PART III

UNDER TABLE X-RAY SOURCE FLUOROSCOPIC AND SPOT FILM SYSTEMS

FORM FDA 2786

REPRINTED
APRIL 2000

ROUTINE COMPLIANCE TESTING

UNDERTABLE X-RAY SOURCE

FLUOROSCOPIC AND SPOT-FILM SYSTEMS

(TEST PROCEDURE UFA - USE FORM FDA 2786)

1.0 GENERAL GUIDANCE

1.1 This procedure is applicable to stationary fluoroscopic systems having an undertable x-ray source and manual, automatic, or both automatic and manual adjustment of technique factors during fluoroscopy. It is not applicable to C-arm or abovetable x-ray source systems. The system need not have a spot-film device.

1.2 When a step or entire section of the procedure is skipped, enter an asterisk in the first data item of that section, explain in Remarks why this was skipped, and continue on with the next appropriate section.

> NOTE: If multiple indicators are provided for a single parameter (e.g., kVp, and so forth) but the indicators do not agree with one another, choose the indicator (1) associated with a certified component and (2) most commonly used. Note in the Remarks that these indicators do not agree, and estimate the amount of discrepancy.

2.0 PRETEST CHECKLIST

2.1 Turn on the main power to the x-ray system.

2.2 Connect the 6-cm^3 ionization chamber to the electrometer. Set the mode selector switch to EXPOSURE RATE and the function selector switch to MEASURE. Allow the electronics 10 seconds to stabilize. After 10 seconds, the exposure rate should be less than 4 mR/min. If it is not, the instrument may be defective and you should contact CDRH for guidance.

2.3 If not already completed, complete the general information test record. Record the five digits that appear preprinted on the general information test record and a unique letter designator in the appropriate block on each page of the undertable fluoroscopic test record. Thus, test records for a combination abovetable radiographic/undertable fluoroscopic system would be identified as follows: "GI12345" - general information; "AR12345A" - abovetable radiographic; and "UF12345B" - undertable fluoroscopic.

2.4 Verify that the assemblers' reports, FD2579's , are correctly prepared. If they are not, write in the correct information above the incorrect information.

2.5 Record the code for the appropriate "Test Procedure" at item 1.

2.6 From the appropriate assembler report, record the beam-limiting device

manufacturer and model name at items 2 and 3, respectively. In some cases, the BLD will be considered an integral part of the table and not be separately certified and identified. For these cases, record the table manufacturer and model code from its identification label.

2.7 Indicate the certification status of each component making up the system at item 4.

2.8 Position movable grids and compression cones out of the path of the beam.

2.9 Move the Bucky tray to one end of the table away from the fluoroscopic source and lock into position.

2.10 If possible, retract the spot-film carriage out of the path of the beam.

2.11 If the system uses a television monitor, turn it on and allow time for stabilization.

IMPORTANT!

Before making an exposure for sections 3.0 and 4.0, put on a leaded apron and gloves, raise the table scatter shield, and position any leaded curtains on the imaging assembly to provide maximum protection to yourself.

3.0 INTERLOCK TEST

Test Setup

a) Position copper attenuators totaling 0.10 inches in thickness on the table near the fluoroscopic x-ray field.

b) Set the GM meter with the sensitive area at the front of the case on top of the copper attenuators.

NOTE: The directionality of this instrument is severe, and therefore, the end "+" mark should be aligned as carefully as possible with the source or suspected source of radiation.

Test Procedure

3.1 Ensure fluoroscopy is possible, then place the imaging support assembly in the park position (away from the table).

3.2 If the system provides for "Manual" and "Automatic" adjustment of fluoroscopic technique factors, select a low kVp and mA and check interlock operation in both modes.

3.3 Before making an exposure, position the exposure foot-switch as far away from the table as possible.

3.4 Momentarily depress the exposure foot-switch. Observe the GM meter and the x-ray

control for any indication of x-ray production.

3.5 Return the imaging support assembly to the ready position (over the x-ray source) and in systems that allow, disconnect the image intensifier from the support assembly. Move the image intensifier out of the way. Repeat steps 3.2, 3.3, and 3.4.

IMPORTANT

If no one is available to disconnect and reconnect the image intensifier, skip over this section of the test. DO NOT PERFORM THE DISCONNECTION AND RECONNECTION YOURSELF.

3.6 Record at item 5 whether the system prevents x-ray production when the primary protective barrier is not in position to intercept the beam. If the answer is "No," explain in Remarks the circumstances under which x-ray production was possible; e.g., image intensifier disconnected and fluoroscopic technique factor control in "Manual."

4.0 SURVEYOR PROTECTION TEST

NOTE: The GM meter is a sensitive instrument, but is extremely energy dependent. It is intended as a qualitative indication. Any quantitative measurements of radiation exposure should be made using the 100-cm^2 ionization chamber. The purpose of this test is to determine the radiation exposure level at any area occupied by the surveyor during fluoroscopic exposures.

Test Setup (see figure on test record)

a) Place the slide assembly, grid side up, on the table such as to intercept the fluoroscopic x-ray field. Place paper beneath the slide assembly, if needed, to protect the table surface.

b) On top of the slide assembly, center copper attenuators totaling 0.10 inches in thickness.

Test Procedure

4.1 Position the imaging assembly from its park position to the ready position over the table. Raise the table scatter shield and position the leaded curtains to provide maximum scatter protection.

SYSTEM HAZARD CHECK

4.2 Observe the visible area of the image receptor while moving the imaging assembly parallel with the tabletop length, to assure that the x-ray source and image receptor are ganged. If they are not and x-ray production **is possible,** discontinue all further

testing. Record at item 6 that the system is hazardous and explain in the Remarks.

4.3 Raise the imaging assembly to the maximum SID and lock in position.

4.4 Fully open the beam-limiting device.

4.5 If available, set the mode of fluoroscopic technique factor control to "Manual" and the control settings to approximately 90 kVp and 2 mA.

4.6 Make several short exposures and with the GM meter, scan the primary barrier, leaded curtains, and table scatter shield. Note the areas of greatest GM meter deflection, including unprotected areas where scatter radiation levels are high. These areas should be avoided during further testing. (Refer to page GM-1 for instructions on the proper Use of the GM meter.)

> NOTE: If the system is image-intensified but there is no spot-film device or similar primary protective barrier other than the image intensifier housing, use fluorescent strips, direct-print paper, or some other means to confirm that the direct x-ray beam does not extend beyond any edge of the primary barrier.

4.7 If the GM meter indication is greater than 15 for the Model 251B instrument or 150 for the TBM-1 instrument, make followup measurements with the 100-cm^2 ion chamber on the MDH 1015. If these follow-up measurements exceed 50 mR/hr, take precautions such as wearing a lead apron, standing behind a lead screen, standing away from the table, etc. while making exposures. Tell the user what you found including the exposure rate and the conditions under which it was obtained. Explain that this is not a noncompliance with the standard but that the measurement is taken so that the surveyor can take adequate protective measures during the survey depending on the measured scattered radiation. Tell the user you are providing this information for consider as part of the facility total radiation safety program. Enter in the remarks, the observed exposure rate and the conditions under which the excessive radiation rate was obtained, then continue to the next test (step 5.1).

5.0 TRACKING TEST

5.1 Lower the fluoroscopic imaging assembly until the bottom of the assembly is about 30 centimeters from the tabletop.

5.2 Adjust the beam-limiting device such that each blade can be seen on the visible area of the image receptor.

5.3 Depress the exposure switch. Raise the fluoroscopic imaging assembly through the entire range of SID's to assure that the system is tracking properly. Because of nonlinearities in the system, the collimator blades may wiggle slightly as the SID changes. However, if the system is tracking properly, the collimator blades will adjust to maintain a relatively fixed area of illumination on the TV monitor as the SID is increased. If the system is not tracking properly, the amount by which the collimator blades must be manually adjusted before they become visible again is an

indication of the misalignment at that SID.

NOTE: Describe in detail in the Remarks any abnormalities, such as the collimator blades moving off the edge of the image receptor.

5.4 Does the beam-limiting device track the image receptor properly? Record at item 7. If the answer is "No," a fluoroscopic x-ray field/image receptor alignment test must be performed at the maximum SID.

6.0 X-RAY FIELD/IMAGE RECEPTOR ALIGNMENT

Test Setup (see figure on test records)

a) Set the test stand without the spacer assembly beneath the imaging assembly.
(NOTE: The spacer assembly will not be used throughout this field test.)

b) Insert the slide assembly, grid side down, into slot 5 of the test stand.

c) On top of the slide assembly, center copper attenuators totaling 0.10 inches in thickness.

d) Set the electrometer on the tabletop, with the rubber feet in contact with the table. Position the 6-cm^3 ion chamber in the center of the test stand bottom.

Test Procedure

6.1 Center the test stand under the imaging assembly according to the following instructions:

a) Adjust technique factors to obtain a good quality image.

b) Using the image of the slide assembly from the image intensifier, center the test stand beneath the imaging assembly by moving the fluoroscopic imaging assembly.

c) Once centered, lock all locks of movement of the fluoroscopic imaging assembly.

6.2 Set the x-ray monitor mode selector to EXPOSURE and the function selector to MEASURE.

6.3 a) If the answer to the tracking question (data item 7) is "No," set the imaging assembly to the maximum SID and lock the vertical movement. Check to assure the beam-limiting device is fully open and continue on with the next step in the test procedure.

b) If the answer to the tracking question (data item 7) is "Yes," skip to step 6.9.

6.4 Insert a plastic cassette containing a sheet of direct-print paper into the slide assembly.

6.5 Make an exposure and read the dimensions of the grid image.

NOTE: See lines 1/4, 2/1, 3/2, and 4/3 of Figure 1. For future reference, note that 1/4 passes between the slide assembly quadrant numbers 1 and 4, and so forth and each small division of the grid represents 0.1 inches.

Record the values in order from 1/4 to 4/3 at items 8 through 11.

6.6 If the accumulated exposure is 2.5 R or greater, the direct-print paper should provide a satisfactory image. Make any additional exposure required to obtain a total of 2.5 R.

6.7 Remove the cassette from the slide assembly and develop the direct-print paper by exposure to fluorescent light. (Refer to page LINA-1 for proper development technique.)

6.8 Measure to the nearest millimeter from the center of the grid to the edge of the image along each of the four lines 1/4 through 4/3.

NOTE: Again observe that 1/4 passes between the slide assembly quadrant numbers 1 and 4, and so forth.

Record the values in order from 1/4 to 4/3 at items 12 through 15.

6.9 Bring the imaging assembly into firm contact with the top of the test stand and lock into position. Open the beam-limiting device fully.

6.10 If testing a dual-field type image intensifier (e.g., one having 6" and 9" diameter modes of operation), select the mode of greatest magnification (e.g., the 6" mode). However, do not use any mode (e.g., a 4" mode) that will not allow the dimensions of the grid to be read.

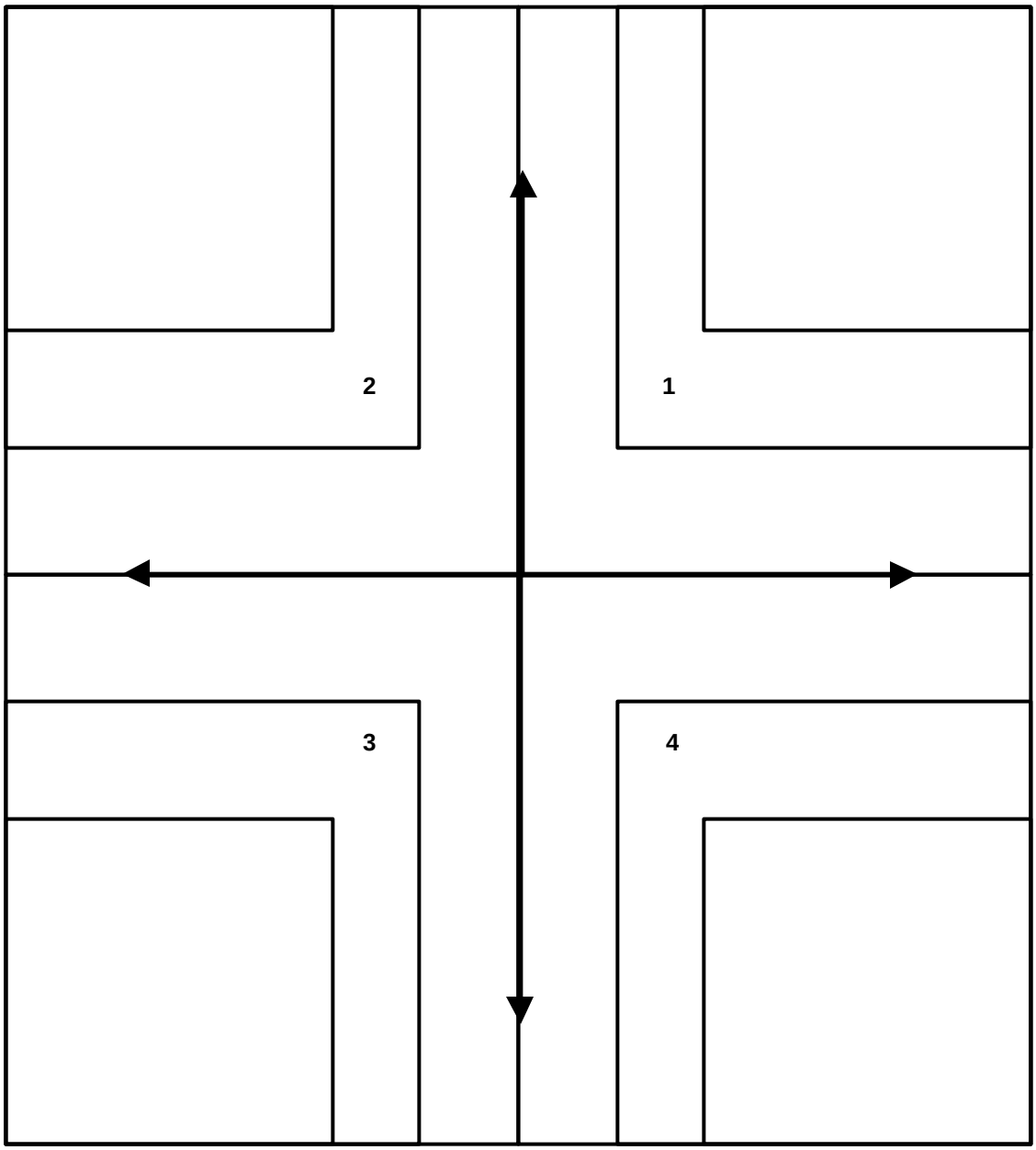
NOTE: Normally, this is the only test that uses a magnification mode.

6.11 Insert a plastic cassette containing a sheet of direct-print paper into the slide assembly.

6.12 Make an exposure and read the dimensions of the grid image.

NOTE: See lines 1/4, 2/1, 3/2, and 4/3 of Figure 1. For future reference, observe that 1/4 passes between the slide assembly quadrant numbers 1 and 4, etc., and each small division of the grid represents 0.1 inches.

Along Table Direction



Across Table Direction

Figure 1

Record the values in order from 1/4 to 4/3 at items 16 through 19.

6.13 If the accumulated exposure is 2.5 R or greater, the direct-print paper should provide a satisfactory image. Make any additional exposure required to obtain a total of 2.5 R.

6.14 Remove the cassette from the slide assembly and develop the direct-print paper by exposure to fluorescent light. (Refer to page LINA-1 for proper development technique.)

6.15 Measure to the nearest millimeter from the center of the grid to the edge of the image along each of the four lines 1/4 through 4/3.

NOTE: Again observe that 1/4 passes between the slide assembly quadrant numbers 1 and 4, etc.

Record the values in order from 1/4 to 4/3 at items 20 through 23.

6.16 Are the tube potential and current continuously indicated during an exposure? This indication need not be provided at the operator's position. Record at item 24.

6.17 Is there a warning label as prescribed in 21 CFR 1020.30(i) present on the control panel containing the main power switch? Record at item 25.

FLUOROSCOPIC TECHNIQUE FACTOR CONTROL TYPE

Are the fluoroscopic technique factors manually controlled, automatically controlled, or are both manual and automatic fluoroscopic technique factor controls provided? Record at item 26.

NOTE: The answer to this question may be postponed until performing the operational checks described in sections 7.0 and 8.0

7.0 ENTRANCE EXPOSURE RATE - AUTOMATIC

Test Setup (see figure on test record)

Change the test setup to:

a) Move the slide assembly, grid side down, into slot 2 of the test stand.

b) On top of the slide assembly, center copper attenuators totaling 0.10 inches in thickness.

c) Insert the focal-spot assembly, brass side up, into slot 7.

d) Insert a plastic cassette containing a sheet of direct print paper into the slide assembly.

NOTE: The image intensifier for some systems may be so large that the lead

sheet will not block the entire radiation field. Either use the next magnification mode or close the collimator blades to eliminate the radiation outside of the lead sheet. This is to protect the II from the unattenuated primary beam.

Test Procedure

7.1 Center a 1/8 inch thick lead sheet on top of the copper attenuators.

7.2 Set the fluoroscopic technique factor control mode to "Automatic" and the "Automatic Brightness Control" for maximum brightness. The "Automatic" mode may be checked by observing the exposure rate with and without the 1/8 inch lead sheet in the x-ray beam. If the system is in "Automatic" mode and the kVp and mA are not at their maximum value, the exposure rate should be appreciably higher with the lead in the beam.

7. 3 Set the x-ray monitor mode selector to EXPOSURE RATE and the function selector to MEASURE. While making an exposure, it is usually necessary to vary the kVp and/or mA settings to obtain the maximum electrometer reading.

NOTE: Some problems have been reported for image-intensified systems with automatic exposure control, but with only direct viewing (i.e., no television monitor). Room light can leak into the system and cause the automatic exposure control to suppress the kVp and mA; therefore, for these systems, turn the room lights as far down as possible when making this exposure measurement. Then turn the room lights up to read the electrometer.

Record the indicated tube potential and tube current at items 27 and 28, respectively, and the exposure rate at item 29.

7.4 If means to activate a high-level control are provided, make an exposure. Note the exposure rate. While making an exposure, activate the high-level control. Vary the kVp and mA settings to maximize the electrometer reading. Record the high-level exposure rate in the Remarks. Use the following format:

7.4 HLC MODE: _____ kVp _____ mA _____ R/min

NOTE: On some systems the hookup of a high-level control is a user option and means to activate a high-level control (e.g., button or double detent foot switch) may be present but not hooked up. Therefore, to determine the presence or absence of such a control, a radiation exposure rate check must be made.

Special means of activation are required for high-level controls, other than that required to activate normal fluoroscopy. Also, continuous manual pressure must be applied for the operation of the high-level control. This means that fluoroscopic operation cannot be "locked" in the high-level control mode.

7.5 If the high-level exposure rate exceeds the low-level rate, record "Y" in item 30.

Otherwise, record "N" in item 30.

7.6 Is a continuous audible signal provided upon activation of the high-level control? Record at item 31. If a high-level control (HLC) is not present, record "X" at item 31. If special means of activation or continuous manual pressure are not provided for the high-level control, explain the operation of the high-level control in the REMARKS section.

NOTE: The EER requirements do not apply to the recording of fluoroscopic images. In addition, the recording mode is not considered high-level control and therefore, no audible signal is required. The Center is looking into the record mode uses and would need manufacturer justification for any unit that could operate only in a record mode.

8.0 ENTRANCE EXPOSURE RATE - MANUAL

Test Setup

Same as previously.

Test Procedure

8.1 Set the fluoroscopic technique factor control mode to "Manual." The "Manual" mode may be checked by inserting additional copper in the beam. Observe the exposure rate with and without the additional copper. If the system is in "Manual" mode, exposure rates in each case should be about the same. Remove additional copper after this check.

8.2 Many systems do not yield their maximum entrance exposure rate at maximum tube potential or tube current; therefore, check the exposure rate at various kVp and mA settings to establish worst case exposure conditions. Set the x-ray monitor mode selector to EXPOSURE RATE. While making an exposure, vary the kVp and mA settings to maximize the electrometer reading. Record the worst case kVp and mA at items 32 and 33, respectively, and the exposure rate at item 34.

NOTE: Since the MDH 1015F provides an indication of the average exposure rate every 1.2 seconds, the kV and mA settings must be varied slowly to maximize the electrometer reading.

8.3 If means to activate a high-level control are provided, make an exposure. Note the exposure rate. While making an exposure, activate the high-level control. Vary the kVp and mA settings to maximize the electrometer reading. Record the high-level exposure rate in the Remarks. Use the following format:

8.3 HLC MODE: _____ kVp _____ mA _____ R/min

NOTE: On some systems the hookup of a high-level control is a user option, means to activate a high-level control (e.g., button or double detent

foot switch) may be present but not hooked up. Therefore, to determine the presence or absence of such a control, a radiation exposure rate check must be made.

Special means of activation are required for high-level controls, other than that required to activate normal fluoroscopy. Also, continuous manual pressure must be applied for the operation of the high-level control. This means that fluoroscopic operation cannot be "locked" in the high-level control mode. For controls manufactured after May 19, 1995, the HLC mode is limited to 20 R/min. Be aware of heat loading conditions and only run long enough to obtain adequate data.

8.4 If the high-level exceeds the low-level rate, record "Y" in item 35. Otherwise, record "N" in item 35.

8.5 Is there a continuous audible signal upon activation of the high level control? Record at item 36. If special means of activation or continuous manual pressure are not provided for the high-level control, explain the operation of the high-level control in the REMARKS section.

NOTE: For x-ray controls manufactured after May19, 1995,the EER requirements do not apply to the recording of fluoroscopic images when operating in a pulsed mode. In addition, the recording mode is not considered high-level control and therefore, no audible signal is required. The Center is looking into the record mode uses and would need manufacturer justification for any unit that could operate only in a record mode.

9.0 PRIMARY BARRIER TRANSMISSION

Test Setup

Remove the lead sheet from the test stand.

Test Procedure

9.1 a) If the system has a manual fluoroscopic technique factor control mode, proceed with the next step.

b) If the system has only an automatic fluoroscopic technique control factor mode, go directly to step 9.3.

MANUAL

9.2 Set the fluoroscopic technique factor control mode to "Manual" and the kVp at its maximum value and the mA at about 1 mA. Skip to step 9.4.

AUTO - ONLY

9.3 a) If the system has only an automatic fluoroscopic technique factor control and the kVp can not be held constant, place 0.1 inches of copper on top of the slide assembly. Skip to step 9.5.

b) If the system has only an automatic fluoroscopic technique factor control and the kVp can be held constant, select the maximum kVp.

9.4 Place a thickness of copper appropriate for the selected kVp on top of the slide assembly. If the image intensifier is larger than a typical 9 inch size (primary radiation will pass around the copper, as will be apparent on the TV monitor). Move the slide assembly with the copper to a lower slot (e.g. slot 5). This will ensure that unattenuated radiation will not pass around the copper sheet.

kVp	Cu (inches)
99 or less	0.08
100 to 125	0.10
greater than 125	0.12

9.5 With the x-ray monitor mode selector at EXPOSURE RATE, make an exposure without activating any available high-level controls. Record the observed kVp and mA at items 37 and 38.

9.6 Using the 6-cm3 ion chamber and the electrometer on the tabletop, record the exposure rate at item 39.

9.7 Make an exposure and with the GM meter scan the surface of the primary barrier, particularly those positions most likely to have insufficient attenuating material (e.g., around bolts, joints, and so forth) and note the position of the highest reading.

NOTE: In some cases, especially when there is no spot-film device, the primary protective barrier is the image intensifier housing. In these cases, measurement of barrier transmission will be significantly biased by radiation scattered from the copper attenuators; therefore, during the GM meter scan and subsequent measurement with the 100-cm2 chamber, position a lead sheet parallel to the tabletop at the plane of the image intensifier input phosphor and positioned to shield the chamber from all radiation except that transmitted through the primary barrier.

9.8 Switch "OFF" the MDH and secure the 100-cm2 chamber assembly at the position of highest reading on the GM meter. Set the x-ray monitor mode selector to EXPOSURE and the function selector to MEASURE.

9.9 Make an exposure of 25 to 30 seconds duration. (A 20-mR/hr transmission rate will

result in a 0.15-mR exposure in 30 seconds). Any useful reading should be at least 0.05 mR or greater. It may be necessary to make an exposure of greater than 30 seconds; however, do not exceed 1 minute. Check the tube rating charts to be sure that the rated limits are not exceeded. Measure the exposure time with the stopwatch.

9.10 Record the exposure and exposure time at items 40 and 41, respectively.

10.0 SOURCE-SKIN DISTANCE DETERMINATION

10.1 An image on direct print paper for minimum SSD determination is obtained during the testing performed in sections 7.0 through 9.0. A satisfactory image will be obtained on the direct print paper only if the total tabletop exposure during the referenced tests is 5.0 R or greater. Make an estimate of the total exposure obtained during the referenced tests before developing the image.

10.2 Remove the cassette from the slide assembly and develop the direct print paper by exposure to fluorescent light.

10.3 Measure the minimum separation of the outside edges of the focal-spot strip images to the nearest millimeter and record at item 42.

NOTE: The distance between the outside separation of the focal-spot strip images should be a value greater than 10 cm.

11.0 BEAM QUALITY

Test Setup (see figure on test record)

Change the test setup to:

a) Remove the slide assembly and focal-spot assembly from the test stand.

b) Insert the 6-cm3 ion chamber through the top mounting hole of the test stand and secure with the retaining ring.

c) Center copper attenuators totaling 0.10 inches in thickness on top of the test stand.

d) Insert the beam defining assembly, lead side up, into slot 7 of the test stand.

e) Place 4.5 mm of aluminum on the beam defining assembly in slot 7.

Test Procedure

11.1 a) If the system has only an automatic fluoroscopic technique factor control mode, go directly to step 11.5.

b) If the system has a manual fluoroscopic technique factor control mode, select this mode.

MANUAL MODE

11.2 Set the tube potential to a commonly used value above 70 kVp and the tube current to at least 2.0 mA. Record the kVp at item 43.

11.3 Five exposures are required for the beam quality determination. With the x-ray monitor mode selector in PULSE EXPOSURE, reset the x-ray monitor by switching the function selector to HOLD and back to MEASURE. The display should indicate -0.00. Make an exposure of at least 15 seconds at the selected kVp. Record the exposure reading at item 44. Switch the function selector to PULSE DURATION and record the time reading at item 45.

NOTE: If a time measurement has not been obtained or appears erroneous, the exposure rate may be too low to trigger the MDH instrument. For this situation, the mA and/or kVp must be increased. If kVp is changed, the kVp recorded at item 43 must also be changed.

11.4 Place totals of 3.5, 2.5, 1.5, and 0.0 millimeters on top of the beam defining assembly. For each total, make an exposure as described in step 11.3 while RESETTING THE X-RAY MONITOR EACH TIME. Record the exposure and time at items 46 through 53, respectively. Skip to step 11.7.

AUTOMATIC MODE ONLY

11.5 Five exposures are required for the beam quality determination. With the x-ray monitor mode selector in PULSE EXPOSURE, reset the x-ray monitor by switching the function selector to HOLD and back to MEASURE. The display should indicate -0.00. Make an exposure of at least 15 seconds at the selected kVp. Record the exposure reading at item 44. Switch the function selector to PULSE DURATION and record the time reading at item 45.

NOTE: if a time measurement has not been obtained or appears erroneous, the exposure rate may be too low to trigger the MDH instrument. For this situation, the mA and/or kVp must be increased. If kVp is changed, the kVp recorded at item 43 must also be changed.

11.6 Move aluminum from the bottom of the test stand to slot 1 of the test stand such that totals of 3.5, 2.5, 1.5, and 0.0 millimeters of aluminum are left on the top of the beam-defining assembly. For each total of aluminum, make an exposure as described in 11.5 while RESETTING THE X-RAY MONITOR EACH TIME record the exposure and time at items 46 through 53, respectively.

11.7 Set the cumulative timer to a very short time interval, only a few seconds if possible, and make an exposure of duration greater than the preset time interval. At the end of the preset interval does either a continuous audible signal indicate the end of the interval and/or is x-ray production terminated? Record at item 54.

12.0 SPOT FILM-REPRODUCIBILITY

Test Setup (see figure on test record)

Change the test setup to:

a) Insert the slide assembly, grid side down, into slot 2.

b) Center copper attenuators totaling 0.10 inches on top of the slide assembly or the test stand.

c) Insert a plastic cassette containing a sheet of direct-print paper into the slide assembly.

Test Procedure

12.1 Is the spot-film exposure timer a manually set timer (or mAs selector) or phototimer? Are both types of timers provided? Record at item 55.

12.2 If available, select the spot-film phototimed mode.

12.3 Open the beam-limiting device fully. Do not further adjust the beam limiting device. The device must automatically adjust to the selected portion of the spot film from this setting.

12.4 Set the x-ray monitor mode selector to PULSE EXPOSURE, the function selector to MEASURE, and the Pulse-Fraction Threshold to 0.5 for three phase equipment and 0.2 for single phase equipment. Record at item 56.

12.5 Set the peak tube potential to a value commonly used for spot-film radiography as long as the value exceeds 70 kVp. Record at item 57.

12.6 a) If testing in the phototimed mode, leave any of items 58 through 60 blank which are not preindicated, and skip steps 12.6 (b) and 12.6 (c).

b) If independently selectable, choose values of tube current and exposure time, and record at items 58 and 59. Leave item 60 blank.

c) If only the mAs is selectable, choose a value commonly used and record at item 60. Leave items 58 and 59 blank.

12.7 Insert an empty cassette into the spot-film device.

12.8 Make sure that the spot-film cassette is in position for an exposure and if possible select a four-on-one format. (For example, selecting a 24cm x 24cm film cassette and a four-on-one format, the selected size will be 12 cm x 12 cm).

NOTE: On some systems, selection of a four-on-one format results in the

compression cone automatically moving into position. Thus, raise the imaging assembly before selecting the format such that the cone will clear the top of the test stand. If the cone comes into position, the imaging assembly's vertical movement should be locked with the cone just clearing the top of the test stand.

12.9 Record the dimensions of the selected spot-film format size at items 61 and 62.

12.10 Measure the distance from the tabletop to the spot-film plane. Record at item 65.

12.11 With the x-ray monitor mode selector at PULSE EXPOSURE, reset the x-ray monitor by switching the function selector to HOLD and then back to MEASURE. The display should indicate -0.00. Make an exposure at the selected tube current. DO NOT record the resultant reading.

IMPORTANT

If testing in the phototimed mode, make a test exposure. If the exposure time recorded by the x-ray monitor is less than 100 milliseconds, reduce the tube potential and/or tube current to increase the exposure time above this minimum value and repeat the test exposure. Correct item 57 if necessary. If the system still is below 100 milliseconds consider adding attenuators to the beam or adjusting the density control settings. Finally, if the system still cannot reach or exceed 100 milliseconds exposure time, record at item 55 for the type of spot film exposure timer the letter “S” and indicate in the comments that the time could not be forced above 100 milliseconds. Procede with the reproduciability test. The “S” designation indicates to the computer that the test deviats from the test protocol and a critical audit failure will not occur. Do not add copper exceeding 0.15 inches or any lead in the beam. Be careful of tube overload.

12.12 Without changing technique factors or the x-ray monitor settings, make an additional exposure. The reading will now have no minus sign. Record this reading of exposure at item 66. Switch the function selector to PULSE DURATION and record this time reading at item 67. Switch the function selector back to PULSE EXPOSURE.

12.13 Make three additional exposures, with the exposure readings being recorded at items 68, 70, and 72 and the time readings at items 69, 71, and 73. If any two exposure readings differ by more than 10 percent of the largest value, make six additional exposures. Record the additional exposure and time readings at items 74 through 85 respectively. All variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement.

NOTE: Varying technique factorsbetween exposures is only applicable to equipment manufactured after September 5, 1978.

12.14 Sum the exposures from steps 12.11 and 12.13. If the sum is 1.3 R or greater, then the direct-print paper should provide a satisfactory image. Make any additional exposure required to obtain a total of 1.3 R.

12.15 Are the spot-film technique factors that are either fixed or selectable, indicated prior to the exposure (fixed technique factors may be indicated by a label)? Record at item 86.

12.16 Did the exposures terminate after one of the following: a preset time interval, a preset mAs, or a preset radiation exposure? Record at item 87.

NOTE: The intent of this question is to identify conditions that pose an imminent hazard; e.g., a system which upon activation of exposure, not one but repeated exposures occur or termination of exposure occurs only upon release of the exposure switch.

13.0 SPOT-FILM X-RAY FIELD/IMAGE RECEPTOR SIZE COMPARISON

13.1 Exposure to the direct print paper for this test measurement is obtained during the spot film reproducibility test.

NOTE: A satisfactory image will be obtained on the direct print paper only if the total exposure at the ion chamber location during the referenced test is 1.3 R or greater.

13.2 Remove the cassette from the slide assembly and develop the direct-print paper by exposure to fluorescent light. (Refer to page LINA-1 for proper development technique).

13.3 Measure the dimensions of the spot-film x-ray field size on the direct print paper. Record at items 63 and 64, respectively.