PART X

C-ARM FLUOROSCOPIC AND SPOT-FILM SYSTEMS

FORM FD 3260
ROUTE COMPLIANCE TESTING

C-ARM FLUOROSCOPES

(Test Procedure CFA - Use Form FDA 3260)

1.0 GENERAL GUIDANCE

1.1 This procedure is applicable to both mobile and stationary C-arm fluoroscopic x-ray systems—with or without a spot-film device. A C-arm fluoroscope is a system where the SID is fixed using a "C" or "U" arm and the spot-film device does not provide for two on one or four on one formats. Variable SID systems are not compatible with this procedure.

1.2 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 or section means that some portion of the Field Test Record will not be completed, enter an "***" in the first column of each inapplicable item in that portion of the Record.

NOTE: If multiple indicators are provided for a single parameter (e.g., kVp, etc.) 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 so 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 If not already completed, complete the General Information Field Test Record. Enter the field test serial number, which appears preprinted on the General Information Field Test Record in the appropriate block on each page of the C-Arm Fluoroscope Field Test Record.

2.3 Verify that the assemblers' reports, FD 2579's, are correctly prepared. If they are not, write in the correct information above the incorrect information.

2.4 Enter the code for the test procedure at item 1.

2.5 Record the system type (mobile or stationary) in item 2.

2.6 Determine from the ID label or from the installation date whether the BLD was manufactured after 5/22/79. Record at item 3.

2.7 Examine the control panel and the BLD to determine if collimator shutter controls are provided. If shutter blades can be continuously varied from the maximum to the minimum field size record a "2" at item 4. If, however, beam limiting is achieved by use of fixed apertures or cones, record a "1" at item 4.
2.8 Indicate the certification status of each component making up the system at item 5.

2.9 If present, remove the clip-on cassette holder from the image intensifier.

2.10 Turn on the television monitor and allow time for stabilization.

2.11 Connect the 6-cm³ ionization chamber to the electrometer of the model 1015F x-ray monitor. Set the x-ray monitor function selector to HOLD and the mode selector to EXPOSURE.

IMPORTANT!
Position the exposure floor-switch as far as possible from the C-arm or behind a protective shield. Also, always be conscious of the presence and direction of the x-ray beam. Try to orient yourself so that the x-ray beam is pointing away from the body.

3.0 INITIAL SETUP (FLUOROSCOPIC MODE) AND SURVEYOR PROTECTION TEST

Test Setup (See figure on test record)

(a) Tilt or rotate the C-arm into the horizontal plane (or as close to it as possible) so that a line from the center of the image intensifier (II) face would be parallel to the floor.

(b) Mount the right side of the test stand onto the tripod so that the MDH holes are on top (see Figure 1). Follow the tripod setup procedure in Appendix B of the test procedures manual, except that the stand need not be leveled using the bubble level.

(c) Measure the diameter of the image intensifier housing before positioning the test stand against the image intensifier. Record at item 27.

(d) 9" Image Intensifier: Move the tripod toward the BLD until the test stand top is approximately centered on and about 1-inch from the face of the BLD or SSD spacer. The bottom opening in the test stand should be centered over the image intensifier face.

6" Image Intensifier: Move the tripod so that the test stand bottom is against the face of the II. Adjust the tripod height and tilt until the bottom opening in the test stand is flush against and centered on the face of the image intensifier.

(e) Center (and tape) 0.1 inches of copper (on slot 7 of the test stand). (See Figure 2, modification of the test stand).

(f) Insert the slide assembly, grid side toward the BLD, into slot 6 of the test stand.

(g) Insert the 6-cm³ ionization chamber through the upper mounting hole (C) of the test stand.
TEST STAND ATTACHED TO TRIPOD

Figure 1
TEST PROCEDURE

3.1 Select the largest cone or aperture that will still permit fluoroscopy, or if a stepless BLD is provided, fully open the shutters.

3.2 Select fluoroscopic technique factors of approximately 90 kVp and 2mA, and set the cumulative fluoro timer to its maximum setting.

3.3 Using the GM survey meter, make several short exposures and scan the work area. Note the greatest GM meter deflection. Refer to page GM-1 for instructions on the proper use of the GM meter.

   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 Model 1015F x-ray monitor with 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.

3.4 If the GM meter indication is greater than 5 for the Model 251B Survey Meter or 150 for the TBM-1 Ratemeter, make follow-up measurements with the 100-cm$^2$ ionization chamber. 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 system and the primary x-ray beam, 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 scattered radiation. Tell the user you are giving him this information is case he/she was not aware of the scatter radiation levels under the conditions measured so that he/she can consider it as part of their total radiation safety program. Enter in the REMARKS, the observed exposure rate and the conditions under which the excessive radiation rate was obtained, and then continue to the next page (step 3.5).

3.5 If the GM meter indication is less than 15 for the Model 251B or less than 150 for the TBM, record "N" in item 6.

3.6 Is there a warning label present on the control panel containing the main power switch as prescribed in 21 CFR 1020.30(j)? Record at item 7.

4.0 FLUOROSCOPIC X-RAY FIELD/IMAGE RECEPTOR ALIGNMENT

**Test Setup**

Same as the initial setup.

**Test Procedure**

4.1 Either the MANUAL or AUTO brightness control modes may be used. Make an
exposure and observe the slide assembly grid image on the TV monitor. Adjust the brightness control or the technique factors until a good quality image of the grid is obtained.

4.2 Verify that the grid is approximately centered on the TV monitor. If it is not, slightly move the tripod with the x-ray beam off until approximate centering is obtained.

4.3 Set the x-ray monitor mode selector to EXPOSURE and the function selector to MEASURE. Leakage on the instrument should not exceed 4 mR in one minute. If it does, the instrument may be defective and you should contact CDRH for guidance.

4.4 Verify that the BLD is still fully open.

4.5 Insert a plastic cassette containing a sheet of direct-print paper into the slide assembly at slot 6.

4.6 If testing in a non-magnification mode, record at items 8-15. If testing in a dual-field type image intensifier (e.g., one having 6" and 9" modes of operation), select the mode of greatest magnification (e.g., the 6" mode). However, do not select any mode (e.g., a 4" mode) that will not allow the dimensions of the grid to be read. If there is no magnification mode leave items 16-23 blank.

4.7 Make an exposure and read the dimensions of the grid that are visible at each edge.

   NOTE: See lines 1/4, 2/1, 3/2, and 4/3 of Figure 3. 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.

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

4.9 If the accumulated exposure is 4 R or greater, the direct-print paper should provide a satisfactory image. Make any additional exposure required to obtain a total of 4R.

4.10 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.)

4.11 Measure to the nearest millimeter the distance 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.

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

4.13 Insert a plastic cassette containing a sheet of direct-print paper into the slide assembly.
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Along Table Direction

Across Table Direction

Figure 3
4.14 Repeat steps 4.7 through 4.12 for the magnification mode and record the data at items 16 through 23.

4.15 Record the shape of the visible area at item 24.

4.16 Tube potential and current must be continuously indicated during exposure but not necessarily at the operator's position. Record at item 25.

4.17 Verify that the maximum setting for the fluoro timer is five minutes or less. Record at item 26.

5.0 PRIMARY PROTECTIVE BARRIER/X-RAY FIELD SIZE COMPARISON

5.1 Measure to the nearest millimeter the distance from the face of the image intensifier to the base of the test stand. Record at item 28. When bottom of test stand is flush against the image intensifier (setup for 6" image intensifier) record 00.0 at item 28.

6.0 MINIMUM FLUORO X-RAY FIELD SIZE

Test Setup

Same as the initial setup.

Test Procedure

6.1 Select the smallest BLD aperture or cone. If a stepless collimator is provided, close the collimator completely and make a short exposure to see if any visible area can be observed. If none is observed, skip the rest of this procedure and record "00.0" at items 29 and 30 and an asterisk at item 31. If a visible area is observed, proceed with step 6.2.

6.2 Insert a plastic cassette containing a sheet of direct-print paper into the slide assembly and insert slide assembly into slot 6.

6.3 Make an exposure to obtain at least 1.5 R to the ionization chamber.

6.4 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.)

6.5 Measure to the nearest millimeter the length and width of the x-ray field image. Record at items 29 and 30. If the field image is circular, record the diameter twice at items 29 and 30.

6.6 Record the x-ray field image shape at item 31.
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 32. It may be necessary to refer to the Users Manual for an exact answer to this question.

7.0 ENTRANCE EXPOSURE RATE - MANUAL MODE

Test Setup (See figure on test record.)

(a) Insert the focal spot assembly, brass strips toward BLD, into slot 1 of the test stand.

(b) Move the test stand until it is against the image intensifier.

Test Procedure

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

7.2 Set the fluoroscopic technique factor control mode to "Manual." To check the "Manual" mode insert 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 any additional copper after this check.

7.3 Some 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 technique factors. 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 at items 33 and 34, respectively. Record the maximum exposure rate at item 35.

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.

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. Is a high-level control present in the manual mode? Record at item 36. Vary the kVp and mA settings to maximize the electrometer reading. Use the following format:

7.4 HLC MODE: _______ kVp _______ mA _________ R/min

NOTE: Since 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 control, 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 exceeds the low-levels rate, record "y" in item 36. Otherwise, record "n" in item 36.

7.5 Is a continuous audible signal provided upon activation of the high-level control? Record at item 37. If a high-level control is not present, record "X" at item 37. 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 May 19, 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.

8.0 ENTRANCE EXPOSURE RATE - AUTOMATIC MODE

Test Setup

Same as manual mode except: Center a 1/8 inch thick lead sheet over the 0.1 inches of copper and tape into place.

8.1 Set the fluoroscopic technique factor control to "Automatic" and any "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 beam. If the system is in "Automatic" and the kVp and mA are not at their maximum values, the exposure rate should be higher with the lead in the beam.

NOTE: The three variables that can be controlled by an automatic brightness control unit are the kVp, the mA, and the width of the x-ray pulses in systems with variable pulse width. A determination of the variable controlled on the system is needed to ensure the measurement of the maximum EER. Consult the User Manual for a description of the automatic brightness control.

Set the x-ray monitor mode selector to EXPOSURE RATE. While making an exposure, vary the kVp and/or mA settings to obtain the maximum electrometer reading. Record the indicated tube potential and the tube current at items 38 and 39, respectively, and the exposure rate at item 40.
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. Is a high-level control present in the manual mode? Record at item 41. Vary the kVp and mA settings to maximize the electrometer reading. Record the high-level exposure rate in the Remarks using the following format.

8.1 HLC MODE: _______ kVp _______ mA __________ R/min

NOTE: Since 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.

8.2 If the high-level exceeds the low-level rate, record “y” in item 41. Otherwise, record “n” in item 41.

8.3 Is a continuous signal provided upon activation of the high-level control? Record at item 42. If a high-level control is not present, record "X" at item 42. If special means of activation or continuous manual pressure are not provided for the high-level control explain the operation of the high control in the REMARKS section.

NOTE: For x-ray controls manufactured after May 19, 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 SID AND MINIMUM SSD

Test Setup

Same as Entrance Exposure Rate.

Test Procedure

9.1 An exposure of at least 4.5 R to the ionization chamber is required to obtain a good image of the focal-spot strips. Estimate the cumulative exposure delivered during entrance exposure rate measurement. If necessary, switch the x-ray monitor mode selector to EXPOSURE and deliver the required additional exposure.

9.2 Measure to the nearest millimeter the distance from the face of the source-skin distance (SSD) spacer (or from the face of the BLD if a spacer is not present) to the
top of the brass strips. Record at item 43.

9.3 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.)

9.4 Measure to the nearest millimeter the minimum separation of the outside edges of the focal-spot strip images. Record at item 44.

10.0 BEAM QUALITY

Test Setup (See figure on test record)

(a) Remove the focal-spot strips and lead and insert the beam-defining assembly, lead side toward BLD, in slot 1 of the test stand.

(b) Move the 6 cm$^3$ ionization chamber to the lower mounting hold (D) of the test stand.

(c) Place 4.5 mm aluminum on the beam defining assembly in slot 1.

(d) Remove the slide assembly from the test stand.

Test Procedure

10.1 (a) If the system has only an automatic mode of operation, go directly to step 10.5.

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

MANUAL MODE

10.2 Set the tube potential to a commonly used value above 70 kV and the tube current to at least 2.0 mA. Record the kVp at item 45.

10.3 Five exposures are required 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 at the selected kVp.

Record the exposure reading in item 46. Switch the function selector to pulse duration and record the time reading at item 47. Reset the x-ray monitor after the exposure by switching the function selector to HOLD and then back to MEASURE.

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 45 must also be changed.
10.4 Remove aluminum to obtain totals of 3.5, 2.5, 1.5, 0.0 millimeters on top of the beam defining assembly. For each total, make an exposure and time at items 48 through 55. Remember to reset the x-ray monitor between each exposure. Skip to 10.7.

**AUTOMATIC MODE ONLY**

10.5 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 at the selected kVp. Record the exposure reading at item 46. Switch the function selector to PULSE DURATION and record the time reading at item 47.

**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 45 must also be changed.

10.6 Move the aluminum from slot 1 of the test stand (toward the BLD) to slot 7 (toward the II) so that the totals of 3.5, 2.5, 1.5, and 0.0 millimeters are left on the top of the beam defining assembly. For each total of aluminum make an exposure as described in 10.5 while RESETTING THE X-RAY MONITOR each time between exposures. Record the exposure and time at items 48 through 55, respectively.

10.7 Set the cumulative fluoro 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 56.

**11.0 RADIOGRAPHIC MODE**

11.1 A radiographic mode is normally available on C-arm fluoroscopes. Usually, but not always, the radiographic images are recorded on a spot-film device (a clip-on holder or a cut-film changer). Occasionally, a fluorographic camera is provided (e.g., a 105 mm camera) for recording images off the output phosphor of the image intensifier. Such a camera is not a spot-film device. Indicate at item 57 the type of spot-film device provided. If only a fluorographic camera is provided, continuation of this section of the test procedure is not appropriate.

11.2 Record the dimensions of the spot-film image receptor or the cut-film nominal size at items 58 and 59.

11.3 If both Manual and Automatic (phototimed) exposure modes are provided, select the most commonly used mode of operation.

11.4 Set the tube potential to a value commonly used. Record at item 67.

11.5 **Automatic:**
(a) If testing in the phototimed mode, record an "*" in the first column of any of item 67 which is not preindicated.

11.6 Manual:

(a) If independently selectable, choose values of tube current and exposure time, and record at item 67.

(b) If only the mAs is selectable, choose a value commonly used and record at item 67.

11.7 Is the system single-phase or three-phase? Record at item 66.

NOTE: Using one or more of the following methods, determine whether the system is single-phase or three-phase.

(1) Consult the user to the information provided to him by the high voltage generator manufacturer.

(2) Check the identification plate to see if the manufacturer has listed the phase of the system along with other electrical characteristics.

(3) Observe the time settings on the control panel. Single-phase timer settings are usually expressed as common fraction multiples of 1/120 second, while three-phase usually have timer settings expressed as decimal fractions.

   If the system is single-phase, set the x-ray Monitor thumbwheel switch to 0.2, and record at item 65.

   If the system is three-phase, set the x-ray Monitor thumbwheel switch to "0.5," and record at item 65.

11.8 Set the x-ray monitor mode selector switch to PULSE EXPOSURE.

11.9 If a clip-on cassette holder is provided, mount it over the face of the image intensifier. Insert an empty cassette into the cassette holder.

11.10 On some systems, a rad-fluoro mode selector switch is provided on the control panel. If this is the case, switch to the radiographic mode.

   *It must be possible to maintain the fluoro field size during spot-filming. The user, at his option, may select automatic full coverage of the spot-film--but there must be an option on the control panel. A system design that always provides for automatic full coverage of the spot-film is noncompliance. Record at item 64.

12.0 REPRODUCIBILITY & LINEARITY

Test Setup (See figure on test record)

(a) Remove the beam defining assembly from slot 1.
(b) Move the 6 cm$^3$ ionization chamber to the upper mounting hole (C) of the test stand.

(c) Center a plastic cassette containing a sheet of direct-print paper on top of the test stand and tape on place.

Test Procedure

12.1 (a) If both "manual" and "automatic" controls are provided for exposure termination, select the mode of operation most commonly used and complete steps 12.2 and 12.12.

(b) If the system has only an automatic technique factor control mode, go directly to 12.13.

12.2 Adjust the BLD for full coverage of the spot-film.

**MANUAL MODE**

12.3 Set the x-ray monitor mode selector to PULSE EXPOSURE. Reset the x-ray monitor mode selector to PULSE EXPOSURE. Without changing the technique factors make an exposure. Do not record the resultant reading.

12.4 Without changing technique factors or the x-ray monitor settings, make an additional exposure. The reading will now have no minus sign present. Record this reading at item 69. Switch the mode selector back to PULSE EXPOSURE.

12.5 Repeat step 12.4 for three additional exposures, with the exposure readings being recorded at items 70, 72, and 74 and the time readings being recorded at items 71, 73, and 75. Do not reset the x-ray monitor between exposures. All variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement.

12.6 Should the above exposure and/or timer readings appear suspect (i.e., any two readings differ by ten percent or more of the greater value) make an additional six exposures, for total of ten data points.

12.7 If the x-ray control is manufactured before May 1994, follow the guidance of paragraph a. under each step for this test section, otherwise use paragraph b.

a. If the unit under test either does not allow specific selection of tube current, or, if only mAs is selectable, then omit procedural steps 12.8 through 12.12, enter an asterisk in the first column of item 88 on the test record, and state in the REMARKS that the mA is fixed, or that mAs is selected.

b. Enter a new mAs product (not to exceed twice the first mAs product) at item 88 on the test record. If a new mAs product cannot be obtained, then enter an asterisk in the first column of item 88 on the test record and state in the REMARKS that the mAs product is fixed.
12.8  a. If tube current selection is in fixed steps, select an adjacent tube current step and record the indicated value at item 88.

b. If tube current or mAs is in fixed steps, select an adjacent setting and record the mAs product at item 88.

12.9  a. If tube current selection is continuous (i.e., not in discrete steps), select a second tube current not differing from the first by more than a factor of 2, and record its value at item 88.

b. If the tube current or mAs is continuous (i.e. not in discrete steps), select a second setting not differing from the first by more than a factor of 2, and record the mAs product at item 88.

12.10 The change in tube current or mAs product may cause a change in tube potential. If manual compensation is available, readjust the tube potential to its original value, and continue with step 12.11. However, if the kVp cannot be compensated back to its original setting, enter an "***" in the first column of item 89, skip procedural step 12.11, and state in the REMARKS that the kVp could not be compensated.

12.11 Make four exposures at the selected technique factors and vary the technique factors between each measurement as in step 12.5 and record the exposure readings at items 89-92.

12.12 Sum the exposure entered in items 68-92. If the sum is 1.5 R or greater, the direct-print paper should provide a satisfactory image. Make additional exposures, if required to total at least 1.5 R to the ionization chamber.

AUTOMATIC MODE

12.13 With the x-ray monitor mode selector at PULSE EXPOSURE, reset the x-ray monitor by switching the mode 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 the exposure time recorded by the x-ray monitor is less than 100 milliseconds, then reduce the tube potential or increase the copper in the beam to increase the exposure time above this minimum value and repeat the test exposure. Correct item 67 if necessary.

12.14 Without changing technique factors or the x-ray monitor settings, make an additional exposure. The reading will now have no minus sign present. Record this reading of exposure at item 68. Switch the function selector to PULSE DURATION and record this reading at item 69. Switch the function selector back to PULSE EXPOSURE.

12.15 Make three additional exposures, with the exposure readings being recorded at items 72, 74, and 76 and the corresponding time readings at 71, 73, and 75. If any
two readings differ by more than 10 percent of the largest value, make six additional exposures. Record the additional exposure and corresponding time readings 76 through 87. All variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement.

12.16 Sum the exposures entered in items 68-86. If the sum is 1.5 R or greater then the direct-print paper should provide a satisfactory image. Make any additional exposure required to obtain a total of 1.5 R.

12.17 Enter a "*" in the first column of item 88.

12.18 Are the technique factors, fixed or selectable, indicated prior to exposure? Record at item 60, and state in the Remarks that mA is fixed or mAs is selected.

12.19 Was there a visible "beam-on" indication during the exposure? This requirement can be met by a meter that deflects during exposure, or an indicator light that is activated during exposure, or some similar indication. Record at item 61.

12.20 Was there an audible indication of exposure termination? This requirement can be met by the sound of the mechanical contractor terminating the exposure or other mechanical or electronic sound-generating devices. Record at item 62.

12.21 Did the radiographic timer terminate the exposure? Record at item 63.

13.0 X-RAY FIELD/SPOT FILM SIZE COMPARISON

Test Setup

Same as Reproducibility and Linearity.

Test Procedure

13.1 Measure to the nearest millimeter the distance from the spot-film place to the SSD spacer (or to face of BLD if spacer is not present). Record at item 93.

13.2 Measure to the nearest millimeter the distance from the spot-film image receptor to the bottom of the test stand. Record at item 94.

13.3 Remove the plastic cassette from the top of the test stand and develop the direct-print paper by exposure to fluorescent light. (Refer to page LINA-1 for proper development technique.)

13.4 Measure to the nearest millimeter the length and width of the x-ray field image. Record at items 95 and 96. If the field is circular, record the diameter twice at items 95 and 96.
Verify that:

1. Items 2, 3, and 4 have been answered.

2. Data items 12 through 15, and 20 through 23 are recorded in centimeters. Thus, these data items should be approximately 2.5 times data items 8 through 11, and 16 through 19, respectively.

3. Image dimensions (items 8 through 11) are not greater than the corresponding x-ray field dimensions (items 12 through 15).

4. Items 24, 27, and 28 have been completed.

5. Item 27 is in the range of 10-40 cm.

6. If data item 32 is marked M, data is present at data items 33 through 37.

7. If data item 32 is marked B, data is present at data items 33 through 42.

8. If data item 32 is marked A, data is present at data items 38 through 42.

9. Values for items 43 and 44 have been entered.

10. Item 44 is in the range of 10-15 cm.

11. If item 57 is answered "1" or "2," then items 58 and 59 have been completed and entered in the appropriate data blocks.

12. A quick check of beam quality indicates that the appropriate amount of aluminum was present during the test by comparing normalized exposures for each data item.

13. If only four exposures are entered for reproducibility, no two exposures differ by more than ten percent of the highest value.

14. If am mA value is entered for linearity at item 88, then items 89 through 92 have been completed.

15. If item 57 is answered "1" or "2," then items 93 through 96 have been completed.

16. If the control is manufactured after May 1994, then item 88 is in units of mAs product.
CALCULATION TECHNIQUE

C-ARM FLUOROSCOPIC AND SPOT-FILM SYSTEMS

(Test Procedure CFA - FORM FDA 3260)

A. Source to Image Distance

1. Refer to data item 44 of the Field Test Record.

\[ Y = \frac{(224.79)}{(\text{Item 44} - 6.35)} \]

Record Y at Result 1.

A = Distance from input phosphor of Image Intensifier to face of Image Intensifier = 3.0 cm. This is a representative value; use this if A is not supplied by the manufacturer (see Table 1).

2. Fluoroscopic SID = Y + 40.2 + A

Record at Result 2.

B. Minimum Source to Skin Distance

1. Refer to data item 43 on the Field Test Record.

Minimum SSD = Result 1 - Item 43.

Record at Result 3.

C. Fluoroscopic X-Ray Field/Image Receptor Alignment

1. Refer to data items 8 through 15 of the Field Test Record. Calculate the misalignment between the x-ray field and the maximum visible area as follows:

   Misalignment 1/4 = data item 12 - (data item 8 x 2.54) cm.
   Misalignment 2/1 = data item 13 - (data item 9 x 2.54) cm.
   Misalignment 3/2 = data item 14 - (data item 10 x 2.54) cm.
   Misalignment 4/3 = data item 15 - (data item 11 x 2.54) cm.

Record the results at Results 4 through 7. Note that the misalignments must be equal to or greater than zero, since the x-ray field cannot be smaller than the visible area. Therefore, small negative misalignments should be taken as zero misalignments.
2. Calculate the source to image receptor distance

\[ SID' = Y + 35.4 \text{ - Item 28 cm. } \text{ Record at Result 8.} \]

3. Calculate the following misalignments:

   a. \((1/4 + 3/2)\) misalignment. \text{ Record at Result 9.}
   
   b. Percent \((1/4 + 3/2)\) misalignment = Result 9 x 100/SID'.
       \text{ Record at Result 10.}
   
   c. \((2/1 + 4/3)\) misalignment. \text{ Record at Result 11.}
   
   d. Percent \((2/1 + 4/3)\) misalignment = Result 11 x 100/SID'.
       \text{ Record at Result 12.}
   
   e. Total misalignment = Result 11. \text{ Record at Result 13.}
   
   f. Percent total misalignment = Result 10 + Result 12.
       \text{ Record at Result 14.}

4. Repeat the Calculations of steps 1 through 3 for data items 16 through 23 and record at Results 15 through 25.

D. Fluoroscopic Entrance Exposure Rate

1. Calculate EER 30 cm from the face of the Image Intensifier.

2. \textbf{Manual Mode}

   Refer to data item 35 of the Field Test Record.

   \[ EER = \text{Item 35} \times \frac{(\text{Result } 1 + 8.9)^2}{(\text{Result } 1 + 10.2)^2} \]
   
   \text{ Record at Result 26.}

3. \textbf{Automatic Mode}

   Refer to data item 40.

   \[ EER = \text{Item 40} \times \frac{(\text{Result } 1 + 8.9)^2}{(\text{Result } 1 + 10.2)^2} \]
   
   \text{ Record at Result 27.}
4. **FLUORO EER**

For Equipment manufactured after May 19, 1995, the EER limit is 10 R/min and HLC mode is limited to 20 R/min. For Equipment manufactured prior to May 19, 1995, the applicable EER limit(s) can be determined from one of the tables below:

**Single Fluoroscopic Technique Factor control Mode Equipment**

<table>
<thead>
<tr>
<th>Mode of Equipment</th>
<th>Without High-level Control (HLC)</th>
<th>With High-level Control (HLC)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automatic</td>
<td>10 R/min</td>
<td>5 R/min</td>
</tr>
<tr>
<td>Manual</td>
<td>10 R/min</td>
<td>5 R/min</td>
</tr>
</tbody>
</table>

*EER without activating HLC

**Dual Fluoroscopic Technique Factor Control Mode Equipment**

<table>
<thead>
<tr>
<th>Mode Selected</th>
<th>Without HLC Mode</th>
<th>Manual Mode</th>
<th>Automatic Mode With HLC*</th>
<th>Both Modes With HLC*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automatic</td>
<td>10 R/min</td>
<td>10 R/min</td>
<td>5 R/min</td>
<td>5 R/min</td>
</tr>
<tr>
<td>Manual</td>
<td>10 R/min</td>
<td>5 R/min</td>
<td>10 R/min</td>
<td>5 R/min</td>
</tr>
</tbody>
</table>

*EER without activating HLC

5. First determine from data item 32 on the Field Test Record whether the system is a dual or a single mode. Then refer to the proper table and using data items 35, 36, 40, and 41 on the Field Test Record, select the applicable EER limit(s).

**E. BEAM LIMITATION REQUIREMENTS**

1. Refer to items 8 - 11 of the field Test Record. Calculate the maximum visible area at the image receptor. Convert inches to centimeters.

\[
\frac{1}{4} + \frac{3}{2} = \text{Width (W)}
\]

Record at Result 28.

\[
\frac{2}{1} + \frac{4}{3} = \text{Length (L)}
\]

Record at Result 29.
2. Calculate the width ($W'$)

$$W' = W \times \left[ \frac{\text{Result 2}}{\text{Result 1} + 35.4 - \text{Item 28}} \right]$$

Record at Result 30.

3. Calculate the length ($L'$)

$$L' = L \times \left[ \frac{\text{Result 2}}{\text{Result 1} + 35.4 - \text{Item 28}} \right]$$

Record at Result 31.

If item 31 = 1 (a circular field),

$$a = \left( \frac{L' \times W'}{4} \right) \times 3.14 \text{ cm}^2$$

Record at Result 32.

If item 31 = 2 (a rectangular field)

$$a = W' \times L' \text{ cm}^2$$

Record at Result 33.

If the maximum visible area is greater than 300 cm$^2$ and item 3 = Y, stepless adjustment is required, and if item 4 = 1, the BLD is noncompliant.

F. Primary Protective Barrier/X-Ray Field Size Comparison

1. Refer to items 12-15 of the Field Test Record.

$$X_w = 1/4 + 3/2$$

Record at Result 34.

$$X_L = 2/1 + 4/3$$

Record at Result 35.

2. $$X_w^1 = \left[ \frac{(Y + 40.2)}{(Y + 35.4 - \text{Item 28})} \right] \times X_w$$

Record at Result 36.

$$X_L^1 = \left[ \frac{(Y + 40.2)}{(Y + 35.4 - \text{Item 28})} \right] \times X_L$$

Record at Result 37.

Select the larger value of $X_w^1$ and $X_L^1$ if $X_w^1 \neq X_L^1$

$X^1$ max must be $\leq$ item 27 otherwise the primary barrier fails to intercept the
complete x-ray field.

G. Minimum Fluoroscopic Field Size

1. Refer to item 29 and 30. Calculate the field dimensions in the place of the image receptor.

\[ L'' = \text{Item 29} \times \frac{\text{Result 2}}{(\text{Result 1} + 35.4 - \text{Item 28})} \]

Record at Result 38.

\[ W'' = \text{Item 30} \times \frac{\text{Result 2}}{(\text{Result 1} + 35.4 - \text{Item 28})} \]

Record at Result 39.

2. If items 31 = 1 (circular field)

\[ a = \frac{L'' \times W''}{4} \times (3.14) \text{ cm}^2 \]

Record at Result 40.

3. If item 31 = 2 (Rectangular field)

\[ a = L'' \times W'' \text{ cm}^2 \]

Record at Result 41

When item 4 = 1, minimum field area must be \( \leq 125 \text{ cm}^2 \)

When item 4 = 2, minimum field size must be \( \leq 5\text{-by-5 cm}^2 \)

Otherwise the BLD is noncompliant

H. BEAM QUALITY

1. Refer to data items 46, 48, 50, 52, and 54 on the field Test Record. Divide each exposure readings by its corresponding time (data items 47, 49, 51, 53, and 55 to get the exposure rate in each case).

Record the exposure rates \( R_4 \) through \( R_0 \) at Results 42-46.

2. Divide each exposure rate \( R_4 \) through \( R_1 \) by \( R_0 \), the exposure rate for zero filtration.

Record at Results 47-50.

3. On semilog paper, plot the five normalized exposure values along the log scale and the corresponding thickness of aluminum along the linear axis. Draw a smooth curve fit to the points and determine the observed HVL as the thickness of added aluminum that would yield a normalized exposure of 0.50.
Record the observed HVL and kVp at Result 51.

4. To determine the actual HVL, correction for geometry effects and instrument energy dependence must be made.
   a. Actual HVL = (1.247 x HVL_{obs}) - 0.432

   Record the actual HVL and kVp at Result 52

The above equation does not represent a universal correction to the observed HVL, it is only applicable to observed HVLs in the limits specified in the X-ray Performance Standard. For extremely large observed HVLs, this equation underestimates the actual HVL. The intent of this equation is to enable accurate compliance determinations for x-ray beams with marginal observed HVLs.

I. Spot-Film Reproducibility

1. Refer to data items 68, 70, 72, and 74 of the Field Test Record. (Also use data item 76, 78, 80, 82, 84, and 86 if ten exposures were made for reproducibility).
   a. Using the following equation, substituting n=4 or n=10, as appropriate, calculate the average exposure, \( \bar{E}_i \)

   \[
   \bar{E}_i = \frac{1}{n} \sum_{i=1}^{n} X_i
   \]

   Record at Result 53.

   b. Calculate the coefficient of variation, C{\text{1}}, as follows:

   \[
   C_1 = \sqrt{\frac{1}{\bar{E}_i} \sum_{i=1}^{n} \left( \frac{X_i - \bar{E}_i}{\bar{E}_i} \right)^2 / (n - 1)}
   \]

   Where n=4 or n=10, depending on the number of exposures.

   Record at result 54.

2. Refer to data item 67 on the Field Test Record and compute the mAs. This may be given as a selected technique factor, or must be calculated as a product of the exposure time and the tube current.

3. Calculate the average exposure per mAs, X{\text{1}} as follows:

   \[
   X_1 = \frac{\bar{E}_i}{\text{mAs}}
   \]

   Record at Result 55.
4. Refer to data items 89-92 and calculate the average, \( \bar{E}_2 \) as follows:

\[
\bar{E}_2 = \frac{1}{n} \sum_{i=1}^{n} X_i
\]

Record at Result 56.

5. Calculate the coefficient of variation, \( C_2 \), as before:

\[
C_2 = \frac{1}{\bar{E}_2} \left( \sum_{i=1}^{n} \frac{(X_i - \bar{E}_2)^2}{(n-1)} \right)^{1/2}
\]

Record at Result 57.

6. Refer to data item 88 on the Field Test Record and compute mAs. For systems manufactured on or after May 1994, item 88 will contain the mAs product. Calculate the average exposure per mAs, \( \bar{X}_2 \), as follows:

\[
\bar{X}_2 = \frac{\bar{E}_2}{mAs}
\]

Record at Result 58.

J. **Linearity**

Refer to Results 55 and 58. Calculate the coefficient of linearity, \( L \), as follows:

\[
L = \frac{\bar{X}_1 - \bar{X}_2}{(\bar{X}_1 + \bar{X}_2)}
\]

where \( \bar{X}_1 \) and \( \bar{X}_2 \) are average exposures per mAs.

Record at Result 59.

K. **X-Ray Field/Spot-Film Size Comparison**

1. Refer to data item 93 of the Field Test Record. Calculate the spot-film SID, as follows:

\[
\text{Spot-film SID} = \text{Item 93} + \text{Result 3}
\]

Record at Result 60.

2. Calculate the length and width in the place of the image receptor, CL and CW, as follows:

\[
\begin{align*}
\text{CL} & = \frac{\text{Item 95} \times (\text{Result 60})}{(\text{Result 60} - \text{Item 94} - 40.2)} \\
\text{CW} & = \frac{\text{Item 96} \times (\text{Result 60})}{(\text{Result 60} - \text{Item 94} - 40.2)}
\end{align*}
\]
Record CL at Result 61.

Record CW at Result 62.

3. Calculate the length and width differences as follows:

\[ \Delta L = CL - \text{Item 58}. \]

Record at Result 63.

\[ \Delta W = CW - \text{Item 59}. \]

Record at Result 64.

Percent \( \Delta L = \left( \frac{\Delta L}{\text{Result 60}} \right) \times 100 \)

Record at Result 65.

Percent \( \Delta W = \left( \frac{\Delta W}{\text{Result 60}} \right) \times 100 \)

Record at Result 66.

Percent \( (\Delta L + \Delta W) = \) percent \( \Delta L + \) percent \( \Delta W \)

Record at Result 67.
A = Distance from input phosphor of the image intensifier to the face of the image intensifier (supplied by manufacturer, if not available use 3.0 cm which is a representative value).

C = Distance from face of the image intensifier to base of the test stand.

Y = Distance from the focal spot to top of the brass strips.

Z = Distance from face of SSD spacer (or from face of BLD if spacer is not present) to top of brass strips.
### Table 1. C-arm fluoroscopic and spot-film system distance from input phosphor of I.I. to face of I.I. (A)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Philips BV-22</td>
<td>3.0 cm</td>
</tr>
</tbody>
</table>
| 2. G.E. 6” Polarix II | Thompson Insert = 3.9 cm  
|                    | Varian Insert = 3.5 cm      |
| 3. Siemens Siremobile | 4.0 cm |
| 4. C.G.R. Optascop | 8.2 cm     |
| 5. Picker Surveyor | Not available |
| 6. OEC/Varian      | Not available |
| 7. Tanka MCA-30    | Not available |
| 8. Kramex STV-903  | Not available |

---

**Image Intensifier**

**Distance "A" in Centimeters**

**GE FLUORICON R L-300 VASCULAR & C-ARMS**

(On digital systems remove user-insertable grid.)

12" Model 46-233653G1 Housing
- Thomson 46-216631P1 Insert: 3.3
- Varian 46-233654P1 Insert: 1.9

9" Model 46-184080G1 Housing
- Thomson 46-174740P1 Insert: 2.3
- Varian 46-174055P1 Insert: 1.5

**GE 6”POLARIX II/II-E**

Model 46-914507G1 Housing
- Thomson 46-216076P1 Insert: 3.9
- Varian 46-223900P1 Insert: 3.5
RESULTS RECORD
C-ARM FLUOROSCOPIC AND SPOT-FILM SYSTEMS
(Test Procedure CFR - Form FDA 3260)

Source to Image Distance

1. Y = _______ cm.
2. Fluoroscopic SID = _______ cm.
3. Minimum SSD = _______ cm.

Fluoroscopic X-Ray Field/Image Receptor Alignment

4. Misalignment 1/4 = _______ cm.
5. Misalignment 2/1 = _______ cm.
6. Misalignment 2/3 = _______ cm.
7. Misalignment 4/3 = _______ cm.
8. SID' = _______ cm.
9. (1/4 + 3/2) misalignment = _______ cm.
10. Percent (1/4 + 3/2) misalignment = _______ cm.
11. (2/1 + 4/3) misalignment = _______ cm.
12. Percent (2/1 + 4/3) misalignment = _______ percent.
13. Total misalignment = _______ cm.
14. Percent total misalignment = _______ percent.
15. Misalignment 1/4 = _______ cm.
16. Misalignment 2/1 = _______ cm.
17. Misalignment 3/2 = _______ cm.
18. Misalignment 4/3 = _______ cm.
19. SID' = _______ cm.
20. (1/4 + 3/2) misalignment = _______ cm.
21. Percent (1/4 + 3/2) misalignment = _______ percent.
22. \((2/1 + 4/3)\) misalignment = _______ cm.

23. Percent \((2/1 + 4/3)\) misalignment = _______ percent.

24. Total misalignment = _______ cm.

25. Percent total misalignment = _______ percent.

**Fluoroscopic Entrance Exposure Rate**

**Manual Mode**

26. Entrance Exposure Rate = _______ R/min.

**Automatic Mode**

27. Entrance Exposure Rate = _______ R/min.

**Beam Limitation Requirements**

28. Width \((1/4 + 3/2)\) = _______ cm.

29. Length \((2/1 + 4/3)\) = _______ cm.

30. \(W'\) = _______ cm.

31. \(L'\) = _______ cm.

32. \(a\) (circular) = _______ cm\(^2\).

33. \(a\) (rectangular) = _______ cm\(^2\).

**Primary Protective Barrier/X-Ray Field Size Comparison**

34. \(X'_w\) = _______ cm.

35. \(X'_l\) = _______ cm.

36. \(X'^1_w\) = _______ cm.

37. \(X'^1_l\) = _______ cm.

**Minimum Fluoroscopic Field Size**

38. \(L''\) = _______ cm.

39. \(W''\) = _______ cm.

40. \(a\) (circular) _______ cm\(^2\).

41. \(a\) (rectangular) _______ cm\(^2\).
Beam Quality

Exposure Rate

42. \( R_4 = \quad \) mR/s at 4.5 mm Al.

43. \( R_3 = \quad \) mR/s at 3.5 mm Al.

44. \( R_2 = \quad \) mR/s at 2.5 mm Al.

45. \( R_1 = \quad \) mR/s at 1.5 mm Al.

46. \( R_0 = \quad \) mR/s at 0.0 mm Al.

Normalized Exposure Rate

47. \( N_4 = \quad \) at 4.5 mm Al.

48. \( N_3 = \quad \) at 3.5 mm Al.

49. \( N_2 = \quad \) at 2.5 mm Al.

50. \( N_1 = \quad \) at 1.5 mm Al.

\[ N_0 = 1.0 \] at 0.0 mm Al.

51. \( HVL_{obs} = \quad \) mm Al at \( \quad \) kVp.

52. Actual HVL = \( \quad \) mm Al at \( \quad \) kVp.

Spot-Film Reproducibility and Linearity

53. Average exposure, \( \bar{E}_1 \) = \( \quad \) mR.

54. Coefficient of variation, \( C_1 \) = \( \quad \).

55. Average exposure/mAs, \( \bar{E}_1 \) = \( \quad \) mR/mAs.

56. Average exposure, \( \bar{E}_2 \) = \( \quad \) mR.

57. Coefficient of variation, \( C_2 \) = \( \quad \).

58. Average exposure/mAs, \( \bar{E}_2 \) = \( \quad \) mR/mAs.

59. Coefficient of linearity, \( L \) = \( \quad \).

X-Ray Field/Spot-Film Size Comparison

60. Spot-Film SID \( \quad \) cm.
61. CL = _______ cm.
62. CW = _______ cm.
63. ΔL = _______ cm.
64. ΔW = _______ cm.
65. Percent ΔL = _______ percent.
66. Percent ΔW = _______ percent.
67. Percent ΔL + Percent ΔW = _______ percent.
PART X CF-33 4/1/2000

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
C-ARM FLUOROSCOPIC AND SPOT-FILM SYSTEMS
FIELD TEST RECORD

(Use Form FDA 2782, Field Test Record Continuation, if more space is needed.)

Card No. (Jan.-Dec.)
Test Procedure

2. System Type
M-Mobile
S-Stationary

Beam Limiting Device Information
3. BLD Manufactured after 5/22/79
Y-yes
N-no

4. BLD type
1-Fixed Aperture
2-Stepless

Component Certification Information
5. Indicate the Status of Each as Follows:
C-Certified
V-Certified with a Variance
N-Not Certified
X-Not Present or not applicable

Tube Housing Assembly
X-Ray Control
Spot Film Device
(after 4/77)

Beam Limiting Device
High Voltage Generator
Fluoroscopic Imaging Assembly
(before 4/77)

Table
Image Intensifier (after 4/77)

Initial Set-up (Fluoroscopic Mode) And Surveyor Protection Test

MDH(Exposure)

6. System Hazardous
Y-yes
N-no

If yes, describe hazard in Remarks and discontinue testing

7. Warning Label Present
Y-yes
N-no

Fluoroscopic X-ray Field/Image Receptor Alignment

Image Dimension
X-ray Field Dimension

1/4
8. 27
29
12. 30
32 cm

2/1
9. 33
35
13. 36
38 cm

3/2
10. 39
41
14. 42
44 cm

4/3
11. 45
47
15. 48
50 cm

NO MAGNIFICATION
## Spot-Film Reproducibility and Linearity

<table>
<thead>
<tr>
<th>MDH Threshold Setting</th>
<th>Generator Type</th>
<th>Technique Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5-3 phase, 0.2-1 phase</td>
<td>1-phase</td>
<td>kVp</td>
</tr>
<tr>
<td>65</td>
<td>35</td>
<td>37</td>
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</tbody>
</table>

### Reproducibility (no AI in beam)

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<th>Item</th>
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### Linearity

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### X-ray Field/Spot-film Size Comparison

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<tr>
<th>Item</th>
<th>cm</th>
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<th>cm</th>
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<td>23</td>
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<tr>
<td>96</td>
<td>32</td>
<td>33</td>
<td>33</td>
<td>34</td>
</tr>
</tbody>
</table>

**Remarks**
### Source — Image Distance and Minimum Source to Skin Distance

43. Distance from face of SSD spacer (or from face of BLD if spacer is not present) to top of brass strips: 47 cm

44. Outside Separation of Image of Focal Spot Strips: 50 cm

### Beam Quality

<table>
<thead>
<tr>
<th>kVp</th>
<th>mR @ 4.5 mm Al</th>
<th>mR @ 3.5 mm Al</th>
<th>mR @ 2.5 mm Al</th>
<th>mR @ 1.5 mm Al</th>
<th>mR @ 0.0 mm Al</th>
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<td>58</td>
<td>64</td>
<td>70</td>
<td>76</td>
<td>13</td>
</tr>
</tbody>
</table>

56. At End of Present Cumulative Time Internal Either YES or NO

### Spot-Film Mode

57. Type of spot-film device:
1. Clip-on cassette holder
2. Cut-film changer
3. N/A (only a fluorographic camera provided)

58. Spot-film length: 18 cm

59. Spot-film width: 22 cm

60. Technique factors fixed or selectable indicated before exposure

61. A visible beam-on indication during exposure

62. An audible indication of exposure termination

63. Exposure terminated at a preset time or mAs

64. Means provided for maintaining the fluoro field size during spot-filming
SUPPLEMENTARY 1: VARIABLE C-ARM FLUOROSCOPIC SYSTEMS

C-ARM FLUOROSCOPIC AND SPOT-FILM SYSTEMS

(Test Procedure CFB - Use Form FDA 3260)

This supplementary procedure is used for testing mobile or stationary C-arm fluoroscopes that have a variable SID. The SID may be changed by moving the position of the imaging assembly (image intensifier and spot-film device or film changer) or the diagnostic-source assembly or both. The same field test record, FDA 3260, is used for recording the data.

1.0 GENERAL GUIDANCE

1.1 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 Field Test Record will not be completed, enter an "**" in the first column of each inapplicable item in that portion of the Record.

NOTE: If multiple indicators are provided for a single parameter (e.g., kVp, etc.) 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 If not already completed, complete the General Information Field Test Record. Enter the field test serial number which appears preprinted on the General Information Field Test Record in the appropriate block on each page of the C-Arm Fluoroscopic and Spot-Film System Field Test Record.

2.3 Verify that the assemblers' reports, FD 2579s', are correctly prepared. If they are not, write in the correct information above the incorrect information.

2.4 Enter the letter "B" in data item 1.

2.5 Record the system type (mobile or stationary) in item 2.

2.6 Determine from the ID label or from the installation date whether the BLD was manufactured after 5/22/79. Record at item 3.

2.7 Examine the control panel and the BLD to determine if collimator shutter controls are provided. If shutter blades can be continuously varied from the maximum to the minimum field size record a "2" at item 4. If, however, beam limitation is achieved by use of fixed apertures or cones, record a "1" at item 4.

2.8 Indicated the certification status of each component making up the system at item
5.

2.9 Set up the system for fluoroscopic operation if not already done (i.e. rotate the radiographic image assembly out of the beam axis and position the fluoroscopic image intensifier into place). If present, remove the clip-on cassette holder from the image intensifier.

2.10 Turn on the television monitor and allow time for stabilization.

2.11 Connect the 6-cm ionization chamber to the electrometer of the model 1015F x-ray monitor. Set the x-ray monitor function selector to HOLD and the mode selector to EXPOSURE.

**IMPORTANT!**

Position the exposure footswitch as far as possible from the C-arm or behind a protective shield. Also, always be conscious of the presence and direction of the x-ray beam. Try to orient yourself so that the x-ray beam is pointing away from the body.

### 3.0 INITIAL SETUP (FLUOROSCOPIC MODE) AND SURVEYOR PROTECTION TEST

Test Setup (See figure on test record)

(a) Tilt or rotate the C-arm into the horizontal plane (or as close to it as possible) so that a line from the focal spot to the center of the image intensifier (II) face would be parallel to the floor.

(b) Adjust the image intensifier and diagnostic source to the maximum SID that the system will allow. On some systems, the SID can be changed by varying wither the position of the image intensifier or the diagnostic source assembly or both. If the test is conducted on a system equipped with an x-ray table, the table might be used instead of the tripod as a support for the test stand. On some stationary systems, it will not be possible to rotate the C-arm into the horizontal plane. If this is the case, use the following steps:

(1) The test stand will need to be attached to the tripod on a vertical orientation (see Figure 4).

(2) On many of these systems, the x-ray beam can only be aimed at the ceiling instead of the floor. The top of the test stand, these cases, should be towards the BLD (the test stand will be upside down).

(3) Check the orientation of the test stand with the bubble level in the test kit to make sure it is level. A certain amount of adjustment may be necessary to make sure that the test stand does not sag.

(c) Mount the right side of the test stand onto the tripod so that the MDH holes are on top (see Figure 1). Follow the tripod setup procedure in Appendix B of the
test procedures manual. Make sure the test stand is level by using the bubble level.

(d) Measure the diameter of the image intensifier housing before positioning the test stand against the image intensifier. The size of the housing should be somewhat larger than the size of the input phosphor of the image intensifier. Record at item 27.

NOTE: For image intensifiers that are between 6" (15.24 cm) and 9" (22.86 cm), the choice of test geometry (either 6" or 9" and larger) depends on which works best for the test procedure. If one test geometry does not work well, the other geometry might work better.

(e) Enter "006" at data item 87 if the 6" (15.24 cm) geometry is used and "009" at item 87 if the 9" (22.86 cm) geometry is used.

NOTE: In this supplement, data items 86 and 87 will not be used for reproducibility values. Only a maximum of nine measurements will be used during this procedure for reproducibility.

(f) 9" (22.86 cm) or Larger Image Intensifier: Move the tripod toward the BLD until the test stand top is approximately centered on and about 3 cm from the face of the BLD or SSD spacer. The bottom opening in the test stand should be centered over the image intensifier face. Insert the slide assembly, grid side toward the BLD, into slot 4 of the test stand.

6" (15.24 cm) Image Intensifier: Move the tripod so that the test stand bottom is against the face of the II. Adjust the tripod height and tilt until the bottom opening in the test stand is flush against and centered on the face of the image intensifier. Insert the slide assembly, grid side toward the BLD, into slot 6 of the test stand.

(g) Center (and tape) 0.1 inch (2.54 mm) of copper on slot 7 of the test stand. (See Figure 2, modification of the test stand.)

(h) Insert the 6 cm$^3$ ionization chamber through the upper mounting hole (C) of the test stand.

TEST PROCEDURE

3.1 Select the largest cone aperture that will still permit fluoroscopy, or if a stepless BLD is provided, fully open the shutters.

3.2 Select fluoroscopic technique factors of approximately 90 kVp and 2 mA, and set the cumulative fluoro timer to its maximum setting.

3.3 Using the GM survey meter, make several short exposures and scan the work area.
Not the greatest GM meter deflection. Refer to page GM-1 for instructions on the

![Diagram of test stand attached to tripod](image)

**Figure 1**
Figure 2
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 Model 1015F x-y monitor with 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.

3.4 If the GM meter indication is greater than 15 for the Model 251B Surveyor Meter or 150 for the TBM-1 Ratemeter, make followup measurements with the 100-cm$^2$ ionization chamber. If these followup measurements exceed 50 mR/hr, take precautions such as wearing a lead apron, standing behind a lead screen, standing away from the system and the primary x-ray beam, 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 scattered radiation. Tell the user you are giving him/her this information in case he/she was not aware of the scatter radiation levels under the conditions measured so that he/she can consider it as part of their total radiation safety program. Enter in the REMARKS, the observed exposure rate and the conditions under which the excessive radiation rate was obtained, and then continue to the next test (step 3.5).

INTERLOCK TEST

3.5 On some systems, the diagnostic source assembly can be angled such that it is no longer aimed at the image intensifier. The purpose of this type of orientation is so the primary beam can be used for radiographic exposures on a wall cassette holder. If the option is available on the system, then the system must be interlocked such that a fluoroscopic exposure is prevented unless the image intensifier (primary protective barrier) is in place to intercept the primary beam. Complete the following for this test:

(a) Change the angle of the diagnostic source assembly (DSA) to approximately 45 degrees from the perpendicular (in relation to the image intensifier). Do not attempt to force the DSA. There may be mechanical locks that must released before rotating the DSA. If the system does not allow this much of an angle, then rotate the DSA until it no longer moves.

(b) Adjust the BLD to an opening just slightly larger than the ion chamber.

(c) Temporarily remove the 6-cm$^3$ ionization chamber from the test stand and place it on the front of the beam-limiting device. If necessary, tape the chamber to the BLD with tape that won't damage the paint on the system. Remember to reinsert the chamber into the test stand upon completion of the interlock test.

(d) Set the x-ray monitor mode selector to EXPOSURE RATE.

(e) If the system provides for both "Manual" and "Automatic" adjustment of fluoroscopic technique factors, select a low kVp and mA control settings and check interlock operation in both modes.
(f) Before making an exposure, position the exposure foot-switch as far from the system as possible. Be sure to stand as far away from the primary beam as possible.

(g) Momentarily depress the exposure foot-switch. Observe the x-ray monitor and x-ray control for any indication of x-ray exposure.

(h) If the system allows an exposure without the image intensifier (primary protective barrier) in place to intercept the primary beam, then enter "Y" in item 6. Otherwise, enter "N".

It is not necessary at this point to discontinue all further testing. However, caution must be used so that accidental depression of the foot switch does not occur if the diagnostic source assembly is no longer aimed at the image intensifier.

3.6 Is there a warning label present on the control panel containing the main power switch as prescribed in 21 CFR 1020.30(j)? Record at item 7.

4.0 FLUOROSCOPIC X-RAY FIELD/IMAGE RECEPTOR ALIGNMENT

Test Setup

Same as initial setup.

Test Procedure

4.1 Either the MANUAL or AUTO brightness control modes may be used. Make an exposure and observe the slide assembly grid image on the TV monitor. Adjust the brightness control or the technique factors until a good quality image of the grid is obtained.

4.2 Verify that the grid is approximately centered on the TV monitor. If it is not, slightly move the tripod with the x-ray beam off until approximate centering is obtained.

4.3 Set the x-ray monitor mode selector to EXPOSURE and the function selector to MEASURE. Leakage on the instrument should not exceed 4 mR in one minute. If it does, the instrument may be defective and you should contact CDRH for guidance.

4.4 Verify that the BLD is still fully open.

4.5 Insert a plastic cassette containing a sheet of direct-print paper into the slide assembly at slot 6 (slot 4 for 9" (22.86 cm) of larger image intensifier).

4.6 Insert the focal-spot into slot 1 of the test stand with the brass strips toward the beam-limiting device. Measure to the nearest millimeter the distance from the face of the source-skin distance (SSD) spacer (or the face of the BLD if a spacer is not present) to the top of the brass strips of the focal-spot assembly. Record at item
43. 
NOTE: If the system is not equipped with a radiographic mode that will be tested in section 13.0, it will be necessary to make an image of the brass strips of the focal-spot assembly during this section of the procedure. If this is necessary, make sure that the image be necessary to move the test stand away from the BLD to see both brass strips on the TV monitor. Be sure, however, that the x-ray field at the slide assembly is not now so large that it extends beyond the edge of the direct-print paper. If you expose a sheet of direct-print paper, but do not get both the image of the brass strips and all edges of the x-ray field on the paper, adjust the position of the test stand and conduct this test a second time with the test sand in this readjust position. Make sure that the test data recorded on the field test record reflects the final position of the test stand and geometry used.

4.7 Some variable C-arm systems are equipped with three-field image intensifiers. If this is the case, start the test in the nonmagnification mode and record the data at items 8-15. If there is no magnification mode leave items 16-23 blank.

4.8 Measure to the nearest millimeter the distance from the face of the image intensifier to the SSD spacer (or face of the BLD if spacer is not present). Record at item 93.

4.9 Make an exposure and read the dimensions of the grid that are visible at each edge.

NOTE: See lines 1/4, 2/1, 3/2 and 4/3 of figure 3. 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 inch (2.54 mm). If the focal-spot strip image is present on the television monitor, make sure that the grid dimensions can be read. If they cannot be read, it may be necessary to remove the focal-spot assembly temporarily before returning it to the test stand.

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

4.11 If the accumulated exposure is 4 R or greater, the direct-print paper should provide a satisfactory image. Make any additional exposure required to obtain a total of 4 R.

4.12 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). If a satisfactory image of the focal-spot strips is visible on the paper, then the focal-spot assembly may be removed from the test stand.

NOTE: If the system does not have a radiographic mode, then this sheet of direct-print paper for the FLUOROSCOPIC X-RAY FIELD/IMAGE RECEPTOR ALIGNMENT test must be retained and
4.13 Measure to the nearest millimeter the distance from the center of the grid to the

Along Table Direction

Across Table Direction

used for later calculation of source-to-skin distance.
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.

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

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

4.16 If the mode of greatest magnification on a three-field image intensifier allows you to read the dimensions of the grid image, then perform this test in this mode. There is no need to test the mode of lesser magnification (e.g. middle mode) unless the grid dimensions cannot be read in the mode of greatest magnification. Repeat steps 4.9 through 4.13 for the magnification mode and record the data at items 16 through 23.

4.17 Record the shape of the visible area at 24.

4.18 Tube potential and current must be continuously indicated during exposure, but not necessarily at the operator's position. Record at item 25.

4.19 Verify that the maximum setting for the fluoro timer is five minutes or less. Record at item 26.

5.0 PRIMARY PROTECTIVE BARRIER/X-RAY FIELD SIZE COMPARISON

5.1 Measure to the nearest millimeter the distance from the face of the image intensifier to the base of the test stand. Record at item 28. When the bottom of test stand is flush against the image intensifier (setup for 6" (15.24 cm) image intensifier), leave item 28 blank for later use.

6.0 MINIMUM FLUORO X-RAY FIELD SIZE

Test Setup

Same as initial setup.

Test Procedure

6.1 Select the smallest BLD aperture or cone. If a stepless collimator is provided, close the collimator completely and make a short exposure to see if any visible area can be observed. If none is observed skin the rest of this procedure and record "00.0" at items 29 and 30 and an asterisk at item 31. If a visible area is observed, proceed with step 6.2.

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

6.3 Make an exposure to obtain at least 1.5 R to the ionization chamber.
6.4 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.)

6.5 Measure to the nearest millimeter the length and width of the x-ray field image. Record at items 29 and 30. If the field image is circular, record the diameter twice at items 29 and 30.

6.6 Record the x-ray field image shape at item 31.

Fluoroscopic Technique Factor Control Type

Are the fluoroscopic technique factors manually controlled, automatically controlled, or are both manual automatic fluoroscopic technique factor controls provided? Record at item 32. It may be necessary to refer to the Users Manual for an exact answer to this question.

7.0 ENTRANCE EXPOSURE RATE - MANUAL MODE

Test Setup (See figure on test record.)

(a) Adjust the image intensifier and diagnostic source assembly to the minimum SID that the system will allow. On some systems, the SID can be changed by varying either the position of the image intensifier or the diagnostic source assembly or both. If the minimum SID does not provide enough space between the image intensifier and the BLD for the test stand, skip to step (f).

(b) Move the test stand until the base of the test stand is against the image intensifier.

(c) If the collimator is equipped with a light localizer, turn it on and adjust the size of the light field at the top of the test stand, such that the light field passes through the opening at the top of the test stand.

(d) Insert the beam-defining assembly into slot 1. If the system is not equipped with a light localizer, but has a variable-aperture collimator, make an exposure. Reduce the size of the x-ray field so that it is just large enough to image the aperture of the beam-defining assembly on the television monitor (this information also applies to the automatic mode).

(e) Measure to the nearest millimeter the distance from the face of the source-skin distance (SSD) spacer (or the face of the BLD if a spacer is not present) to the center of the ion chamber. Record at item 86 (10th data item box for reproducibility in the main procedure is used to record this distance when using this supplement).

(f) Short Minimum SID - Some systems have a minimum SID which allows less than 40 cm. of space between the face of the source-skin distance (SSD) spacer (or the face of the BLD if a spacer is not present) and the face of the image intensifier. Since this is the height of the test stand, it cannot be placed in the x-ray beam for
EER measurements. Proceed with steps (1) through (6).

(1) Remove the test stand from the space between the BLD and the image intensifier.

(2) Reverse the 6-cm$^3$ ion chamber at the top mounting hole of the test stand such that the ion chamber is sticking out of the side of the test stand. Center the ion chamber beneath the source assembly. The bottom of the test stand must be even with the face of the image intensifier.

(3) Lower the source assembly such that the end of the face of the source-skin distance (SSD) spacer (or the face of the BLD if a spacer is not present) is as close as possible to the ion chamber.

(4) Center 0.1 inch (2.54 mm) of copper on the center of the image intensifier. Be careful to cover the face of the image intensifier with paper or cloth to prevent scratches to the face of the image intensifier.

(5) Make an exposure and observe the image of the ion chamber on the TV monitor. Make sure the aperture of the BLD is opened sufficiently to cover the entire ion chamber.

(6) Measure to the neatest millimeter the distance from the face of the source-skin distance (SSD) spacer (or the face of the BLD if a spacer is not present) to the center of the ion chamber. Record at item 86 (10th data item box for reproducibility in the main procedure is used to record this distance when using this supplement). If the ion chamber is touching the face of the source-skin distance (SSD) spacer (or the face of the BLD if a spacer is not present), then enter 000.0 at item 86.

Test Procedure

7.1 Remove the slide assembly from the test stand, if present.

7.2 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 any additional copper after this check.

7.3 Some 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 technique factors. 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 33 and 34, respectively. Record the maximum exposure rate at item 35.

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

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

7.4 HLC MODE: _______ kVp ______ mA _________ R/min

NOTE: Since 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.

7.5 If the high-level exceeds the low-levels rate, record "y" in item 36. Otherwise, record "n" in item 36.

7.6 Is there a continuous audible signal provided upon activation of the high-level control? Record at item 37. If a high-level control is not present, record "X" at item 37. 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 May 19, 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.

8.0 ENTRANCE EXPOSURE RATE - AUTOMATIC MODE

Test Setup

Same as manual mode except: Center a 1/8 inch (3.18 mm) thick lead sheet over the 0.1 inch (2.54 mm) of copper and tape into place. Remove the slide assembly from the test stand, if present.
Do not change the SID from the EER test that was conducted in the manual mode. When testing large image intensifiers, the beam may extend around the lead sheet present in slot 7. If this happens, the edge of the image intensifier becomes illuminated and the EER drops accordingly. Place the beam-defining assembly in slot 1 to determine if the EER changes. If this makes a difference, conduct the test with the beam-limiting assembly in place. If the focal-spot assembly is still in the test stand from section 4.0 then remove it.

**Short Minimum SID** - Some systems have a minimum SID which allows less than 40 cm. of space between the face of the source-skin distance (SSD) spacer (or the face of the BLD if a spacer is not present) and the face of the image intensifier. Since this is the height of the test stand, it cannot be placed in the x-ray beam for EER measurements. The setup will be essentially the same as in the manual mode (step f). Be careful to cover the face of the image intensifier with paper or cloth to prevent scratches to the face of the image intensifier. If the beam extends around the lead sheet, reduce the size of the x-ray field with the BLD shutters to see if the EER changes. If this makes a difference, conduct the test with the shutters in this position, but open enough not to shield the ion chamber. This may be checked by observing the image of the ion chamber on the TV monitor when the lead is not in the beam.

Measure to the nearest millimeter the distance from the face of the source-skin distance (SSD) spacer (or the face of the BLD if a spacer is not present) to the center of the ion chamber. Record at item 86 if not already recorded in section 7.0 (10th data item box for reproducibility in the main procedure; used to record this distance when using this supplement). If the ion chamber is touching the face of the source-skin distance (SSD) spacer (or the face of the BLD if a spacer is not present), then enter 0000.0 at item 86.

**Test Procedure**

8.1 Set the fluoroscopic technique factor control to "Automatic" mode and any "Automatic Brightness Control" for maximize brightness. The "Automatic" mode may be checked by observing the exposure rate with and without the 1/8 inch (3.18 mm) lead sheet in the beam. If the system is in "Automatic" and the kVp and mA are not at their maximum values, the exposure rate should be higher with the lead in the beam.

8.2 Set the x-ray monitor mode selector to EXPOSURE RATE. While making an exposure, vary the kVp and/or mA settings to obtain the maxim electrometer reading. Record the indicated tube potential and tube current at items 38 and 39, respectively, and the exposure rate at item 40.

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 setting to maximize the electrometer reading. Record the high-level exposure rate in the Remarks section using the following format

8.3 HLC MODE: _______ kVp _______ mA _________ R/min

NOTE: Since 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.

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 provided upon activation of the high-level control? Record at item 42. If a high-level control is not present, record "X" at item 42. 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 May 19, 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 SID AND MINIMUM SSD

(This section is moved to follow section 12.0 in order to facilitate proper data collection sequence.)

10.0 BEAM QUALITY

Test Setup (See figure on test record)

(a) Remove the lead from slot 7 (if present from section 8.0).

(b) Move the 6 cm$^3$ ionization chamber to the lower mounting hole (D) of the test stand.

(c) Place 4.5 mm aluminum of the beam defining assembly in slot 1.

Test Procedure

10.1 (a) If the system has only an automatic mode of operation, go directly to step 10.5.

(b) If the system has a manual fluoroscopic technique factor control mode, select
10.2 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 45.

10.3 Five exposures are required for the beam quality determination. With the x-ray monitor 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 10 seconds at the selected kVp. Record the exposure reading in item 46. Switch the function selector to pulse duration and record the time reading at item 47. Reset the x-ray monitor after the exposure by switching the function selector to HOLD and then back to MEASURE.

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 45 must also be changed.

10.4 Remove aluminum to obtain totals of 3.5, 2.5, 1.5, 0.0 millimeters on top of the beam defining assembly. For each total, make an exposure as described in step 10.3. Record the exposure and time at items 48 through 55. Remember to reset the x-ray monitor between each exposure. Skip to 10.7.

10.5 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 45. 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 10 seconds at the selected kVp. Record the exposure reading at item 46. Switch the function selector to PULSE DURATION and record the time reading at item 47.

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 the situation, the mA and/or must be increased. If kVp is changed, the kVp recorded at item 45 must also be changed.

10.6 Move aluminum from slot 1 of the test stand (toward the BLD) to slot 7 (toward the II) so that the totals of 3.5, 2.5, 1.5, and 0.0 millimeters are left on the top of beam defining assembly. For each total of aluminum, make an exposure as described in 10.4 while RESETTING THE X-RAY MONITOR EACH TIME. Record the exposure and time at items 48 through 55, respectively.

10.7 Set the cumulative fluoro 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 56.

11.0 RADIOGRAPHIC MODE

11.1 A radiographic mode is normally available on C-arm fluoroscopes. Usually, but not always the radiographic images are recorded on a spot-film device (a clip-on cassette holder or a cut-film changer). Occasionally, a fluorographic camera is provided (e.g. a 105 mm camera) for recording images off the output phosphor of the image intensifier. Such a camera is not a spot-film device. Indicate at item 57 the type of spot-film device provided. If only a fluorographic camera is provided, continuation of the test procedure is not appropriate. Skip sections 11, 12, and 13 and enter and "**" at data item 57.

NOTE: Determination from the user if the system allows radiographic exposure if no present in the film changer. If film is required, then make sure the user does not object to the film usage during the radiographic portions of the procedure. As an alternative to making exposure on unexposed film, the film changer magazine can be filled with exposed film.

11.2 Record the dimensions of the spot-film image receptor or the cut-film nominal size at items 58 and 59.

11.3 If both Manual and Automatic (phototimed) exposure modes are provided, select the most commonly used mode of operation.

11.4 Set the tube potential to a value commonly used. Record at item 67.

11.5 Automatic:

(a) If testing in the phototimed mode, record an "**" in the first column of any of item 67 which is not preindicated.

11.6 Manual:

(a) If independently selected, choose values of tube current and exposure time, and record at item 67.

(b) If only the mAs is selectable, choose a value commonly used and record at item 67.

11.7 Is the system single-phase or three-phase? Record at item 66.

NOTE: Using one or more of the following methods, determine whether the system is single-phase or three-phase:

(1) Consult the user or the information provided to him by the high voltage
generator manufacturer.

(2) Check the identification plate to see if the manufacturer has listed he phase of the system along with other electrical characteristics.

(3) Observe the time setting on the control panel. Single-phase timer setting are usually expressed as common fraction multiples of 1/120 second, while three-phase systems usually have timer settings expressed as decimal fractions.

If the system is single-phase, set the x-ray Monitor thumbwheel switch to 0.2, and record at item 65.

If the system is three-phase, set the x-ray Monitor thumbwheel switch to 0.5 and record at item 65.

11.8 Set the system to the maximum SID. This should be the worst-case condition for the size comparison test. If a variable-aperture collimator is present, adjust it to the largest possible x-ray field size.

11.9 For systems equipped with 9" (22.86 cm) or larger image intensifiers, move the test stand to the exact position that it was located at in section 4.6. The distance from the SSD spacer or BLD to the focal-spot assembly should have been recorded at item 43.

For systems equipped with a 6" (15.24 cm) image intensifier, position the test stand such that the top of the test stand is approximately 3 cm from the SSD spacer (or the face of the BLD if a spacer is not present).

11.10 Set the x-ray monitor mode selector switch to PULSE EXPOSURE.

11.11 If a clip-on cassette holder is provided, mount it over the face of the image intensifier. Insert an empty cassette into the cassette holder.

11.12 If the system is equipped with a permanently-mounted film changer, rotate or move it into the beam.

11.13 On some systems, a rad-fluoro mode selector switch is provided on the control panel. If this is the case, switch to the radiographic mode.

NOTE: It must be possible to maintain the fluoro field size during spot-filming. The user, at his option, may select automatic full coverage of the spot-film, but there must be an option on the control panel. A system design that always provides for automatic full coverage of the spot-film is noncompliance. Record at item 64.

12.0 REPRODUCIBILITY AND LINEARITY

Test Setup  (See figure on test record)
(a) Remove the beam defining assembly from slot 1 and replace it with the focal-spot assembly with the brass strips toward the BLD. Tape down the focal-spot assembly.

(b) Move the 6 cm$^3$ ionization chamber to the upper mounting hole (C) of the test stand.

(c) If the test stand top has the optional Plexiglas railings attached, remove these railings by loosening the retaining screws. Center a plastic cassette containing a sheet of direct-print paper on top of the test stand and tape in place.

(d) Insert the slide assembly, grid side up, into slot 6 of the test stand. Insert a plastic cassette containing direct-print paper into the slide assembly.

Test Procedure

12.1 Adjust the BLD so that it is fully open.

12.2 (a) If both "manual" and "automatic" controls are provided for exposure termination, select the mode of operation most commonly used. If the "manual" mode of operation is chosen, complete steps 12.3 through 12.11 and skip steps 12.12 through 12.16.

(b) If the "automatic" technique factor control mode is selected, go directly to 12.12.

MANUAL MODE

12.3 Set the x-ray monitor mode selector to PULSE EXPOSURE. Reset the x-ray monitor so that the display reads -0.00. Without changing the technique factors, make an exposure. Do not record the resultant reading.

12.4 Without changing technique factors or the x-ray monitor settings, make and additional exposure. The reading will now have no minus sign present. Record this reading of pulse exposure at item 68. Switch the mode selector to PULSE DURATION and record this reading at item 69. Switch the mode selector back to PULSE EXPOSURE.

12.5 Make three additional exposures, with the exposure readings being recorded at items 70, 72, and 74, and the corresponding time readings at 71, 73, and 75. Do not reset the x-ray monitor between exposures. If any two readings differ by more than 10 percent of the largest value, make five additional exposures. Record the additional exposures and corresponding time readings at items 76 through 85 for a total of nine data points (items 86 and 87 have already been used). All variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement.

12.6 If the x-ray control is manufactured before May 1994, follow the guidance of paragraph a. under each step for this test section, otherwise use paragraph b.
a. If the unit under test either does not allow specific selection of tube current, or, if only mAs is selectable, then omit procedural steps 12.7 through 12.12, enter an asterisk in the first column of item 88 on the test record, and state in the REMARKS that the mA is fixed, or that only mAs is selectable.

b. Enter a new mAs product (not to exceed twice the first mAs product) at item 88 on the test record. If a new mAs product cannot be obtained, then enter an asterisk in the first column of item 88 on the test record and state in the REMARKS that the mAs product is fixed.

12.7 a. If tube current selection is in fixed steps, select an adjacent tube current step and record the indicated value at item 88.

b. If tube current or mAs is in fixed steps, select an adjacent setting and record the mAs product at item 88.

12.8 a. If tube current selection is continuous (i.e., not in discrete steps), select a second tube current not differing from the first by more than a factor of 2, and record its value at item 88.

b. If the tube current or mAs is continuous (i.e. not in discrete steps), select a second setting not differing from the first by more than a factor of 2, and record the mAs product at item 88.

12.9 The change in tube current may cause in tube potential. If manual compensation is available, readjust the tube potential to its original value, and continue with step 12.11. However, if the kVp cannot be compensated back to its original setting, enter an "***" in the first column of item 89, skip procedural step 12.11, and state in the REMARKS that the kVp could not be compensated.

12.10 Make four exposures at the selected technique factors and vary the technique factors between each measurement as in step 12.5 and record the exposure readings at items 89-92.

12.11 Sum the exposures entered in items 68-92. If the sum is 1.5 R or greater, the direct-print paper should provide a satisfactory image. Make additional exposures, if required, to obtain at least 1.5 R to the ionization chamber. Remove the slide assembly from the test stand and proceed to step 12.17.

AUTOMATIC MODE

12.12 With the x-ray monitor mode selector at pulse exposure, reset the x-ray monitor by switching the mode 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 the exposure time recorded by the x-ray monitor is less than 100 milliseconds, then reduce the tube potential or increase the copper in the...
beam in slot 7 to increase the exposure time above this minimum value and repeat the test exposure. Adjustment of the density setting for the automatic mode may increase the exposure time. Correct item 67 if necessary.

12.13 Without changing technique factors or the x-ray monitor settings, make an additional exposure. The reading will now have no minus sign present. Record the reading of exposure at item 68. Switch the function selector to PULSE DURATION and record this reading at item 69. Switch the function selector back to PULSE EXPOSURE.

12.14 Make three additional exposures, with the exposure readings being recorded at items 70, 72, and 74, and the corresponding time readings at 71, 73, and 75. Do not reset the x-ray monitor between exposures. If any two readings differ by more than 10 percent of the largest value, make five additional exposures. Record the additional exposures and corresponding time readings at items 76 through 85 for a total of nine data points (items 86 and 87 have already been used). All variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement.

12.15 Sum the exposures entered in items 68-85. If the sum is 1.5 R or greater, then the direct-print paper should provide a satisfactory image. 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.)

12.16 Enter an "***" in the first column of item 88.

12.17 Are the technique factors, fixed or selectable, indicated prior to exposures? Record at item 60, and state in the remarks whether the mA is fixed or mAs is selectable.

12.18 Was there a visible "beam-on" indication the exposure? This requirement can be met by a meter that deflects during exposure, an indicator light that is activated during exposure, or some similar indication. Record at item 61.

12.19 Was there an audible indication of exposure termination? This requirement can be met by the sound of the mechanical contractor terminating the exposure or other mechanical or electronic sound-generating devices. Record at item 62.

12.20 Did the radiographic timer terminate the exposure? Record at item 63.

9.0 SID AND MINIMUM SSD

Test Procedure

9.1 If the system has a radiographic mode, then the direct-print paper from step 12.11 or step 12.15 will be used in step 9.3 below for calculation purposes.

9.2 If the system is not equipped with a radiographic mode, such as a film changer or a
clip-on spot-film device, then refer back to the image on the direct-print paper that was developed in step 4.12. There should be an image of the focal-spot strips on the direct-print paper. This paper should be used in step 9.3 below for calculation purposes.

9.3 Measure to the nearest millimeter the minimum separation of the outside edges of the focal-spot strip images. Record at item 44.

13.0 X-RAY FIELD/SPOT FILM SIZE COMPARISON

Test Setup

Same as Reproducibility and Linearity.

Test Procedure

13.1 Measure to the nearest millimeter the distance from the spot-film image receptor to the bottom of the test stand. Record at item 94. On many systems, it will be difficult to obtain the film plane inside a film changer. It may be recessed 5 cm. from the front panel of the changer. Ask the operator or check the user’s manual to determine this location if it is not indicated on the unit.

13.2 Remove the plastic cassette from the top of the test stand and develop the direct-print paper by exposure to fluorescent light. (Refer to page LINA-1 for proper development technique>)

13.3 Measure to the nearest millimeter the length and width of the x-ray field image. Record at items 95 and 96. If the field is circular, record the diameter twice at items 95 and 96. For systems equipped with a 6” (15.24 cm) image intensifier, measure to the nearest millimeter the distance from the face of the source-skin distance (SSD) spacer (or the face of the BLD if a spacer is not present) to the top of the brass strips. Record at item 28.
Verify that:

1) Items 2, 3, and 4 have been answered.

2) Data items 12 through 15, and 20 through 23 are recorded in centimeters. Thus, these data items should be approximately 2.5 times data items 8 through 11, and 16 through 19, respectively.

3.) Image dimensions (items 8 through 11) are not greater than the corresponding x-ray field dimensions (items 12 through 15).

4) Items 24, 27, and 28 have been completed.

5) Item 27 is in the range of 10-40 cm.

6) The distance from the bottom of the test stand to the face of the image intensifier (6" geometry) or the distance from the source-skin spacer or BLD to the top of the brass strips (9" geometry) (item 28) is less than 75 cm.

7) If data item 32 is marked M, data is present at data items 33 through 37.

8) If data item 32 is marked B, data is present at data items 33 through 42.

9) If data item 32 is marked A, data is present at data items 38 through 42.

10) Values for items 43 and 44 have been entered.

11) The distance from the source-skin spacer or BLD to the top of the brass strips (6" geometry) or the distance from the bottom of the test stand to the face of the image intensifier (9" geometry) (item 43) is less than 75 cm.

12) Item 44 is in the range of 10-15 cm.

13) If item 57 is answered "1" or "2", then items 58 and 59 have been completed and entered in the appropriate data blocks.

14) A quick check of beam quality indicates that the appropriate amount of aluminum was present during the test by comparing normalized exposures for each data item.

15) If only four exposures are entered for reproducibility, no two exposures differ by more than ten percent of the highest value.

16) The distance from the source-skin spacer or BLD to the top of the brass strips (item 86) is less than 75 cm.
17) The identification code for the test geometry used (item 87) is either "006" or "009".

18) If a mA value is entered for linearity at item 88, then items 89 through 92 have been completed.

19) If item 57 is answered "1" or "2", then items 93 through 96 have been completed.

20) The distance from the bottom of the test stand to the face of the image intensifier (item 94) is less than 75 cm.

21) If the control is manufactured after May 1994, then item 88 is in units of mAs product.
CALCULATION TECHNIQUE

C-ARM FLUOROSCOPIC AND SPOT-FILM SYSTEMS

SUPPLEMENTARY CALCULATIONS FOR SYSTEMS WITH VARIABLE SID

(Test Procedure CFB - Form FDA 3260)

A. Calculation of Value "Y"

1. Refer to data Item 44 of the Field Test Record.

For systems equipped with a 6" image intensifier (with or without a radiographic mode):

\[ Y = \frac{225.19}{(\text{Item 44} - 6.35)} \]

For systems equipped with a 9" or larger image intensifier and a radiographic (film) mode, use the above equation. For systems without a radiographic mode and a 9" or larger image intensifier:

\[ Y = \frac{95.43}{(\text{Item 44} - 6.35)} \]

Record Y at Result 1.

B. Minimum Source to Skin Distance and Fluoroscopic SSD

1. Refer to either data item 43 or data item 28 on the Field Test Record.

For 9" or greater image intensifiers (or 6" image intensifiers without radiographic modes):

Minimum SSD = Result 1 - Item 43

For 6" image intensifiers with radiographic modes:

Minimum SSD = Result 1 - Item 28

Record at Result 3.

2. Fluoroscopic SID = Result 3 + A + Item 93.

Record at Result 2.

A = Distance from input phosphor of Image Intensifier to face of Image Intensifier = 3.0. This is representative value; use if A not supplied by the manufacturer (see Table 1).
C. Fluoroscopic X-Ray Field/Image Receptor Alignment

1. Refer to data items 8 through 15 of the field Test Record. Calculate the misalignment between the x-ray field and the maximum visible area as follows:

   Misalignment 1/4 = data item 12 - (data item 8 x 2.54) cm.
   Misalignment 2/1 = data item 13 - (data item 9 x 2.54) cm.
   Misalignment 3/2 = data item 14 - (data item 10 x 2.54) cm.
   Misalignment 4/3 = data item 15 - (data item 11 x 2.54) cm.

   Record the results at Results 4 through 7. Note that the misalignment must be equal to or greater than zero, since the x-ray field cannot be smaller than the visible area. Therefore, small negative misalignments should be taken as zero misalignments.

2. Refer to data item 28 of the Field Test Record. Calculate the source to image receptor distance.

   For 6" image intensifiers:
   
   \[ \text{SID}' = \text{Result} - A - 4.57 \text{ cm}. \]

   For 9" or larger image intensifiers:

   \[ \text{SID}' = \text{Result} 2 - A - \text{Item} 28 - 24.89 \text{ cm}. \]

   Record at Result 8.

3. Calculate the following misalignments:

   a. \((1/4 + 3/2)\) misalignment:
      
      Record at Result 9

   b. Percent \((1/4 + 3/2)\) misalignment = Result 9 x 100/SID'.
      
      Record at Result 10.

   c. \((2/1 + 4/3)\) Misalignment.
      
      Record at Result 11.

   d. Percent \((2/1 + 4/3)\) misalignment = Result 11 x 100/SID'.
      
      Record at Result 12.

   e. Total misalignment = Result 9 + Result 11.
      
      Record at Result 13.
f. Total percent misalignment = Result 10 + Result 12.

Record at Result 14.

4. Repeat the Calculations of steps 1 through 3 for data items 16 through 23 and record at Result 15 through 25.

D. Fluoroscopic Entrance Exposure Rate

1. Calculate EER 30 cm from the face of the Image Intensifiers.

2. **Manual Mode**

   Refer to data item 35 of the Field Test Record.

   If data item 86 = 0.00, then EER = Data item 35, otherwise:

   \[
   EER = \text{Item 35} \times \frac{(\text{Result 3} + \text{Item 86})^2}{(\text{Result 3} + \text{Item 86} + 1.37)^2}
   \]

   Record EER at Result 26.

3. **Automatic Mode**

   Refer to data item 40.

   If data item 86 = 0.00, then EER = data item 40, otherwise:

   \[
   EER = \text{Item 40} \times \frac{(\text{Result 3} + \text{Item 86})^2}{(\text{Result 3} + \text{Item 86} + 1.37)^2}
   \]

   Record EER at Result 27.

4. **Fluoro EER**

   The applicable EER limit(s) can be determined from one of the following tables below:

---

**FOR SYSTEMS MANUFACTURED BEFORE May 19, 1995**

**Manual Mode Systems**

Without High-Level Control (HLC) ........................................ 5 R/min

With High-Level Control (HLC) ........................................... 5 R/min*
Automatic Only Systems

Without High-Level Control (HLC) ................................................. 10 R/min
With High-Level Control (HLC) ...................................................... 5 R/min*

Dual (both manual and automatic modes) Systems

Manual Mode Selected:
Without High-Level Control (HLC) ............................................... 10 R/min
With High-Level Control (HLC) ...................................................... 5 R/min*

Automatic Mode Selected:
Without High-Level Control (HLC) ............................................... 10 R/min
With High-Level Control (HLC) ...................................................... 5 R/min*

*Except when the HLC is activated, then the entrance exposure is unlimited.
For systems manufactured after May 19, 1995, the EER limit is 10 R/min and the HLC is limited to 20 R/min.

5. First determine from item 32 on the Field Test record whether the system is a dual or a single mode. Then refer to the proper table and using data items 36 and 41 and Result 26 and 27 on the Field Test Record select the applicable EER limit(s).

E. Beam Limitation Requirements

1. Refer to items 8 - 11 of the Field Test Record. Calculate the maximum visible area at the image receptor. Convert inches to centimeters.

\[
(1/4 + 3/2) = \text{Width (W)}
\]

Record at Result 28.

\[
(2/1 + 4/3) = \text{Length (L)}
\]

2. Calculate the width (W)

\[
W' = W \times \frac{(\text{Result 2})}{(\text{Result 8})}
\]

Record at Result 30.

3. Calculate the length (L')
F. Primary Protective Barrier/X-Ray Field Size Comparison

1. Refer to items 12-15 of the Field Test Record.

\[ X_w = \frac{1}{4} + \frac{3}{2} \]

Record at Result 34.

\[ X_L = \frac{2}{1} + \frac{4}{3} \]

Record at Result 35.

2. 

\[ X_w' = \frac{\text{(Result 2 - A)}}{\text{(Result 8)}} \times X_w \]

Record at Result 36.

\[ X_L' = \frac{\text{(Result 2 - A)}}{\text{(Result 8)}} \times X_L \]

Record at Result 37.

Select the larger value of \( X_w' \) and \( X_L' \) if \( X_w' \neq X_L' \)

\( X^1 \) max must be \( \leq \) item 27 otherwise the primary barrier fails to intercept the complete x-ray field.

G. Minimum Fluoroscopic Field Size

1. Refer to item 29 and 30. Calculate the field dimensions in the place of the image receptor.

\[ L'' = \text{Item 29} \times \frac{\text{(Result 2)}}{\text{(Result 8)}} \]
Record at Result 38.

\[ W'' = \text{Item 30} \times \frac{(\text{Result 2})}{(\text{Result 8})} \]

Record at Result 39.

2. If data item 31 = 1 (circular field)

\[ a = \frac{L'' \times W''}{4} \times (3.14) \text{ cm}^2 \]

Record at Result 40.

3. If item 31 = 2 (Rectangular field)

\[ a = L'' \times W'' \text{ cm}^2 \]

Record at Result 41.

When data item 4 = 1, minimum field area must be \( \leq 125 \text{ cm}^2 \)

When data item 4 = 2, minimum field size must be \( \leq 5\text{-by-5 cm} \)

Otherwise the BLD is noncompliant

**H. Beam Quality**

1. Refer to data items 46, 48, 50, 52, and 54 on the Field Test Record. Divide each exposure reading by its corresponding exposure item (data items 47, 49, 51, 53, and 55 to get the exposure rate in each case).

Record the exposure rates \( R_4 \) through \( R_0 \) at Results 42-46.

2. Divide each exposure rate \( R_4 \) through \( R_0 \), the exposure rate for zero filtration.

Record at Result 47-50.

3. On semilog paper, plot the five normalized exposures along the log axis and the corresponding thickness of aluminum along the linear axis. Draw a smooth curve fit to the points and determine the observed HVL as the thickness of added aluminum that would yield a normalized exposure of 0.50.

Record the observed HVL and kVp at Result 51.

4. To determine the actual HVL, correction for geometry effects and instrument energy dependence must be made.

   a. Actual HVL = \( (1.247 \times \text{HVL}_{\text{obs}}) - 0.432 \)

Record the actual HVL and kVp at Result 52.
The above equation does not represent a universal correction to the observed HVL, it is only applicable to observe HVL’s in the limits specified in the X-ray Performance Standard. For extremely large observed HVL’s, this equation underestimates the actual HVL. The intent of this equation is to enable accurate compliance determination for x-ray beams with marginal observed HVL’s.

I. Spot-Film Reproducibility

1. Refer to data items 68, 70, 72, and 74 of the Field Test Record. (Also use data items 76, 78, 80, 82, and 84 if nine exposures were made for reproducibility).

   a. Using the following equation, substituting n=4 or n=9, as appropriate, calculate the average exposure, $E_i$:

   $$ E_i = \frac{1}{n} \sum_{i=1}^{n} X_i $$

   Record at Result 53.

   b. Calculate the coefficient of variation, $C_1$, as follows:

   $$ C_1 = \frac{1}{E_i} \left( \sum_{i=1}^{n} \left( \frac{X_i - E_i}{E_i} \right)^2 \right)^{1/2} $$

   Where n=4 or n=9, depending on the number exposures.

   Record at Result 54.

2. Refer to data item 67 on the Field Test Record and compute the mAs. This may be given as a selected technique factor, or must be calculated as a product of the exposure time and the tube current.

3. Calculate the average exposure per mAs, $X_i$, as follows:

   $$ X_i = \frac{E_i}{\text{mAs}} $$

   Record at Result 55.

4. Refer to data items 89-92 and calculate the average exposure, $E_2$, as follows:

   $$ E_2 = \frac{1}{n} \sum_{i=1}^{n} X_i $$

   Record at Result 56.
5. Calculate the coefficient of variation, \( C_2 \), as before:

\[
C_2 = \frac{1}{E_2} \left( \frac{1}{n} \sum_{i=1}^{n} (X_i - \overline{X}_2)^2 \right)^{1/2}
\]

Record at Result 57.

5. Refer to data item 88 on the Field Test Record and compute mAs. For systems manufactured on or after May 1994, item 88 will contain the mAs product. Calculate the average exposure per mAs, \( \overline{X}_2 \), as follows:

\[
\overline{X}_2 = \frac{E_2}{\text{mAs}}
\]

Record at Result 58.

J. Linearity

Refer to Results 55 and 58. Calculate the coefficient of linearity, \( L \), as follows:

\[
L = \frac{X_1 - X_2}{(X_1 + X_2)}
\]

where \( \overline{X}_1 \) and \( \overline{X}_2 \) are average exposures per mAs.

Record at Result 59.

K. X-Ray Field/Spot-Film Size Comparison

1. Spot Film SID = Y + 40.03 + Item 94 (see Figure 4).

   Record at Result 60.

2. Calculate the length and width in the plane of the image receptor, CL and CW, as follows:

   \[
   \text{CL (Calculate x-ray field length)} = \frac{\text{Item 95 x Result 60}}{\text{Result 60 - Item 94 - 40.2}}
   \]

   \[
   \text{CW (Calculate x-ray field width)} = \frac{\text{Item 96 x Result 60}}{\text{Result 60 - Item 94 - 40.2}}
   \]

   Record CL at Result 61.

   Record CW at Result 62.

3. Calculate the length and width differences as follows:

   \[
   L = \text{CL} - \text{Data Item 58}
   \]

   Record at Result 63.

   \[
   W = \text{CW} - \text{Data Item 59}
   \]
Record at Result 64.

\[ L = \frac{(\Delta L)}{(\text{Result 60})} \times 100 \]

Record at Result 65

\[ \text{Percent } W = \frac{(\Delta W)}{(\text{Result 60})} \times 100 \]

Record at Result 66.

\[ \text{Percent } (\Delta L + \Delta W) = \text{percent } \Delta L + \text{percent } \Delta W \]

Record at Result 67.
Supplement 1: Variable C-Arm Fluoroscopic System

C-arm Fluoroscopic and Spot-Film Systems

A = Distance from input phosphor of the image intensifier to the face of the image intensifier (supplied by manufacturer, if not available use 3.0 cm which is a representative value)

C = Distance from face of the image intensifier to base of the test stand.

Y = Distance from the focal spot to top of the brass strips.

Z = Distance from face of SSD spacer (or from face of BLD if spacer is not present) to top of brass strips.

Figure 4
PART XI

HEAD AND NECK
RADIOGRAPHIC
SYSTEMS

FORM FD 3297
ROUTINE COMPLIANCE TESTING

HEAD AND NECK RADIOGRAPHIC SYSTEMS

(Test Procedure HNA - Use Form FDA 3297)

1.0 GENERAL GUIDANCE

1.1 This procedure is applicable to stationary radiographic x-ray systems specifically designed for head and neck radiography. It applies to systems operating at fixed as well as variable SID’s and that are equipped with either fixed aperture, manual, or positive beam-limiting devices.

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

2.0 PRETEST CHECKLIST

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

2.2 Set the x-ray monitor 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 NCDRH for guidance.

2.3 If not already done, complete the general information field test record.

2.4 Record the five digits that appear preprinted on the general information field test record, and a unique letter designator, in the appropriate block on each page of the Head and Neck Radiographic Systems field test record.

2.5 Record the code for the appropriate test procedure at item 1.

2.6 Indicate the certification status of each component at item 2.

3.0 INITIAL SETUP

3.1 Rotate the tubehead and image receptor support to a horizontal position (central axis of x-ray beam is horizontal). If the tubehead and/or the cassette holder provides angulation, be sure that the system is adjusted so that the cassette holder is aligned perpendicular to the beam axis.

NOTE: For systems with stepless adjustment collimators, and either fixed or variable SID, the survey can be performed with the x-ray system in a vertical configuration and the test stand sitting on the cassette holder provided the following precautions are observed:

a. The cassette holder device is sturdy enough to support the weight of the test
The light field can be adjusted so that it passes through the opening in the top of the test stand while still wide enough to image the focal-spot assembly and also "fit" on the direct-print paper in the slide assembly.

c. If the SID is variable, it is adjusted to an SID that is numerically indicated on the beam-limiting device as called for in step 3.4, and this indicated SID is recorded at data item 3.

d. The distance from the base of the stand to the front panel of the cassette holder is recorded as 000.0 cm at data item 42.

3.2 Remove any head constraint or support devices attached to the cassette holder.

3.3 If the system does not have stepless adjustment collimation but uses cones or fixed apertures instead, select a collimator according to the following:

   a. For an SID of 40 inches or greater, use a collimator with an indicated field size no larger than 10" x 12".

   b. For an SID of less than 40 inches, use a collimator with an indicated field size no larger than 8" x 10".

3.4 If the SID is adjustable, adjust it to the maximum for which the collimator selected in 3.3 is designed, or if the collimator is stepless, adjust the SID to one that is numerically indicated on the beam-limiting device. Record the indicated SID at item 3. If the SID is fixed and not indicated, look in the user's manual.

3.5 Place a loaded film cassette into the cassette holder. If film is not available, use direct-print paper in the following manner: precisely center and tape a plastic cassette containing a piece of direct-print paper onto an empty film cassette selected for the survey. Insert the film cassette into the cassette holder.

   NOTE: If the film cassette with the plastic cassette attached will not slide into the cassette holder because it is too thick, remove the plastic cassette from the film cassette, and reattach it (precisely centered) to the front plate of the cassette holder.

3.6 Set up test stand and equipment as follows (see figure on test record):

   a. Mount the test stand onto the tripod so that the MDH holes are on top.

   b. Position the test stand and tripod assembly so that the stand is centered in the x-ray beam axis with the base of the test stand towards the image receptor.

   NOTE: On some systems such as Continental X-Ray Corporation's Compere
with a fixed SID and fixed aperture cone length, the space between the end of
the cone and the image receptor is not enough for the test stand to fit
lengthwise. For such systems, see page HN-12 for the appropriate test
setup and procedure.

c. For systems with stepless adjustment collimation, the test stand can be
positioned at any point along the x-ray beam axis provided that the "top" of the
stand is not closer than 12 inches from the source.

d. For systems with cones or fixed apertures, in order to image both brass
strips of the focal-spot assembly, move the test stand and tripod assembly
so that the top of the stand is as close as possible to the end of the cone or
beam-limiting device, but no closer than 12 inches from the source.

NOTE: On those systems which have long cones or large fixed
aperture collimators, the distance from the source to the end of the
collimator will often be greater than 12 inches, thus the test stand
should be positioned against the end of the collimator. On short
cone systems or systems with small fixed aperture collimators,
the distance between the source and the end of the collimator is
less than 12 inches, so that the test stand must be positioned a
few inches from the end of the collimator to ensure that it is at
least 12 inches from the source.

e. Insert the slide assembly, grid side towards the BLD, into slot 6 of the test
stand.

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

g. Position the 6 cm³ chamber in hole "D" of the test stand and secure with the
retaining ring.

h. Insert the focal-spot assembly, brass side towards the BLD, into slot 1 of the
test stand.

3.7 If the system has stepless adjustment collimation with light localizer, perform the
following additional steps:

a. Turn on the light localizer to ensure that it is operable. If it is not, explain in
the "Remarks" section and skip sections 9.0, 10.0, 11.0, and 13.0.

b. Center the test stand by centering the light field on the slide assembly grid. A
piece of white paper in the slide assembly makes visualization of the light
field easier during setup.

c. Adjust the beam-limiting device so that the light field is approximately 4" x
6" at the slide assembly with the longer dimension parallel to the long
dimension of the slide assembly. Using a piece of white paper, at the "top" of the test stand, check all edges of the light field against those of the opening in the top of the test stand to make sure that the light field is not shielded by the stand and passes through the opening in the top of the test stand.

d. Be sure that both brass strip images from the focal-spot assembly can be seen within the light field at the slide assembly.

e. Define the edges of the light field on the slide assembly grid by placing the metal marker strips so that the outside edge of the marker is along the inside edge of the light field and one end of the marker is along the central line of the grid. Avoid disturbing the slide assembly or the test stand.

3.8 Place 4.5 mm of aluminum on "top" of the focal-spot assembly.

4.0 BEAM QUALITY

4.1 Whenever a manual mode of operation for exposure termination (Manually set time or mAs) is provided, select this mode of operation over the automatic mode (phototimer). Record the mode of operation used during testing at item 4.

4.2 Select a commonly used technique in the above 70 kVp range. Record the selected kVp at item 5.

4.3 a. If independently selectable, choose values of tube current and exposure time commonly used, and record at items 6 and 7. Leave item 8 blank.

b. If only mAs is selectable, choose a value commonly used, and record at item 8. Leave items 6 and 7 blank.

4.4 If testing in the phototimed mode, select a commonly used value of tube current (or the fixed value if mA is fixed) and record at item 6. Leave item 7 and 8 blank.

4.5 Set the x-ray monitor to PULSE EXPOSURE and the function selector to MEASURE. The display should indicate -0.00. If any other reading is present, reset the monitor by switching the function selector to HOLD and then back to MEASURE.

CAUTION: Consult the system's duty cycle information and anode cooling curves to ensure that the following series of exposure will not exceed the manufacturer’s anode heat loading specifications. If proper cooling time between exposures cannot be determined, use the following guidance:

a. Rotating anode tubes: Wait 60 seconds after every accumulated 5,000 heat units loading of the anode.

b. Stationary anode tubes: Wait 30 seconds between exposures of less than 900 heat units and 60 seconds between exposures of 900 to 1800 heat units.
NOTE: If a loaded film cassette is used at step 3.5, make an exposure at the selected techniques. Have the film processed, and if a readable image is not obtained at these technique factors, adjust the technique factors appropriately and repeat the exposure with another film. Set the developed film aside for later determination of the centers alignment and continue with the next step.

MANUALLY SET TIMER OR mAs MODE

4.6 Make an exposure and record the reading (without the minus sign) at item 9.

4.7 Remove successive aluminum filters to obtain totals of 3.5, 2.5, and 1.5 mm, and make an exposure for each total. Record the exposure readings at items 10, 11, and 12.

4.8 Skip to 4.11.

PHOTOTIMER MODE

4.9 Make an exposure and record the reading (without the minus sign) at item 9.

NOTE: For the reproducibility test in the next section (5.0), the exposure time must be equal to or greater than 100 milliseconds. Therefore, switch the x-ray monitor mode selector to PULSE DURATION and ensure that the exposure time is at least 100 msec. If it is not, reduce the tube potential to increase the exposure time above the minimum value, and repeat the test exposure. Correct items 5 and 9 if necessary.

4.10 Transpose successive aluminum filters from the "top" of the stand to slot 7 such that the totals of 3.5, 2.5, and 1.5 mm remain at the "top" and make an exposure for each total. Record the readings at items 10, 11, and 12.

4.11 Are the technique factors indicated before the exposure? Record at item 13.

4.12 Is the exposure terminated after a preset time interval, preset mAs, or preset radiation exposure to the image receptor? Record at item 14.

NOTE: The intent of this question is to identify conditions that pose an eminent radiation 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.

4.13 Is there a warning label as prescribed in 21 CFR 1020.30(j) present on the control panel containing the main power switch? Record at item 15.

5.0 REPRODUCIBILITY LINEARITY
Test Setup

Same as BEAM QUALITY except all aluminum filters removed unless testing in phototimer mode, then all aluminum filters transposed to slot 7.

Test Procedure

5.1 Maintain the technique factors used for beam quality testing. All variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement.

NOTE: The adjustment of all variable controls for technique factors to alternate settings and then back to the test setting is only applicable to equipment manufactured after September 5, 1978.

5.2 a. If the system is single-phase, set the x-ray monitor Pulse Fraction Threshold to 0.2 and record this number at item 16.

b. If the system is three-phase, set the x-ray monitor Pulse Fraction Threshold to 0.5 and record this number at item 16.

5.3 Set the x-ray monitor mode selector to PULSE EXPOSURE and the function selector to MEASURE. The display should indicate -0.00. If any other reading is present, reset the monitor by switching the function selector to HOLD and then back to MEASURE.

5.4 Make an exposure. DO NOT record the resultant reading. Without resetting the x-ray monitor, make another exposure. The reading will now have no minus sign present. Record the exposure reading at item 17. Switch the mode selector to PULSE DURATION and record the time reading at item 18. DO NOT reset the x-ray monitor.

5.5 a. Make three additional exposures with the exposure readings being recorded at items 19, 21, and 23, and the time readings at items 20, 22, and 24 DO NOT reset the x-ray monitor.

b. If any two exposure readings differ by more than 10 percent of the higher exposure reading, make an additional 6 exposures. Record the exposure readings at items 25, 27, 29, 31, 33, and 35, and the time readings at items 26, 28, 30, 32, 34, and 36.

5.6 If testing in the phototimed mode, or if the system was manufactured before May 1994 and the system either does not allow specific selection of tube current, or if only mAs is selectable, then omit steps 5.7 through 5.10 and enter an asterisk in the first column of item 37 on the Field Test Record, and state in Remarks, that mA is fixed, mAs is selected, or the system is phototimed only.

5.7 Use step (a) for systems manufactured before May 1994 and step (b) for systems manufactured on or after May 1994.

(a) (1) If tube current selection is in fixed stations, select an adjacent tube current
station and record the indicated value at item 37.

(2) If tube current selection is continuous (i.e., not in discrete steps), select a second tube current not differing from the first by more than a factor of 2. Record at item 37.

(b)(1) If tube current or mAs is in fixed steps, select an adjacent setting and record the mAs product at item 37.

(2) If the tube current or mAs is continuous (i.e. not in discrete steps), select a second setting not differing from the first by more than a factor of 2, and record the mAs product at item 37.

5.8 The change in tube current may cause a change in the indicated tube potential. If manual compensation is available, readjust the tube potential to its original value, and continue with steps 5.9 and 5.10. However, if the kVp cannot be compensated back to its original setting, enter an asterisk in the first column of item 38, skip steps 5.9 and 5.10 and state in the Remarks that kVp could not be compensated.

5.9 Make an exposure at the selected technique factors. Record the reading at item 38.

5.10 While varying technique factors between each measurement as described in step 5.1, make three additional exposures. Record the exposure readings at items 39, 40, and 41. It is not necessary to reset the x-ray monitor between exposures.

5.11 Sum the exposures entered on the test record. If the sum is 1 R or greater, the direct-print paper in the slide assembly should provide a satisfactory image. Make additional exposures, if required, to obtain at least 1 R to the ion chamber.

5.12 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). If a readable image has not been obtained, a new cassette with fresh direct-print paper should be inserted and exposed with sufficient radiation to produce an image.

6.0 ADDITIONAL EXPOSURES TO CASSETTE HOLDER

If you use a plastic cassette containing direct-print paper instead of film (step 3.5), a total exposure of 6 to 8 R to the ion chamber when testing at 48" SID, or 3 to 4 R when testing at 40" SID is necessary to provide a readable image on the direct-print paper. If the total exposure to the ion chamber (step 5.11) is greater than 6 R (3 R for 40" SID) skip to step 6.2. However, if the total exposure to the ion chamber is less than 6 R (3 R for 40" SID), perform step 6.1.

NOTE: If the survey is being performed with the x-ray system in a vertical configuration with the test stand sitting on the cassette holder, the required exposure to the chamber is reduced to approximately 2 to 3 R.
6.1 Make additional exposures as required to obtain at least 6 R (3 R for 40" SID) to the ion chamber. Check the anode cooling curves to ensure that the rated anode limits are not exceeded.

6.2 Remove the cassette and develop the direct-print paper as before.

7.0 SID DETERMINATION

7.1 With the test stand still in position, measure to the nearest millimeter the distance from the base of the test stand to the front panel of the cassette holder. Record at item 42. If the cassette holder does not have a front panel, then load a film cassette into the holder and measure the distance from the base of the test stand to the film cassette. Record this distance at item 42, record 00.0 at item 43, and skip steps 7.2 and 7.3.

7.2 Place a film cassette into the cassette holder.

7.3 Measure to the nearest millimeter the distance from the film cassette to the plane of the face of the cassette holder and record at item 43.

7.4 Take the developed direct-print paper that had been in the slide assembly and was developed in step 5.12, and while viewing the radiographic image, locate the outside edges of the image of the focal-spot assembly. Measure the minimum separation of the outside edges to the nearest millimeter and record at item 44.

7.5 Remove the test stand and other test equipment, but do not disassemble the tripod and test stand if the system has positive beam-limitation as it will be used later to test the PBL operation.

8.0 X-RAY FIELD/INDICATED FIELD SIZE COMPARISON (Fixed Collimation Only)

If the system being tested uses cones or fixed aperture collimation, complete the steps in this section and skip sections 9.0, 10.0, 11.0, and 13.0. If the system being tested has stepless adjustment collimation, skip this section.

8.1 Record the field size dimensions indicated on the cone or fixed aperture selected in step 3.3 at items 45 and 46.

8.2 Take the developed direct-print paper that had been in the slide assembly and reconstruct the outline of the x-ray field using a straight edge and pencil or pen.

8.3 Measure to the nearest millimeter the dimensions of the x-ray field image on the direct-print paper. Record the dimensions at items 47 and 48.
9.0 ACTUAL VERSUS INDICATED FIELD SIZE

9.1 Does the beam-limiting device numerically indicate the field size at the SID at which the diagnostic source assembly is set? Record at item 49.

9.2 Being careful not to change the SID previously set in step 3.4, select the largest film cassette available for the system, and insert it into the cassette holder.

9.3 Manually adjust the beam-limiting device for an indicated field size, but smaller than the selected film cassette. Record the indicated field size at items 50 and 51.

9.4 Turn on the light localizer and measure to the nearest millimeter the dimensions of the light field at the surface of the film cassette (or the surface of the front panel if the cassette holder has a front panel). Record the dimensions at items 52 and 53.

10.0 ILLUMINANCE OF LIGHT LOCALIZER

10.1 If the SID is variable, set it so that the source assembly is at a distance of 42.5 inches (108 cm) from the front panel of the cassette holder (or film plane if there is no front panel) or to the maximum SID, whichever is less. Turn on the light localizer and open the BLD to an approximate field size of 10” x 10”.

10.2 Set the photometer against the front panel (or film cassette if there is no front panel) and hold into place. (Refer to page PHOTO-1 for proper use of the photometer). At or near the center of one quadrant of the light field, determine the illuminance by subtracting the ambient light level from the corresponding light level when the light localizer is engaged. Do not move the photometer between measurements, and be careful not to cover or shade the detector element with your hand or body. Record this illuminance at item 54.

   NOTE: Do not apply the correction factor provided on the photometer to any of the measurements. The recorded illuminance values must be uncorrected.

10.3 Repeat the measurement at or near the center of the other three quadrants of the light field and record at items 55, 56, and 57.

11.0 X-RAY FIELD/LIGHT FIELD ALIGNMENT AND SIZE COMPARISON

11.1 Take the direct-print paper that had been in the slide assembly and reconstruct the outline of the x-ray field using a straight edge and pencil or pen.

11.2 Reconstruct the image of the metal markers to their actual size (usually 0.5” x 1.5”).

11.3 Measure the dimensions of the x-ray field image on the direct-print paper to the nearest millimeter. Record the x-ray field dimensions at items 58 and 59.

11.4 Measure the light field dimensions by measuring the distance from the outside edges
of the image of the marker strips which define the edge of the light field in each direction. Record the light field dimensions at items 60 and 61.

11.5 Measure the distance from the outside edges of the marker strips to the outline of the x-ray field in the horizontal direction. Sum the two distances for the total horizontal misalignment. Record at item 62.

11.6 Determine the total vertical misalignment in the same manner as the total horizontal misalignment is determined in step 11.5. Record at item 63.

12.0 X-RAY FIELD/IMAGE RECEPTOR CENTERS COMPARISON

12.1 Still referring to the direct-print paper from the slide assembly, draw diagonals from opposite corners of the x-ray field image to define the center of the field.

12.2 Make note of the center location in reference to the grid image.

12.3 Refer now to the x-ray film or direct-print paper that was positioned at the cassette holder (step 3.5). Draw diagonals from opposite corners of the film or direct-print paper to define the center.

12.4 From the noted center location from step 12.2, transcribe this center mark to the same geometrical location on the film (or direct-print paper) form the cassette holder. Use the grid image on the film to ascertain the proper location.

12.5 Measure to the nearest millimeter the misalignment between the center of the x-ray field and the center of the film (or direct-print paper) and record at item 64.

13.0 PBL X-RAY FIELD IMAGE RECEPTOR SIZE COMPARISON

13.1 If the system has positive beam-limitation operation, complete this section (13.0), otherwise enter an asterisk in the first data block of item 65 and leave items 66 through 78 blank.

13.2 Select a commonly used size cassette. Record the film dimensions of the cassette at items 65 and 66.

13.3 Place the cassette into the cassette holder. Select two SID’s at which the PBL sensors operate.

13.4 Set the source assembly to the shorter of the selected SID’s and lock it into place. Make an exposure to ensure that the system operates at this SID. If an exposure is not possible, move to an SID at which an exposure may be made. Record this indicated SID at item 67.

13.5 Record at item 68 the type of PBL. Either the PBL system automatically adjusts the x-ray field when the cassette is inserted, or the PBL system prevents production of x-rays until manual adjustments are made.

13.6 Determine if the PBL is functioning as intended.
a. If an automatic PBL, does the unit automatically adjust field size?

NOTE: Since PBL devices by definition must be positive beam-limiting, the following has been useful in testing the PBL operation:

1. Partially withdraw the film cassette, putting the system into the "bypass" or manual mode.

2. Manually open the collimator blades fully.

3. Turn on the light localizer.

4. Reinsert the film cassette.

5. Watch the image of the light field to see if it adjusts down.

b. If a manual PBL, does it prevent the production of x-rays until manual adjustment are made?

Record at item 69. If the PBL is not functioning according to its intended design, skip over the rest of this section and explain in the Remarks.

13.7 Position the test stand and tripod assembly in the x-ray beam with the base of the stand towards the beam-limiting device. Tape a plastic cassette flat against the base of the stand with its long axis parallel with the longer dimension of the film cassette in the cassette holder.

13.8 Turn on the light localizer and move the test stand towards or away from the BLD until the light field "fits" completely within the edges of the plastic cassette.

13.9 Measure to the nearest millimeter the distance from the film cassette to the plastic cassette. Record this dimension at item 70.

13.10 Turn on the light localizer, and being careful not to disturb the test stand, measure to the nearest millimeter the dimensions of the light field at the plastic cassette. Record the light field dimensions at items 71 and 72.

13.11 Set the source assembly to the second (longer) SID and lock it into place. After ensuring that an exposure can be made at this SID, repeat step 13.10. Record the indicated SID at item 73 and the light field dimensions at items 74 and 75.

13.12 Turn on the light localizer and close the beam-limiting device to the smallest field possible. Is it possible to manually adjust the x-ray field size smaller than the image receptor? Record at item 76.

13.13 With the x-ray field size adjusted to a size smaller than the image receptor, remove the film cassette and insert one of a different size, or the same one rotated 90º. Does the beam-limiting device return to positive beam-limitation? Record at item 77.
13.14 If possible, move the source assembly to an SID greater then 36" where the PBL system is not intended to operate. Attempt to make an exposure. Is x-ray production prevented at SID's where operation is not intended? Record at item 78.
SUPPLEMENT FOR COMPERE AND SIMILAR SYSTEMS

For systems that have a fixed SID and fixed aperture cone length in which the space between the end of the cone and the image receptor is not enough for the test stand to fit lengthwise, use the following procedure:

1. If not already done, complete steps 2.1 through 3.6a. of the main procedure except choose the smallest collimator available at step 3.3b.

   NOTE: If the smallest collimator available is not less than 8" x 10", then film is required at step 3.5. The film size must be larger than the indicated field size of the selected collimator.

2. Change the code at data item 1 from "A" to "B".

3. Position the test stand and tripod assembly in the x-ray beam axis such that the long axis of the stand is perpendicular to the x-ray beam axis (the stand is sideways in the beam).

4. Mount the 6 cm³ chamber in either hole "C" or hole "D" such that the chamber can be positioned in the x-ray beam.

5. Using masking tape, tape 4.5 mm of aluminum onto the test stand between the 6 cm³ chamber and the beam-limitation device.

   NOTE: This configuration will require the aluminum filters to be suspended in the test stand between the top and bottom surfaces, and for phototimed only systems, will require transposing the filters to the opposite side when performing the radiation measurements. Be sure that the test stand is positioned close enough to the end of the beam-limiting device so that the x-ray beam will not be larger than the aluminum filters.

6. Complete sections 4.0 (BEAM QUALITY), 5.0 (REPRODUCIBILITY AND LINEARITY), and 6.0 (ADDITIONAL EXPOSURES TO CASSETTE HOLDER) of the main procedure, except skip steps 5.11 and 5.12 since there will not be plastic cassette or slide assembly in the test stand.

7. Remove the test stand and other test equipment.

8. If the plastic cassette was taped to the front panel of the cassette holder instead of to an empty film cassette (step 3.5 of the main procedure), then measure to the nearest millimeter the distance from the front panel to the film cassette and record at item 43. Otherwise, record 00.0 at item 43.

9. Leave items 42 and 44 blank.

10. Record the indicated field size dimensions of the selected collimator (step #1 above) at items 45 and 46.

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11. If direct-print paper was used instead of film at step 3.5, reconstruct the outline of the x-ray field on the developed paper using a straight edge and pencil or pen.

12. Measure to the nearest millimeter the dimensions of the x-ray field image on the film (or direct-print paper). Record the dimensions at item 47 and 48.

13. Draw diagonals from opposite corners of the x-ray field image to define the center of the field. Likewise, draw diagonals from opposite corners of the film (direct-print paper) to define the center of the film.

14. Measure to the nearest millimeter the misalignment between the center of the x-ray field and the center of the film (direct-print paper). Record at item 64.

15. Leave all other items blank.
HEAD AND NECK RADIOGRAPHIC SYSTEMS

FIELD TEST RECORD EDIT CHECKS

(Test Procedure HNA - Form FDA 3297)

Verify that:

1. The certification status of each component is indicated at data item 2.

2. The kVp at data item 5 is in the above 70 kV range.

3. The mA at data item 6 does not equal the mA in data item 37, and the two mA settings do not differ by more than a factor of two.

4. If values of mA and time are entered at data items 6 and 7, the space for the mAs value (item 8) is blank. Likewise, if a value is given for mAs at data item 8, items 6 and 7 are blank.

5. The exposure values for beam quality increase sequentially from data item 9 to data item 12.

6. The x-ray monitor threshold setting is recorded at data item 16.

7. For reproducibility, if only four values are entered (data items 17 through 24), no two exposures differ by more than 10 percent of the highest value.

8. If data item 4 is marked "P", the exposure times at data items 18, 20, 22, and 24 are greater than 100 milliseconds.

9. If data item 4 is marked "P", data is not present at data items 37 through 41.

10. If data item 45 is less than data item 46, then data item 47 is less than data item 48, or vice versa.

11. The total horizontal misalignment (data item 62) is at least as great as the difference between the x-ray field horizontal dimension (data item 58) and the light field horizontal dimension (data item 60). If this is not the case, check the direct-print paper to verify the figures. Repeat for the vertical measurements.

12. A standard size cassette was used for PBL sizing.

13. If the control was manufactured on or after May 1994 then data entered at item 37 is mAs product (mA x s) and not just mA.
A. **REPRODUCIBILITY**

1. Refer to data items 17, 19, 21, and 23 of the Field Test Record. (Also use data items 25, 27, 29, 31, 33, and 35 if ten exposures were made for reproducibility).

   a. Using the following equation, substituting n=4 or n=10, as appropriate calculate the average exposure, $E_i$:

   $$\overline{E_i} = \frac{1}{n} \sum_{i=1}^{n} X_i$$

   Record the value of $\overline{E_i}$ at Result 1.

   b. Calculate the coefficient of variation, $C_1$, as follows:

   $$C_1 = \frac{1}{E_1} \left( \sum_{i=1}^{n} (X_i - \overline{E_i})^2 / (n - 1) \right)^{1/2}$$

   where n=4 or n=10, depending on the number of exposures.

   Record the value of $C_1$ at Result 2.

2. Refer to data items 6, 7, and 8 on the Field Test Record and compute the mAs. This may be given as a selected technique factor, or must be calculated as a product of the exposure time and the tube current.

3. Calculate the average exposure per mAs, $\overline{X_i}$, as follows:

   $$\overline{X_i} = \overline{E_i} / \text{mAs}_i$$

   Record the value of $\overline{X_i}$ at Result 3.

4. Refer to data items 38 to 41, calculating the average exposure, $\overline{E_2}$, as follows:

   $$\overline{E_2} = \frac{1}{n} \sum_{i=1}^{n} X_i$$

   Record the value of $\overline{E_2}$ at Result 4.

5. Calculate the coefficient of variation, $C_2$, as follows:

   $$C_2 = \frac{1}{E_2} \left( \sum_{i=1}^{n} (X_i - \overline{E_2})^2 / (n - 1) \right)^{1/2}$$

   Record the value of $C_2$ at Result 5.
6. For controls manufactured before May 1994 refer to data items 7 and 37 on the Field Test Record and compute the mAs by multiplying the exposure time in 7 by the tube current in 37. For controls manufactured on or after May 1994, data item 37 should be in mAs units already.

Calculate the average exposure per mAs, $\bar{X}_2$, as follows:

$$\bar{X}_2 = \frac{E_2}{mAs_2}$$

Record the value of $\bar{X}_2$ at result 6.

B. LINEARITY

Refer to Results 3 and 6. Calculate the coefficient of linearity, $L$, as follows:

$$L = \frac{\bar{X}_1 - \bar{X}_2}{(X_1 + X_2)}$$

Where $\bar{X}_1$ and $\bar{X}_2$ are the average exposures per mAs. Record the value of $L$ at Result 7.

C. BEAM QUALITY

1. Refer to data items 9 to 12 and convert to normalized exposures by dividing each item by $E_i$ (Result 1). Record the normalized exposures at the indicated locations; Results 8 through 11.

2. On semi-log paper, plot the five normalized exposures along the logarithmic scale with the corresponding thickness of aluminum attenuators along the linear axis. Draw a smooth curve fit to the points and determine the observed half-value layer (HVL) as that thickness of added aluminum which would yield a normalized exposure of 0.50. Record the observed HVL and selected kVp (data item 5) at Result 12.

3. To determine the actual HVL, corrections for geometry effects and energy dependence must be made. For testing with the MDH x-ray monitor:

$$\text{Actual HVL} = (0.923 \times \text{Observed HVL}) + 0.165$$

This equation does not represent a universal correction to the observed HVL. The equation is only applicable to observed HVL's in the vicinity of the limits specified in the x-ray performance standard. For extremely large observed HVL's the equation underestimates the actual HVL. The intent of the equation is to enable accurate compliance determinations for x-ray beams with marginal observed HVL's. Record the value of the actual HVL and the selected kVp (data item 5) at Result 13.

D. TIMER ACCURACY
1. Refer to the time setting of data item 7, and if left blank, omit the timer accuracy calculation. Otherwise, record it at Result 14 as the indicated time setting.

2. Refer to data items 18, 20, 22, and 24, and if ten exposures were made, to data items 26, 28, 30, 32, 34, and 36 also. Choose the one value which has the maximum deviation from the indicated time setting. Calculate the maximum deviation as the absolute value of the measured time from the indicated time. Record the deviation at Result 15.

3. Calculate the timer inaccuracy as follows:
   \[
   \text{percent timer inaccuracy} = \frac{\text{maximum deviation}}{\text{indicated timer setting}} \times 100
   \]

   Record the percent timer inaccuracy at Result 16.

E. SID DETERMINATION

1. Refer to data items 42, 43, and 44 on the Field Test Record.

   Calculate the SID as follows:
   \[
   \text{SID} = \left( \frac{224.47}{\text{Item 44} - 6.35} \right) + 39.92 + \text{Item 42} + \text{Item 43}
   \]

   Record the SID at Result 17.

F. X-RAY FIELD/INDICATED FIELD SIZE COMPARISON (Fixed Collimation Only)

1. Refer to data items 45 and 46 on the Field Test Record and record at Results 18 and 19. Convert any item given in inches to centimeters prior to recording on the results record.

2. Refer to data items 44, 47, and 48 and calculate the x-ray field size at the image receptor:
   \[
   \text{Calculated horizontal dimension} = \text{Item 47} \times \text{SID} \times \frac{\text{Item 44} - 6.35}{\text{Item 44} \times 35.35}
   \]
   \[
   \text{Calculated vertical dimension} = \text{Item 48} \times \text{SID} \times \frac{\text{Item 44} - 6.35}{\text{Item 44} \times 35.35}
   \]

   Record these values at Result 20 and 21.

3. Calculate the horizontal and vertical differences and percent differences:
   \[
   \text{Horizontal difference} = \text{Result 18} - \text{Result 20}
   \]
Vertical difference = Result 19 - Result 21

Record at Results 22 and 23, respectively.

If Result 22 is negative, calculate the percent difference:

$$\text{Percent horizontal difference} = \frac{\text{Result } 22 \times 100}{\text{SID}}$$

Record at Result 24. (If Result 22 is positive, record 0.00 at Result 24).

If Result 23 is negative, calculate the percent difference:

$$\text{Percent vertical difference} = \frac{\text{Result } 23 \times 100}{\text{SID}}$$

Record at Result 25. (If Result 23 is positive, record 0.00 at Result 25).

G. X-RAY FIELD/LIGHT FIELD ALIGNMENT AND SIZE COMPARISON

1. Refer to data items 62 and 63 and record at Result 26 and 27.

2. Determine the distance from the source to the center of the light field as follows:

$$\text{SID}' = (\text{Result } 17 - \text{data item } 42 - \text{data item } 43 - 4.6) \text{ cm}$$

Record SID' at Result 28.

3. Calculate the misalignment as a percent of the SID':

$$\text{Percent horizontal misalignment} = \frac{\text{Result } 26 \times 100}{\text{SID}'}$$

$$\text{Percent vertical misalignment} = \frac{\text{Result } 27 \times 100}{\text{SID}'}$$

Record the percent horizontal and vertical misalignments at Results 29 and 30, respectively.

4. Refer to data items 58 through 61 and calculate the horizontal correction factor (HCF) and the vertical correction factor (VCF) as follows:

$$\text{HCF} = \frac{\text{data item } 58}{\text{data item } 60}$$

$$\text{VCF} = \frac{\text{data item } 59}{\text{data item } 61}$$

Record the HCF at Result 31 and the VCF at Result 32.
H. X-RAY FIELD/IMAGE RECEPTOR CENTERS COMPARISON

1. Refer to data item 64 on the Field Test Record and record at Result 33.

2. Calculate the centers misalignment as a percent of the SID (Result 17):
   \[ \text{Percent centers misalignment} = \frac{\text{Result 33} \times 100}{\text{Result 17}} \]
   Record the percent centers misalignment at Result 34.

I. ACTUAL VERSUS INDICATED FIELD SIZE

1. Refer to data items 50 and 51, the indicated field horizontal and vertical dimensions. Convert to centimeters, if necessary, before recording at Results 35 and 36.

2. Refer to data items 52 and 53 and calculate the x-ray field horizontal and vertical dimensions as follows:
   \[ \text{CHD} = \text{HCF} \times \text{data item 52} \times \left( \frac{\text{Result 17}}{\text{Result 17} - \text{data item 43}} \right) \]
   \[ \text{CVD} = \text{VCF} \times \text{data item 53} \times \left( \frac{\text{Result 17}}{\text{Result 17} - \text{data item 43}} \right) \]
   Record at Results 37 and 38.

3. Calculate the horizontal and vertical differences and the percent differences:
   \[ \text{Horizontal difference} = \text{CHD} - \text{Result 35} \]
   \[ \text{Vertical difference} = \text{CVD} - \text{Result 36} \]
   \[ \text{Percent difference (horizontal)} = \frac{\text{horizontal difference} \times 100}{\text{Result 17}} \]
   \[ \text{Percent difference (vertical)} = \frac{\text{vertical difference} \times 100}{\text{Result 17}} \]
   Record at Results 39-42.

J. ILLUMINANCE OF LIGHT LOCALIZER

Refer to data items 54, 55, 56, and 57. If the SID has been set to 108 cm or it is fixed at less than 108 cm, calculate the average illuminance value by summing the four values and dividing by four. Record at Result 43. If the SID is fixed at greater than 108 cm (Result 17), calculate the average illuminance as follows:

\[ \text{Average illuminance} = \frac{(\text{SID} - \text{data item 43})^2}{(108)^2} \times \frac{(\text{data items 54 + 55 + 56 + 57})}{4} \]
Record at Result 43.

K. PBL X-RAY FIELD/IMAGE RECEPTOR SIZE COMPARISON

1. Refer to data items 65, 66, and 67 and record at Results 44-46. Convert any item given in inches to centimeters prior to recording on the results record.

2. Refer to data items 70, 71, and 72 and calculate the horizontal and vertical x-ray field dimensions:

   \[
   \begin{align*}
   CAH &= HCF \times \text{data item } 71 \times \left( \frac{\text{ISID}}{\text{ISID} - \text{data item } 70} \right) \\
   CAV &= VCF \times \text{data item } 72 \times \left( \frac{\text{ISID}}{\text{ISID} - \text{data item } 70} \right)
   \end{align*}
   \]

   where the ISID is Result 46.

   Record at Results 47 and 48.

3. Calculate the horizontal and vertical differences, the percent differences, and the sum of percent horizontal and vertical differences:

   \[
   \begin{align*}
   \text{Horizontal difference} &= \text{CAH} - \text{Result } 44 \\
   \text{Vertical difference} &= \text{CAV} - \text{Result } 45 \\
   \% \text{ Horizontal difference} &= \frac{\text{Horizontal difference} \times 100}{\text{Result } 46} \\
   \% \text{ Vertical difference} &= \frac{\text{Vertical difference} \times 100}{\text{Result } 46}
   \end{align*}
   \]

   \[
   \text{Sum of } \% \text{ differences} = |(\% \text{ horizontal difference}) + (\% \text{ vertical difference})|
   \]

   Record at Results 49-53.

4. Refer to data item 73 and, if necessary, convert into centimeters before recording at Result 54.

5. Refer to data items 74 and 75 and repeat the calculations of step 2 and 3 using the ISID of Result 54. Record at Results 55-61.
SUPPLEMENTARY CALCULATION TECHNIQUE 

FOR 

"COMBERE TYPE" SYSTEMS 

(Test procedure HNB - Form FDA ----) 

Use the main calculation technique for reproducibility, linearity, beam quality, and timer accuracy, recording the values as appropriate at Result 1 through 16. 

ACTUAL VERSUS INDICATED FIELD SIZE COMPARISON 

1. Refer to data items 45 and 46 on the Field Test Record and record at Results 18 and 19. Convert any items given in inches to centimeters prior to recording on the results record. 

2. Refer to data items 3, 43, 47, and 48 and calculate the x-ray field size at the image receptor: 

   \[
   \text{Calculate horizontal dimension } = \frac{\text{data item 47} \times \text{data item 3}}{\text{data item 3} - \text{data item 43}} 
   \]

   \[
   \text{Calculate vertical dimension } = \frac{\text{data item 48} \times \text{data item 3}}{\text{data item 3} - \text{data item 43}} 
   \]

   Record these values at Results 20 and 21. 

3. Calculate the horizontal and vertical differences and percent differences: 

   \[
   \text{Horizontal difference } = \text{Result 18} - \text{Result 20} 
   \]

   \[
   \text{Vertical difference } = \text{Result 19} - \text{Result 21} 
   \]

   Record at Results 22 and 23, respectively. 

   If Result 22 is negative, calculate the percent difference: 

   \[
   \text{Percent horizontal difference } = \frac{\text{Result 22} \times 100}{\text{data item 3}} 
   \]

   Record at Result 24. (If Result 22 is positive, record 0.00 at Result 24). 

   If Result 23 is negative, calculate the percent difference: 

   \[
   \text{Percent vertical difference } = \frac{\text{Result 23} \times 100}{\text{data item 3}} 
   \]

   Record at Result 25. (If Result 23 is positive, record 0.00 at Result 25).
X-RAY FIELD/IMAGE RECEPTOR CENTERS COMPARISON

1. Refer to data item 64 on the Field Test Record and record at Result 33.

2. Calculate the centers misalignment as a percent of the SID (data item 3):

   \[
   \text{Percent centers misalignment} = \left( \frac{\text{Result 33 x 100}}{\text{data item 3}} \right)
   \]

   Record the percent centers misalignment at Result 34.
RESULTS RECORD
HEAD AND NECK RADIOGRAPHIC SYSTEMS
(Test Procedure HNA - Form FDA 3297)

Field Test
Serial No. _______

REPRODUCIBILITY AND LINEARITY

1. Average exposure, \( \bar{E}_1 = \) ________ mR
2. Coefficient of variation, \( C_1 = \) ________
3. Average exposure/mAs, \( \bar{E}_1 = \) ________ mR/mAs
4. Average exposure, \( E_2 = \) ________ mR
5. Coefficient of variation, \( C_2 = \) ________
6. Average exposure/mAs, \( \bar{E}_2 = \) ________ mR/mAs
7. Coefficient of linearity, \( L = \) ________

BEAM QUALITY

Normalized Exposure:

8. \( N_4 = \) ________ at 4.5 mm Al
9. \( N_3 = \) ________ at 3.5 mm Al
10. \( N_2 = \) ________ at 2.5 mm Al
11. \( N_1 = \) ________ at 1.5 mm Al

\( N_0 = 1.00 \) at 0.00 mm Al

12. Observed HVL = ________ mm Al at ________ kVp
13. Actual HVL = ________ mm Al at ________ kVp

TIMER ACCURACY

14. Indicated time setting = ________ seconds
15. Maximum deviation from indicated setting = ________ seconds
16. Percent timer inaccuracy = ________ percent

SID DETERMINATION
17. Measured SID = __________ cm

X-RAY FIELD/INDICATED FIELD SIZE COMPARISON (Fixed Collimation Only)

18. Indicated field size horizontal dimension = __________ cm
19. Indicated field size vertical dimension = __________ cm
20. Calculated horizontal dimension = __________ cm
21. Calculated vertical dimension = __________ cm
22. Horizontal difference = __________ cm
23. Vertical difference = __________ cm
24. Percent horizontal difference = __________ percent
25. Percent vertical difference = __________ percent

X-RAY FIELD/LIGHT FIELD ALIGNMENT AND SIZE COMPARISON

26. Total horizontal misalignment = __________ cm
27. Total vertical misalignment = __________ cm
28. SID’ = __________ cm
29. Percent horizontal misalignment = __________ percent
30. Percent vertical misalignment = __________ percent
31. HCF = __________
32. VCF = __________

X-RAY FIELD/IMAGE RECEPTOR CENTERS COMPARISON

33. Centers misalignment = __________ cm
34. Percent centers misalignment = __________ percent

ACTUAL VERSUS INDICATED FIELD SIZE

35. Indicated field horizontal dimension = __________ cm
36. Indicated field vertical dimension = __________ cm
37. CHD = __________ cm
38. CVD = __________ cm
39. Horizontal difference = __________ cm
40. Vertical difference = __________ cm
41. Percent difference (horizontal) = __________ percent
42. Percent difference (vertical) = __________ percent

ILLUMINANCE OF LIGHT LOCALIZER
43. Average illuminance = __________ footcandles

PBL X-RAY FIELD/IMAGE RECEPTOR SIZE COMPARISON
44. Horizontal film dimension = __________ cm
45. Vertical film dimension = __________ cm
46. Indicated SID (ISID) = __________ cm
47. CAH = __________ cm
48. CAV = __________ cm
49. Horizontal difference = __________ cm
50. Vertical difference = __________ cm
51. Percent horizontal difference = __________ percent
52. Percent vertical difference = __________ percent
53. Sum percent horizontal and vertical differences = __________ percent
54. Indicated SID (ISID) = __________ cm
55. CAH = __________ cm
56. CAV = __________ cm
57. Horizontal difference = __________ cm
58. Vertical difference = __________ cm
59. Percent horizontal difference = __________ percent
60. Percent vertical difference = __________ percent

61. Sum percent horizontal and vertical difference = __________ percent
## Component Certification Information

2. Indicate the status of each as follows:
   - C—Certified
   - N—Not Certified
   - X—Not Present or Not Applicable
   - Beam Limiting Device: 14
   - High Voltage Generator: 15
   - Cassette Holder: 16
   - Tube Housing Assembly: 17
   - Tube Housing Assembly: 18
   - With Beam Limiting Device: 19
   - Other (Specify): 20

## Indicated Source To Image Distance (SID)

3. Indicated Source To Image Distance (SID): 
   - Inches: 21
   - cm: 22

## Test Setup

4. Timer mode of operation during testing:
   - kVp: 29
   - mA: 30
   - sec: 31
   - Pulse: 32
   - mAs: 33

## Technique Factors

5. Technique Factors Indicated Before Exposure:
   - Y—Yes
   - N—No

6. Exposure Terminated After Preset Time Interval:
   - Y—Yes
   - N—No

## Reproducibility

7. MDH Threshold Setting, 0.53 phase, 0.2—1 phase:
   - mR: 15
   - msec: 16

8. mR: 17
   - msec: 18

9. mR: 19
   - msec: 20

10. mR: 21
    - msec: 22

11. mR: 23
    - msec: 24

12. mR: 25
    - msec: 26

13. mR: 27
    - msec: 28

14. mR: 29
    - msec: 30

15. mR: 31
    - msec: 32

16. mR: 33
    - msec: 34

17. mR: 35
    - msec: 36

18. mR: 37
    - msec: 38

19. mR: 39
    - msec: 40

20. mR: 41
    - msec: 42

21. mR: 43
    - msec: 44

22. mR: 45
    - msec: 46

23. mR: 47
    - msec: 48

24. mR: 49
    - msec: 50
### Reproducibility (Continued)

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<th>Item</th>
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<th>mR</th>
<th>Data Here If Any Two Of Items 17, 19, 21, And 23 Differ By More Than 10 Percent Of Largest Value</th>
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### Linearity

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### X-Ray Field/Indicated Field Size Comparison (Fixed Collimation Only)

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<th>Value</th>
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<tr>
<td>45</td>
<td>Indicated Field Size Horizontal Dimension</td>
<td>11 . 13 inches OR 14 . 16 cm</td>
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<tr>
<td>46</td>
<td>Indicated Field Size Vertical Dimension</td>
<td>17 . 19 inches</td>
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<tr>
<td>47</td>
<td>X-Ray Field Image Horizontal Dimension</td>
<td>23 . 25 cm</td>
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<tr>
<td>48</td>
<td>X-Ray Field Image Vertical Dimension</td>
<td>26 . 28 cm</td>
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### Actual Versus Indicated Field Size

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<td>Beam Limiting Device Numerically Indicates Field Size</td>
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<td>50</td>
<td>Indicated Field Horizontal Dimension</td>
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<td>51</td>
<td>Indicated Field Vertical Dimension</td>
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<tr>
<td>52</td>
<td>Light Field Horizontal Dimension</td>
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<td>Light Field Vertical Dimension</td>
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### FIELD TEST RECORD

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<td>59 fc</td>
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### X-Ray Field/Light Field Alignment and Size Comparison

|  |  |
|---|---|---|---|
|58. | X-Ray Field |  |  |
|Horizontal Dimension | 60 | 62 cm |
|59. | X-Ray Field |  |  |
|Vertical Dimension | 63 | 65 cm |
|60. | Light Field |  |  |
|Horizontal Dimension | 66 | 68 cm |
|61. | Light Field |  |  |
|Vertical Dimension | 69 | 71 cm |
|62. | Horizontal Misalignment | 72 | 73 cm |
|63. | Vertical Misalignment | 74 | 75 cm |

### X-Ray Field/Image Receptor Centers Comparison

|  |  |
|---|---|---|
|64. | Centers Misalignment | 11 | 12 cm |

### PBL X-Ray Field/ Image Receptor Size Comparison

|  |  |
|---|---|---|---|
|65. | Horizontal Film Dimension | 15 | 16 cm |
|66. | Vertical Film Dimension | 19 | 22 cm |
|67. | Indicated SID | 25 | 28 inches OR 31 cm |
|68. | Type of Positive Beam Limitation (PBL) |  | A. Automatically Adjusts X-ray Field |
|  |  |  | B. Prevents Production of X-rays Until Manual Adjustments are Made |
|69. | Is the PBL Currently Operating in Conformance with its Design | Y-YES |
|  |  |  | N-NO |

### Distance from Film Cassette to Plastic Cassette

|  |  |
|---|---|---|
|70. | Distance from Film Cassette to Plastic Cassette | 34 | 37 cm |

### Light Field Alignment and Size Comparison

|  |  |
|---|---|---|---|
|71. | Light Field Horizontal Dimension | 38 | 40 cm |
|72. | Light Field Vertical Dimension | 41 | 43 cm |
|73. | Indicated SID | 44 | 46 inches OR 47 cm |
|74. | Light Field Horizontal Dimension | 51 | 53 cm |
|75. | Light Field Vertical Dimension | 54 | 56 cm |

### PBL Operation

|  |  |
|---|---|---|
|76. | In PBL Mode, Adjustment Possible To Field Size Smaller Than Image Receptor | Y-YES |
|  |  | N-NO |
|77. | Automatic Return To PBL When Image Receptor is Changed | Y-YES |
|  |  | N-NO |
|78. | X-ray Production Prevented At SID's Where Operation Is Not Intended | Y-YES |
|  |  | N-NO |

**REMARKS**