS OF FACILITY AND SPECIFIC LOCATION OF X-RAY SYSTEM

NAME OF FACILITY (18-60)

BB

STREET NO. AND NAME, RURAL ROUTE NO. OR AIRLINE AND AIRPORT (18-60)

CITY (18-32) | STATE CODE (33-34) | ZIP CODE (35-39)

DD

ROOM NO. OR OTHER LOCATION OF SYSTEM (18-32) | PERSON INTERVIEWED (33-54)

CERTIFICATION LABEL PRESENT (55) Y – YES N – NO | INSTRUMENTS: (Type and serial number) | TELEPHONE NO. (56-64)

1.2 MANUFACTURER AND PRODUCT IDENTIFICATION

A. MANUFACTURER (Responsible Firm) | B. MFR CODE (18-22)

C. SYSTEM MODEL NO. AND/OR NAME | D. UNIQUE I.D. (38-41)

E. SYSTEM SERIAL NO. (42-49) | F. DATE OF MFR Month (70-71) Year (72-73)

01

1.3 SYSTEM TYPE (74) B – Baggage Inspection, G – General Purpose, S – Special Purpose, U – Other

1.4 OPERATOR INSTRUCTIONS AVAILABLE (75) Y – YES N – NO

1.5 MAINTENANCE SCHEDULE AVAILABLE (76) Y – YES N – NO

1.6 DESIGNED TO ADMIT HUMANS (77) Y – YES N – NO

2.0 WARNING LABELS AND INDICATORS

2.1 WARNING LABELS PRESENT AT CONTROLS STATING: "CAUTION: X-RAYS PRODUCED WHEN ENERGIZED" (78) Y – YES N – NO

2.2 WARNING LABELS PRESENT AT PORTS STATING "CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED. X-RAY HAZARD" (79) Y – YES N – NO

2.3 TWO INDICATORS LABELED "X-RAY ON" PRESENT AT CONTROLS (One May Be Labeled "mA Meter") (80) Y – YES N – NO

2.4 AT LEAST ONE INDICATOR, MARKED "X-RAY ON", VISIBLE FROM EACH PORT, DOOR, AND ACCESS PANEL (10) Y – YES N – NO

3.0 INTERLOCKS

3.1 "CAPTURED KEY" CONTROL (11) Y – YES N – NO

3.2 DOOR SAFETY INTERLOCKS

A. MINIMUM NUMBER OF INTERLOCKS VISIBLE AT ANY ONE DOOR (12)

B. AT LEAST ONE INTERLOCK DEPENDENT ON NO MOVING PART EXCEPT DOOR (13) Y – YES N – NO U – NOT DETERMINABLE

3.3 PREVENTION OF X RADIATION BY INTERLOCKS

A. ALL DOORS AND ACCESS PANELS THAT WERE TESTED PREVENT GENERATION OF X RADIATION (14) Y – YES N – NO

B. USE OF X-RAY CONTROL NECESSARY TO RESUME OPERATION FOLLOWING INTERRUPTION (15) Y – YES N – NO

4.0 PORTS AND/OR APERTURES

4.1 SOME PART OF THE BODY CAN BE INSERTED THROUGH A PORT INTO THE PRIMARY BEAM (16) Y – YES N – NO U – NOT APPLICABLE

4.2 SOME PART OF THE BODY CAN BE INSERTED INTO AN APERTURE (17) Y – YES N – NO U – NOT APPLICABLE

02

5.0 SYSTEMS DESIGNED TO ADMIT HUMANS

5.1 PREVENTION OF X RADIATION FROM WITHIN THE CABINET

A. CONTROLS WITHIN THE CABINET FOR PREVENTING AND TERMINATING X-RAY GENERATION (18) Y – YES N – NO U – NOT DETERMINABLE

B. FROM OUTSIDE THE CABINET, IT IS POSSIBLE TO OVERRIDE, RESET, OR BYPASS THE MEANS PROVIDED FOR TERMINATION OR PREVENTION OF X-RAYS (19) Y – YES N – NO U – NOT DETERMINABLE

5.2 MEANS PROVIDED TO INITIATE X-RAY GENERATION FROM WITHIN THE CABINET (20) Y – YES N – NO

5.3 AUDIBLE AND VISIBLE SIGNALS CONTAINED WITHIN THE CABINET WHICH ACTIVATE AT LEAST 10 SECONDS PRIOR TO X-RAY GENERATION (21) Y – YES N – NO U – NOT DETERMINABLE

5.4 VISIBLE WARNING SIGNAL WITHIN THE CABINET WHICH REMAINS ACTIVATED WHEN AND ONLY WHEN X-RAYS ARE GENERATED (22) Y – YES N – NO U – NOT DETERMINABLE

5.5 ILLUMINATED SIGNS PROVIDED INDICATING MEANING OF WARNING SIGNALS AND USE OF INSIDE CONTROLS (23) Y – YES N – NO

6.0 BAGGAGE INSPECTION SYSTEMS

6.1 MEANS PROVIDED TO ENSURE OPERATOR PRESENCE AT THE CONTROL AREA (24) Y – YES N – NO

6.2 MEANS PROVIDED TO OPERATOR FOR TERMINATING EXPOSURES OF GREATER THAN ONE-HALF SECOND AND PREVENTING ADDITIONAL EXPOSURES OF LESS THAN ONE-HALF SECOND (25) Y – YES N – NO

Original: BRH, White Copy – Home District, Blue Copy – BRH, Yellow Copy – Investigator

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CABINET X-RAY SYSTEMS
FIELD TEST RECORD

(Use Form 2783, Field Test Record Continuation, if more space is needed.)

Print Legibly. Use Black Ball Point Pen. Enter One Character Per Box.

CARD NO.

PART II – SPECIFIC PROCEDURE

7.0 LEAKAGE RADIATION

03 — SPECIFIC TEST PROCEDURE USED (10) | 7.1 SCATTER BLOCK DESCRIPTION (13–37)

04 — (10–39) (40–69)

05 — 7.2 Technique Factors: kVp (10–12) mA (13–18)

06 — 7.3

Location	Exposure Levels	Circle Correct Unit	Non-Continuously Activated Systems Only: Number of Exposures Initiated	Time of Each Exposure
01 (19–20)	(21–24)	mR or mR/hr	exp. (25–27)	sec. (28–32)
02 (33–34)	(35–38)	mR or mR/hr	exp. (39–41)	sec. (42–46)
03 (47–48)	(49–52)	mR or mR/hr	exp. (53–55)	sec. (56–60)
04 (61–62)	(63–66)	mR or mR/hr	exp. (67–69)	sec. (70–74)
05 (10–11)	(12–15)	mR or mR/hr	exp. (16–18)	sec. (19–23)
06 (24–25)	(26–29)	mR or mR/hr	exp. (30–32)	sec. (33–37)
07 (38–39)	(40–43)	mR or mR/hr	exp. (44–46)	sec. (47–51)
08 (52–53)	(54–57)	mR or mR/hr	exp. (58–60)	sec. (61–65)
09 (66–67)	(68–71)	mR or mR/hr	exp. (72–74)	sec. (75–79)
10 (10–11)	(12–15)	mR or mR/hr	exp. (16–18)	sec. (19–23)

07 — Reasonable Number of Exposures That May Be Initiated in One Hour (24–27) OR Duty Cycle of System Indicated as a Percentage of One Hour (28–30) %

8.0 ADDITIONAL INFORMATION

08 — 8.1 (10–44) (45–79)

09 — 8.2 (10–44) (45–79)

10 — 8.3 (10–44) (45–79)

11 — 8.4 (10–44) (45–79)

12 — 8.5 (10–44) (45–79)

SURVEYOR INFORMATION

13 — SURVEYOR NAME (10–72) (Print: Last, First, Middle)

SURVEYOR SIGNATURE

DATE OF SURVEY: MONTH (73–74) DAY (75–76) YEAR (77–78)

SURVEYING AGENCY CODE (79–80)

REMARKS:

For Additional Remarks Use Field Test Record Continuation Form FD 2782.

CHECK IF CONTINUATION SHEET USED

FORM FD 2093 (12-75) Page 2 of 2 Pages.

Original–BRH, State Copy–Home District
Blue Copy–RRMC, Yellow Copy–Investigator

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE Food and Drug Administration	PRINT – USE BLACK BALL POINT PEN FIELD TEST SERIAL NUMBER

NAME OF SURVEYOR (Print)	TITLE	
NAME OF SURVEYING AGENCY	SIGNATURE	DATE

APPENDIX B

EQUIPMENT DESCRIPTIONS FOR THE CDRH ROUTINE COMPLIANCE TEST PROCEDURES FOR CABINET X-RAY SYSTEMS

SECTION I

DESCRIPTION
OF THE
VICTOREEN MODEL 440 RF/C
SURVEY INSTRUMENT

DESCRIPTION OF THE VICTOREEN MODEL 440 RF/C SURVEY INSTRUMENT

A. PURPOSE

The Model 440 RF/C low energy RF shielded survey meter is a high sensitivity, low energy RF shielded instrument which is ideally suited for quantifying low levels of ionizing radiation such as that emanating from cabinet x-ray systems.

The model 440 RF/C operates only in a rate mode and may not be used to integrate over short exposure times.

The instrument consists of a radiation detector, an electrometer, and a readout, all packaged in a single 10 7/8" x 4 7/8" case. The radiation detector is a guarded, unsealed, air-equivalent ionization chamber.

Response to x-radiation to +10 percent over the energy range of 12.5 KeV eff. to 42 KeV eff. is achievable with a maximum full-scale range of 100 mR/hr.

B. INSTRUMENT OPERATION

The desirable characteristics of low-level current detection and good stability are obtained with 440 RF/C.

The air-equivalent ionization chamber has a cross sectional area of 10 cm^2 and a volume of 60 cc. The chamber window is constructed of 1 mg/cm^2 aluminized mylar. Location of the ion chamber is indicated by a black circle on the 13 mg/cm^2 magnesium window of the case. The center of the active volume is located 5 centimeters behind the plane defined by the tops of the three plastic bumpers on the outside ring of the magnesium window.

Operation of the meter is controlled by a single switch mounted on the front panel. The instrument has full scale ranges of 1, 3, 10, 30, and 100 mR/hr. The ionization chamber's energy response is flat to within +10 percent for photon energies from 12.5 KeV eff. to 42 KeV eff. The instrument, exclusive of energy dependence, is accurate to within +10 percent of full scale indication. The response time of the 440 RF/C is 12 seconds. Condition of the four "D" cell batteries is checked by means of the batter - check position. For this check, the needle should indicate in the black zone of the meter arc, from 0.91 to full scale. When the source check is utilized by using the flip switch at the front of the unit the meter reading should correspond to the approximate reading stamped on the end of the meter.

C. SPECIFICATIONS

1. Ranges

0-1, 0-3, 0-10, 0-30, 0-100, mR/hr full scale.

2. X and Gamma Energy Response

+10 percent from 12.5 KeV to 42 KeV.

3. Accuracy

Maximum instrument inaccuracy, exclusive of energy dependence, is less than + percent full scale indication.

4. Response Time

Less than 12 seconds for 0 to 90 percent of final indication.

5. Ion Chamber

10 cm^2 and a volume of 60 cc. The chamber window is constructed of 1 mg/cm^2 aluminized mylar.

6. Battery

Four "D" size cells (NEDA type B). Battery life: approximately 100 hours at 4 hours per day.

7. Net Weight

Instrument 8 1/2 pounds.

SECTION II

DESCRIPTION OF THE CDRH WIDE AREA SURVEY INSTRUMENT

Description of the CDRH Wide Area Survey Meter

A. PURPOSE

The CDRH (Center for Devices and Radiological Health) wide area survey meter is a portable survey meter originally designed to locate areas of x-ray emission from television receivers. The instrument uses six IB85 Geiger-Mueller tubes as the sensing elements. The GM tubes which are sensitive to photon energies as low as 6 KeV effective, are overlapped in a manner so as to produce a continuous active probe length of 16 1/2 inches. The overall dimensions of the instrument are 26 1/4" x 4 1/2" x 1 1/2".

B. INSTRUMENT OPERATION

The CDRH wide area survey meter circuitry is designed to automatically and continuously select and measure the output of the GM tube with the highest incident exposure rate. The selected tube is indicated by an adjacent light bulb which, when powered, is visible in the probe assembly. The instrument has four ranges, indicated as 3, 10, 30, and 100 full scale. No direct conversion from the meter reading to mR/hr is possible. Typically, in a uniform 0.5 mR/hr radiation field from a cabinet x-ray system, the instrument will indicate approximately 15. The condition of the eight "AA" cell batteries power the instrument is checked by placing the range switch in the HV (high voltage) position. Any up scale reading indicates a satisfactory battery condition. Zero is checked by placing the range switch in the "zero" position. Adjustment is made with the screwdriver-adjust pot below the meter face.

C. SPECIFICATIONS

1. Ranges

3, 10, 30, and 100 full scale (No direct conversion to mR/hr possible).

2. X and Gamma Energy Response

As low as 6 KeV effective.

3. GM Tubes

Six - 1B85 Geiger-Mueller tubes.

4. Battery

Eight "AA" size cells. Battery life; approximately 100 hours at 4 hours per day.

5. Not Weight

Instrument 4 pounds.

SECTION III

SELECTION OF SCATTER BLOCK FOR WORST CASE LEAKAGE RADIATION

Selection of Scatter Block for Worst Case Leakage Radiation

In order to properly evaluate the radiation emanating from cabinet x-ray systems the selection of a scatter block for worst case scatter conditions is needed. The cabinet x-ray systems performance standard states that those conditions of scatter radiation which produce the maximum x-ray exposure at the external surface must be used. Because of the wide variety of sizes and operation characteristics of cabinet x-ray systems a single standard object is not practical. Therefore, it will be up to the discretion of the surveyor using the following guidelines as to the selection of the object.

In making measurements of leakage on Special Purpose Systems (those systems are designed for radiography or fluoroscopy of one type of object) the object for which the system was designed will be used as the object for worst case conditions.

For all other systems:

A. Material

Through testing and field evaluation, Lucite has been selected as the material providing maximum scatter in the kV range of 50 - 150 kVp. Pads or stacks of paper also give similar characteristics and may be substituted if Lucite is not available.

B. Size

The thickness of the scatter medium (Lucite) needed to produce the maximum exposure from scattered radiation is approximately 8 centimeters. This gives a maximum exposure in the field of scattered radiation at approximately 110 degrees (0 degrees being the direction of the incident beam). Width and length of the scatter object should be as large as practical considering the size of the system and resources available to the surveyor. With Baggage Inspection Systems a typical briefcase containing the Lucite block or legal size pads of paper (8 cm. thick) serves as an adequate worst case condition scatter object. Consideration must also be given to the fact the carry-on airline baggage is restricted in size to fitting beneath the airplane seats.