PART X

C-ARM FLUOROSCOPIC AND SPOT-FILM SYSTEMS

FORM FD 3260

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ROUTINE 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 form the image intensifier.

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

2.11 Connect the 6-cm_3 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-ram 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.

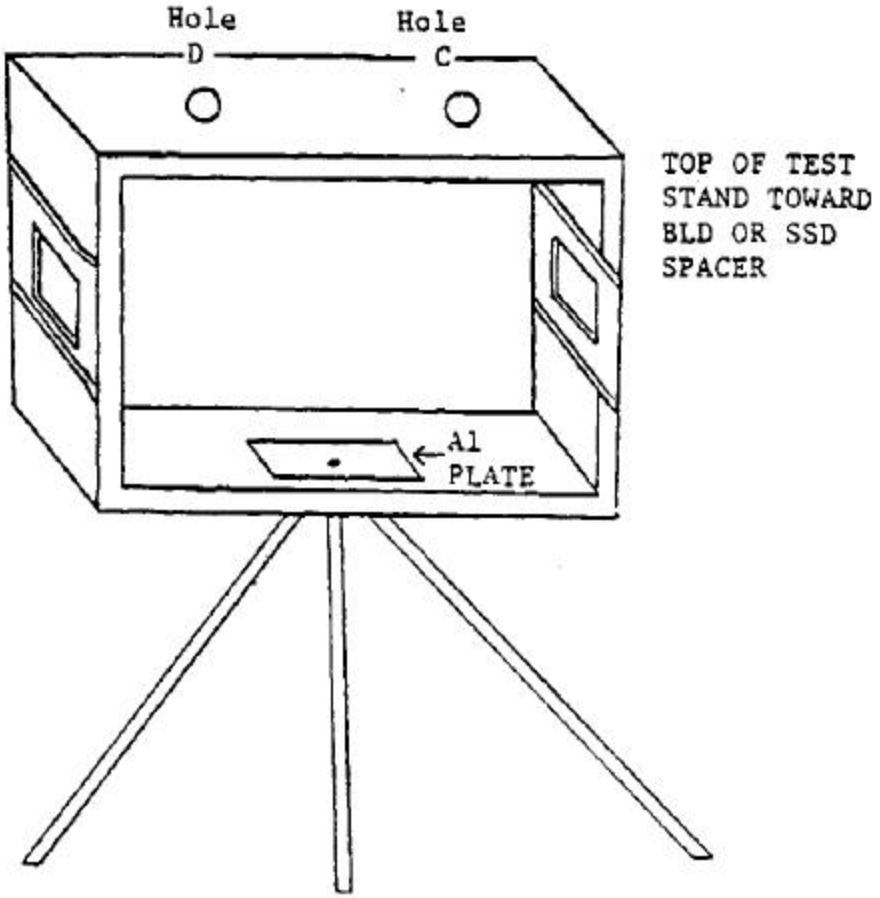
(d) 9" Image Intensifier: Move the tripod toward the BLD until the test stand top is approximately centered on and about 1-inch from the face of the BLD or SSD spacer. The bottom opening in the test stand should be centered over the image intensifier face.

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-cm ionization chamber through the upper mounting hole (C) of the test stand.



TEST STAND ATTACHED TO TRIPOD

Figure 1

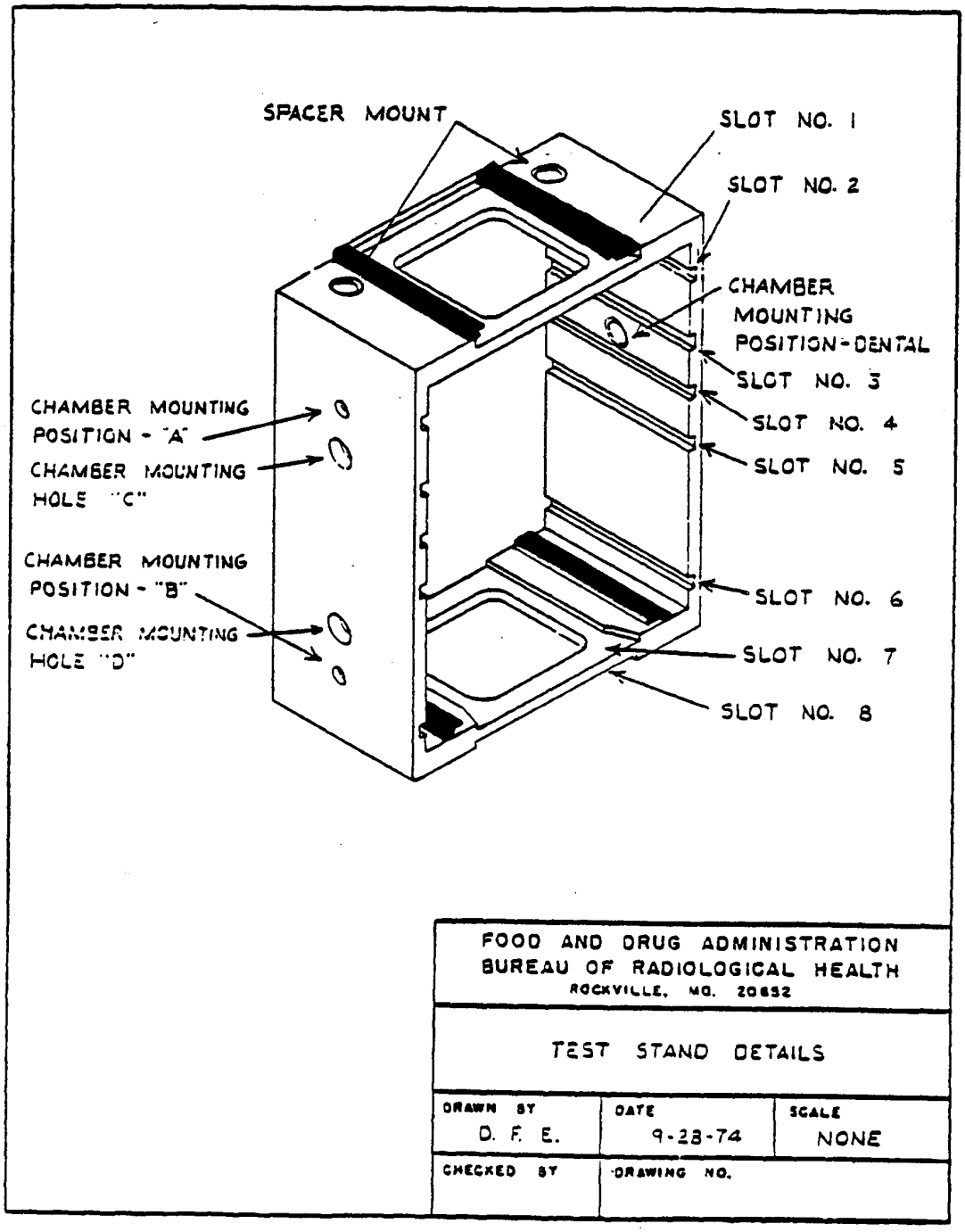

SPACER MOUNT
SLOT NO. 1
SLOT NO. 2
CHAMBER MOUNTING POSITION - DENTAL
SLOT NO. 3
SLOT NO. 4
SLOT NO. 5
CHAMBER MOUNTING POSITION - "A"
CHAMBER MOUNTING HOLE "C"
CHAMBER MOUNTING POSITION - "B"
CHAMBER MOUNTING HOLE "D"
SLOT NO. 6
SLOT NO. 7
SLOT NO. 8
FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND DETAILS
DRAWN BY
D. F. E.
DATE
9-28-74
SCALE
NONE
CHECKED BY
DRAWING NO.

Figure 2

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. Tel 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 form 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.

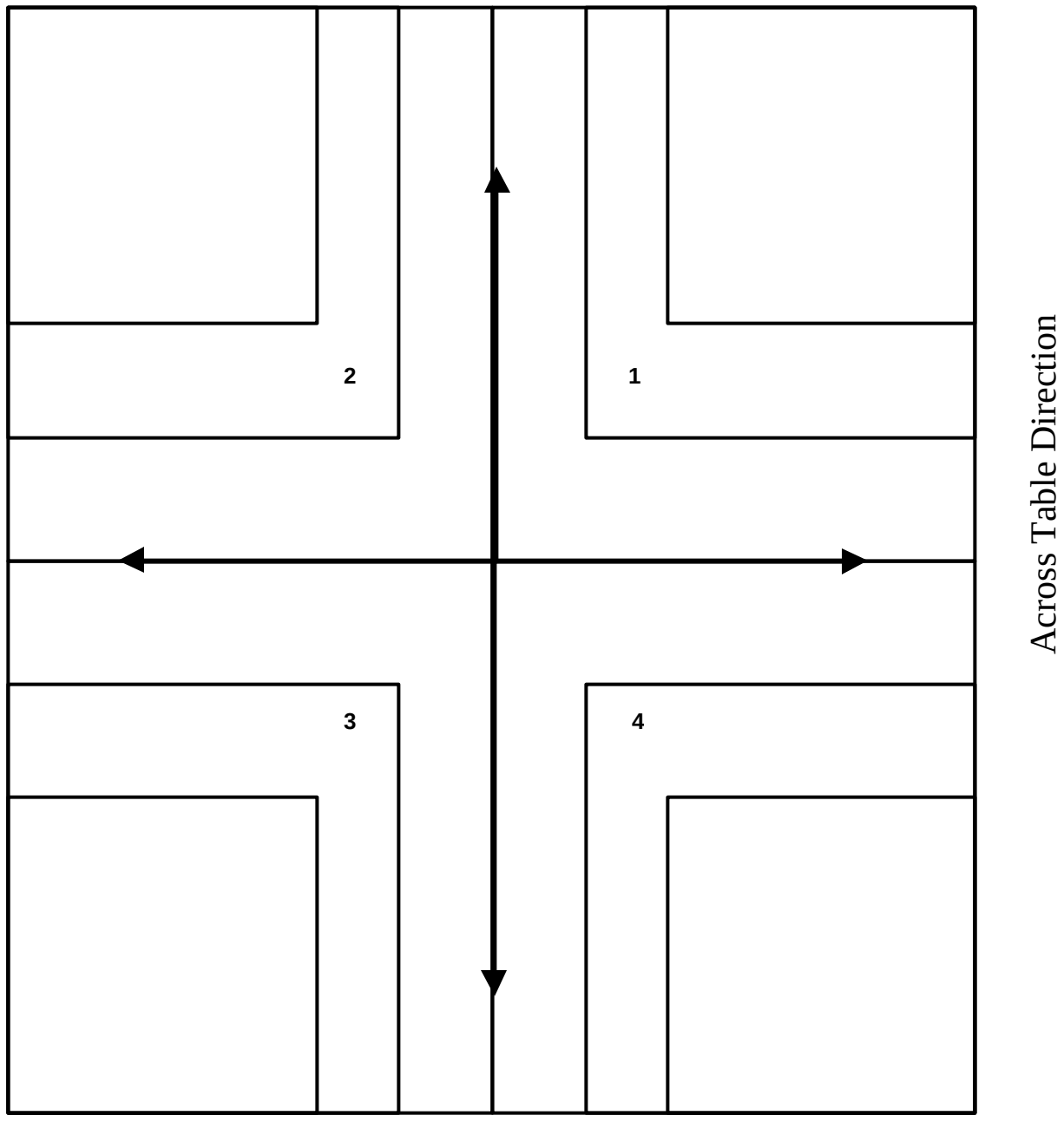


Figure 3

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

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

9.0 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 form 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.

C-ARM FLUOROSCOPIC AND SPOT-FILM SYSTEMS

FIELD TEST RECORD EDIT CHECKS

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 - Item 28 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 11. Record at Result 13.

   f. Percent total 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 Results 15 through 25.

D. Fluoroscopic Entrance Exposure Rate

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

2. Manual Mode

   Refer to data item 35 of the Field Test Record.

$$EER = \text{Item } 35 \times \frac{(\text{Result } 1 + 8.9)^2}{(\text{Result } 1 + 10.2)^2}$$

   Record at Result 26.

3. Automatic Mode

   Refer to data item 40.

$$EER = \text{Item } 40 \times \frac{(\text{Result } 1 + 8.9)^2}{(\text{Result } 1 + 10.2)^2}$$

   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

Mode of Equipment	Without High-level Control (HLC)	With High-level Control (HLC)*
Automatic	10 R/min	5 R/min
Manual	10 R/min	5 R/min

*EER without activating HLC

Dual Fluoroscopic Technique Factor Control Mode Equipment

Mode Selected	Without HLC	Manual Mode With HLC*	Automatic Mode With HLC*	Both Modes With HLC*
Automatic	10 R/min	10 R/min	5 R.min	5 R/min
Manual	10 R/min	5 R/min	10 R/min	5 R/min

*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.

   (1/4 + 3/2) = Width (W)

   Record at Result 28.

   (2/1 + 4/3) = Length (L)

   Record at Result 29.

2. Calculate the width (W')

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

Record at Result 30.

3. Calculate the length (L')

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

Record at Result 31.

If item 31 = 1 (a circular field),

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

Record at Result 32.

If item 31 = 2 (a rectangular filed)

a = W' x L' cm^2

Record at Result 33.

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

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

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

Record at Result 36.

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

Record at Result 37.

Select the larger value of X^1_w and X^1_L if $X^1_w + X^1_L$

X^1 max must be <u>≤</u> 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)

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

Record at Result 40.

3. If item 31 = 2 (Rectangular field)

$a = L'' \times W''\ cm^2$

Record at Result 41

When item 4 = 1, minimum field area must be $\leq$ 125 cm^2

When item 4 = 2, minimum field size must be $\leq$ 5-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, $\overline{E_1}$

   $$\overline{E_1} = \frac{1}{n}\sum_{i=1}^{n} X_i$$

   Record at Result 53.

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

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

   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_1 as follows:

   $X_1 = \overline{E_1}$ / mAs

   Record at Result 55.

4. Refer to data items 89-92 and calculate the average, $\overline{E_2}$ as follows:

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

Record at Result 56.

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

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

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, X_2, as follows:

$$\overline{X}_2 = \frac{\overline{E}_2}{mAs_2}$$

Record at Result 58.

J. Linearity

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

$$L = \frac{\left|\overline{X_1} - \overline{X_2}\right|}{(\overline{X_1} + \overline{X_2})}$$

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

Spot-film SID = Item 93 + Result 3

Record at Result 60.

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

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

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

Record CL at Result 61.

Record CW at Result 62.

3. Calculate the length and width differences as follows:

   ?L = CL - Item 58.

   Record at Result 63.

   ?W = CW - Item 59.

   Record at Result 64.

   $$\text{Percent } ?L = \frac{(\ ?L\ )}{(\text{Result 60})} \times 100$$

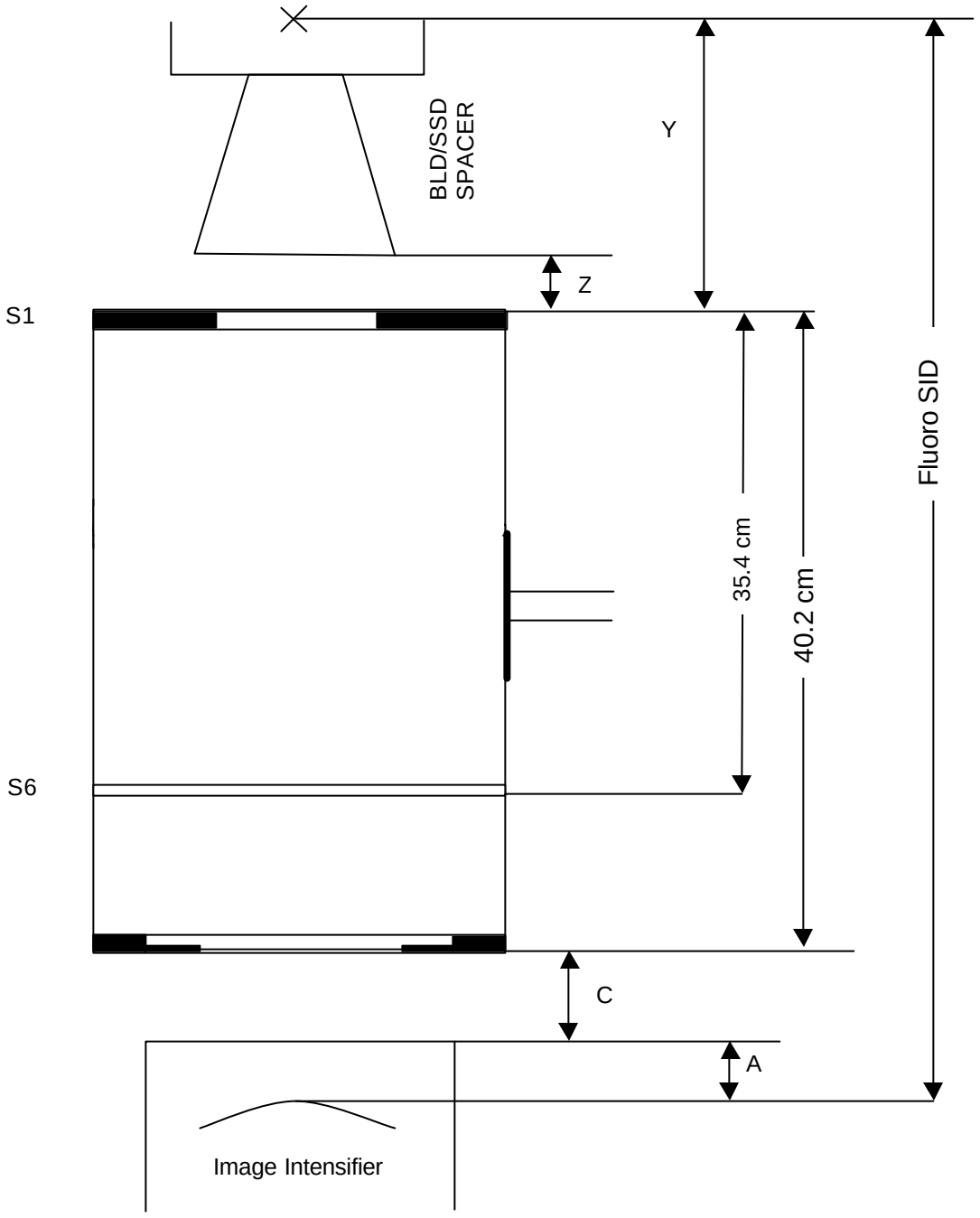
   Record at Result 65.

   $$\text{Percent } ?W = \frac{(\ ?W\ )}{(\text{Result 60})} \times 100$$

   Record at Result 66.

   Percent (?L + ?W) = percent ?L + percent ?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.

Figure 4

Table 1. C-arm fluoroscopic and spot-film system distance from input phosphor of I.I. to face of I.I. (A)

	Manufacturer	A
1.	Philips BV-22	3.0 cm
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_w^1 = _____ cm.

37. X_L^1 = _____ 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 = _____ mR/s at 4.5 mm Al.

43. R_3 = _____ mR/s at 3.5 mm Al.

44. R_2 = _____ mR/s at 2.5 mm Al.

45. R_1 = _____ mR/s at 1.5 mm Al.

46. R_0 = _____ mR/s at 0.0 mm Al.

Normalized Exposure Rate

47. N_4 = _____ at 4.5 mm Al.

48. N_3 = _____ at 3.5 mm Al.

49. N_2 = _____ at 2.5 mm Al.

50. N_1 = _____ at 1.5 mm Al.

N_0 = 1.0 at 0.0 mm Al.

51. HVL_{obs} = _____ mm Al at _____ kVp.

52. Actual HVL = _____ mm Al at _____ kVp.

Spot-Film Reproducibility and Linearity

53. Average exposure, $\overline{E}_1$, = _____ mR.

54. Coefficient of variation, C_1, = _____.

5. Average exposure/mAs, $\overline{X}_1$ = _____ mR/mAs.

56. Average exposure, $\overline{E}_2$, = _____ mR.

57. Coefficient of variation, C_2, = _____.

58. Average exposure/mAs $\overline{X}_2$, = _____ mR/mAs.

59. Coefficient of linearity, L, = _____.

X-Ray Field/Spot-Film Size Comparison

60. Spot-Film SID _____ cm.

61. CL = _____ cm.

62. CW = _____ cm.

63. ?L = _____ cm.

64. ?W = _____ cm.

65. Percent ?L = _____ percent.

66. Percent ?W = _____ percent.

67. Percent ?L + Percent ?W = _____ percent.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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C-ARM FLUOROSCOPIC AND SPOT-FILM SYSTEMS
FIELD TEST RECORD

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

Print Legibly. Use Black Ball Point Pen. Enter One Character Per Box. Do Not Write in Shaded Area.

FIELD TEST SERIAL NO. *(1-8)*: CF

REGIONAL REVIEW *(NAME)*:

Card No. *(9-10)*: 10

Test Procedure: CF 1 (11–13)

2. System Type (14): M—Mobile S—Stationary

Beam Limiting Device Information

3. BLD Manufactured after 5/22/79 (15): Y—yes N—no

4. BLD type (16): 1—Fixed Aperture 2—Stepless

Component Certification Information

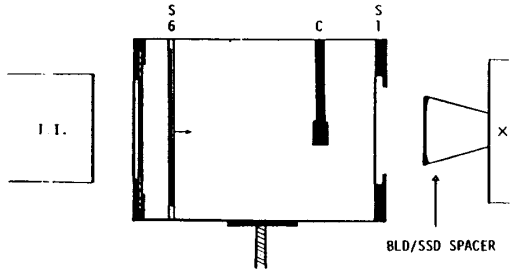
5. Indicate the Status of Each as Follows:

C—Certified
N—Not Certified
V—Certified with a Variance
X—Not Present or not applicable

(17) Tube Housing Assembly	(18) X—Ray Control	(19) Spot Film Device *(after 4/77)*
(20) Beam Limiting Device	(21) High Voltage Generator	(22) Fluoroscopic Imaging Assembly *(before 4/77)*
(23) Table	(24) Image Intensifier *(after 4/77)*	

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

MDH(Exposure)



6. System Hazardous (25): Y—yes N—no

If yes, describe hazard in Remarks and discontinue testing

7. Warning Label Present (26): Y—yes N—no

Fluoroscopic X—ray Field/Image Receptor Alignment

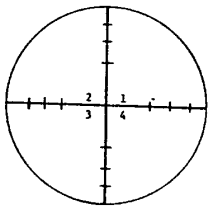


	Image Dimension	X—ray Field Dimension
1/4	8. (27) . (29) in	12. (30) . (32) cm
2/1	9. (33) . (35) in	13. (36) . (38) cm
3/2	10. (39) . (41) in	14. (42) . (44) cm
4/3	11. (45) . (47) in	15. (48) . (50) cm

NO MAGNIFICATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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FIELD TEST SERIAL NO. *(1-8)* CF

REGIONAL REVIEW *(NAME)*

10

Fluoroscopic X-ray Field/Image Receptor Alignment

	Image Dimension	X-ray Field Dimension
1/4	16. ___ . ___ in (51, 53)	20. ___ . ___ cm (54, 56)
2/1	17. ___ . ___ in (57, 59)	21. ___ . ___ cm (60, 62)
3/2	18. ___ . ___ in (63, 65)	22. ___ . ___ cm (66, 68)
4/3	19. ___ . ___ in (69, 71)	23. ___ . ___ cm (72, 74)

24. Visible Area: ___ (75) 1—Circular 2—Rectangular

25. Tube Potential and Current Continuously Indicated During Exposure ___ (76) Y—yes N—no

26. Maximum Cumulative Setting for Fluoro Timer is 5 minutes or less ___ (77) Y—yes N—no

Primary Protective Barrier/X-ray Field Size Comparison

27. Diameter of the Image Intensifier Housing ___ . ___ cm (11, 13)

28. Distance from face of I.I. to base of stand ___ . ___ cm (14, 16)

Minimum Fluoro Field Size

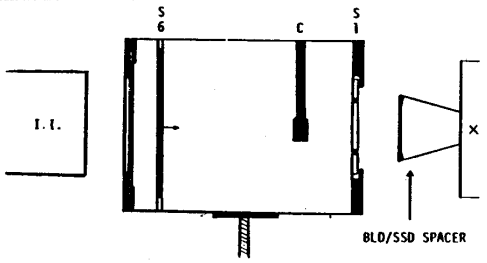
29. X-ray field image length ___ . ___ cm (17, 19)

30. X-ray field image width ___ . ___ cm (20, 22)

31. Field Shape ___ (23) 1—Circular 2—Rectangular

11

Entrance Exposure Rate: (BLD fully open, no magnification)



32. Fluoroscopic Technique Factor Control Type ___ (24)

M—Manual Only
A—Automatic Only
B—Both Manual and Automatic

MDH (Exposure rate)

MANUAL	33. ___ kVp (25, 27)	34. ___ . ___ mA (28, 29)	35. ___ . ___ R/min (30, 33)
AUTO	38. ___ kVp (36, 38)	39. ___ . ___ mA (39, 40)	40. ___ . ___ R/min (41, 44)

36. Is a high level control present? ___ (34) Y—YES N—NO

37. Continuous Audible Signal Upon Activation of High Level Control ___ (35) Y—YES N—NO X—N/A

41. Is a high level control present? ___ (45) Y—YES N—NO

42. Continuous Audible Signal Upon Activation of High Level Control ___ (46) Y—YES N—NO X—N/A

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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C-ARM FLUOROSCOPIC AND SPOT-FILM SYSTEMS
FIELD TEST RECORD

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FIELD TEST SERIAL NO. *(1-8)*: CF

REGIONAL REVIEW *(NAME)*

11

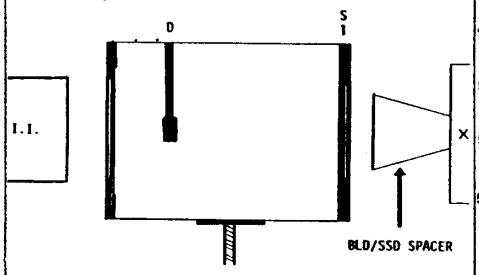
Source — Image Distance and Minimum Source to Skin Distance

43. Distance from face of SSD spacer (or from face of BLD if spacer is not present) to top of brass strips [47] . [49] cm

44. Outside Separation of Image of Focal Spot Strips [50] . [52] cm

Beam Quality

45 . [53 55] kVp



MDH (Pulse Exposure 4.5mm Al

46. [56 58] mR @ 4.5 mm Al — 47. [59] . [61] sec

48. [62 64] mR @ 3.5 mm Al — 49. [65] . [67] sec

50. [68 70] mR @ 2.5 mm Al — 51. [71] . [73] sec

52. [74 76] mR @ 1.5 mm Al — 53. [77] . [79] sec

54. [11 13] mR @ 0.0 mm Al — 55. [14] . [16] sec

56. At End of Present Cumulative Time Internal Either Continuous Audible Signal and /or Termination of X-rays [17] Y-YES N-NO

12

Spot—Film Mode

57. Type of spot-film device [18]
1. Clip-on cassette holder
2. Cut-film changer
3. N/A (only a fluorographic camera provided)

58. Spot-film length [19] . [21] cm

59. Spot-film width [22] . [24] cm

60. Technique factors fixed or selectable indicated before exposure [25] Y-yes N-no

61. A visible beam-on indication during exposure [26] Y-yes N-no

62. An audible indication of exposure termination [27] Y-yes N-no

63. Exposure terminated at a preset time or mAs [28] Y-yes N-no

64. Means provided for maintaining the fluoro field size during spot-filming [29] Y-yes N-no X-N/A

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C-ARM FLUOROSCOPIC AND SPOT-FILM SYSTEMS
FIELD TEST RECORD
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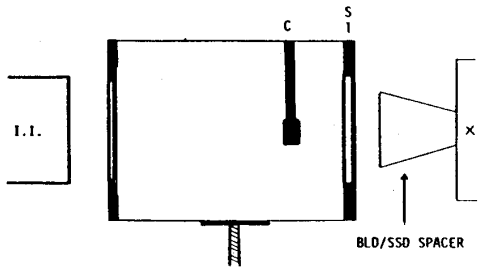
Print Legibly. Use Black Ball Point Pen. Enter One Character Per Box. Do Not Write in Shaded Area.

FIELD TEST SERIAL NO. *(1-8)* CF

REGIONAL REVIEW *(NAME)*

12

Spot-Film Reproducibility and Linearity



65. MDH Threshold Setting. 0.5-3 phase, 0.2-1 phase [0] . [ ] (30)

66. Generator Type [ ] (31) 1-single phase 3-three phase

67. Technique Factors
kVp (32 34) mAs (35 37)
mA (38 40) [ ] . [ ] sec. (41 43)

13

Reproducibility (no Al in beam)

68.	mR (44 48)	69.	msec (49 51)	78.	mR (52 56)	79.	msec (57 59)
70.	mR (60q 64)	71.	msec (65 67)	80.	mR (68 72)	81.	msec (73 75)
72.	mR (11 15)	73.	msec (16 18)	82.	mR (19 23)	83.	msec (24 26)
74.	mR (27 31)	75.	msec (32 34)	84.	mR (32 34)	85.	msec (40 42)
76.	mR (43 47)	77.	msec (48 50)	86.	mR (51 55)	87.	msec (56 58)

Linearity

88. mA (59 62)
If change in mA causes a kVp shift, readjust kVp (if possible) to value selected at Item

89. mR (63 67)

90. mR (68 72)

91. mR (11 15)

92. mR (16 20)

14

X-ray Field/Spot-film Size Comparison

93. Distance from the spot-film plane to the SSD spacer (or from face of BLD if spacer is not present) [ ] . [ ] cm (21 23)

94. Distance from Image Receptor to bottom of test stand [ ] . [ ] cm (24 26)

95. Length [ ] . [ ] cm (For circular field enter diameter twice) (28 30)

96. Width [ ] . [ ] cm (31 33)

REMARKS

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.)

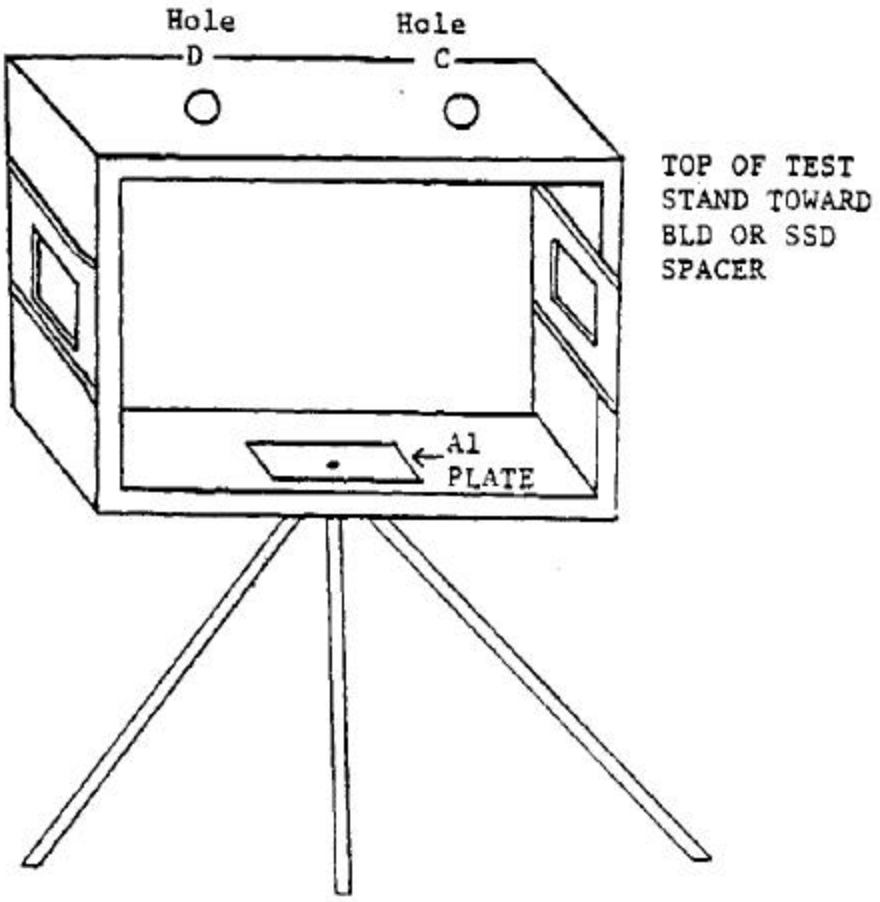
(h) Insert the 6 cm^3 ionization chamber through the upper mounting hole (C) of the test stand.

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 proper use of the GM meter.



TEST STAND ATTACHED TO TRIPOD

Figure 1

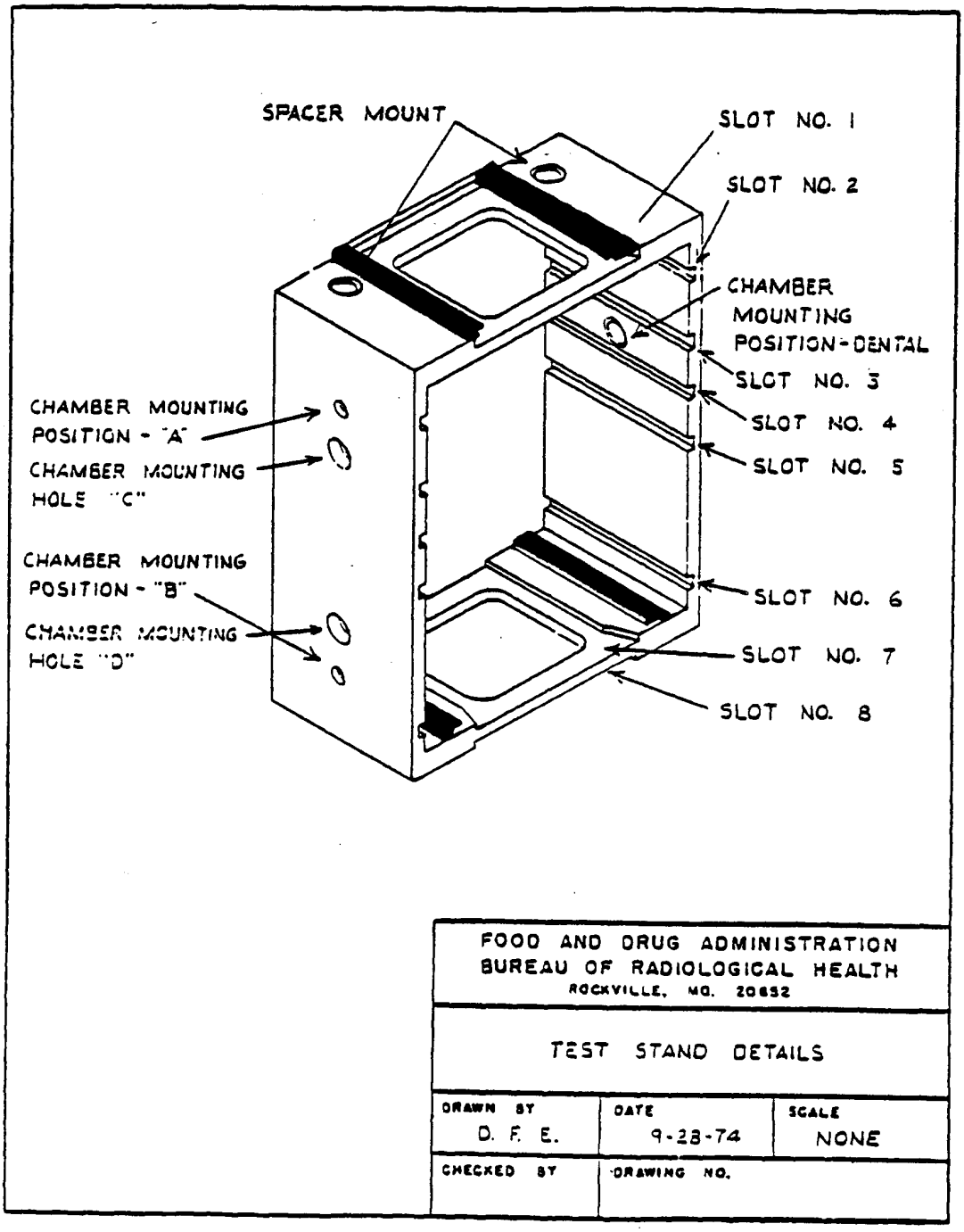

SPACER MOUNT
SLOT NO. 1
SLOT NO. 2
CHAMBER MOUNTING POSITION - DENTAL
SLOT NO. 3
SLOT NO. 4
SLOT NO. 5
SLOT NO. 6
SLOT NO. 7
SLOT NO. 8
CHAMBER MOUNTING POSITION - "A"
CHAMBER MOUNTING HOLE "C"
CHAMBER MOUNTING POSITION - "B"
CHAMBER MOUNTING HOLE "D"
FOOD AND DRUG ADMINISTRATION
BUREAU OF RADIOLOGICAL HEALTH
ROCKVILLE, MD. 20852
TEST STAND DETAILS
DRAWN BY
D. F. E.
DATE
9-28-74
SCALE
NONE
CHECKED BY
DRAWING NO.

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. Tel 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 nonmagification 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 form the test stand.

NOTE: If the system does not hove a radiographic mode, then this sheet of direct-print paper for the FLUOROSCOPIC X-RAY FIELD/IMAGE RECEPTOR ALIGNMENT test must be retained and used for later calculation of source-to-skin distance.

4.13 Measure to the nearest millimeter the distance from the center of the grid to the

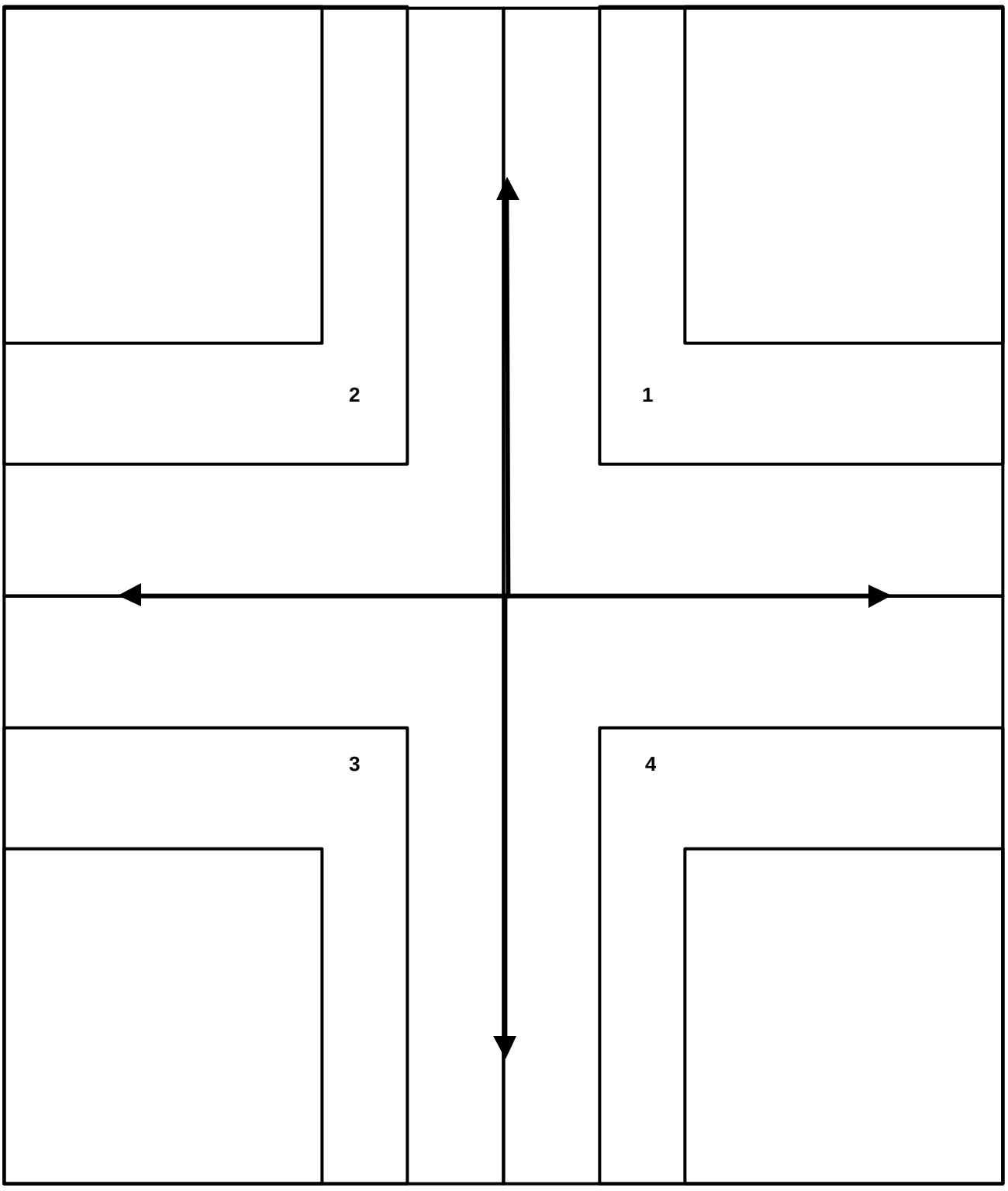


Figure 3

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

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

9.0 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 this manual mode.

MANUAL MODE

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.

AUTOMATIC MODE ONLY

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 be 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 u 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 of 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.

SUPPLEMENT 1: VARIABLE SID C-ARM FLUOROSCOPIC SYSTEMS

FIELD TEST RECORD EDIT CHECKS

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:

   SID' = Result - A - 4.57 cm.

   For 9" or larger image intensifiers:

   SID' = Result 2 - A - Item 28 - 24.89 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:

$$\text{EER} = \text{Item } 35 \text{ x } \frac{(\text{Result } 3 + \text{Item } 86)^2}{(\text{Result } 3 + \text{Item } 86 + 1.37)^2}$$

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:

$$\text{EER} = \text{Item } 40 \text{ x } \frac{(\text{Result } 3 + \text{Item } 86)^2}{(\text{Result } 3 + \text{Item } 86 + 1.37)^2}$$

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 be 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) = Width (W)

   Record at Result 28.

   (2/1 + 4/3) = 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')

$$L' = L \times \frac{(\text{Result } 2)}{(\text{Result } 8)}$$

Record at Result 31.

If data item 31 = 1, the circular area,

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

Record at Result 32.

If data item 31 = 2, the rectangular area

$a = W' \times L'\ cm^2$

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. $$X^1_w = \frac{(\text{Result } 2 - A)}{(\text{Result } 8)} \times X_w$$

Record at Result 36.

$$X^1_L = \frac{(\text{Result } 2 - A)}{(\text{Result } 8)} \times X_L$$

Record at Result 37.

Select the larger value of X^1_w and X^1_L if $X^1_w \neq X^1_L$

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)

$a = L'' \times W''\ cm^2$

Record at Result 41.

When data item 4 = 1, minimum field area must be $\leq$ 125 cm^2

When data item 4 = 2, minimum field size must be $\leq$ 5-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 = $(1.247 \times HVL_{obs}) - 0.432$

   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 observe HVL's in the limits specified in the X-ray Performance Standard. For extremely large observed HVL's, this equation under estimates 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, $\overline{E}_1$,:

   $$\overline{E_1} = \frac{1}{n}\sum_{i=1}^{n} X_i$$

   Record at Result 53.

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

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

   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, $\overline{X}_1$, as follows:

   $$\overline{X_1} = \frac{\overline{E_1}}{mAs}$$

   Record at Result 55.

4. Refer to data items 89-92 and calculate the average exposure, _2, as follows:

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

   Record at Result 56.

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

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

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:

$$\overline{X_2} = \frac{\overline{E_2}}{\text{mAs}}$$

Record at Result 58.

J. Linearity

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

$$L = \frac{\left| \overline{X_1} - \overline{X_2} \right|}{(\overline{X_1} + \overline{X_2})}$$

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:

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

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

Record CL at Result 61.

Record CW at Result 62.

3. Calculate the length and width differences as follows:

L = CL - Data Item 58.

Record at Result 63.

W = CW - Data Item 59.

Record at Result 64.

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

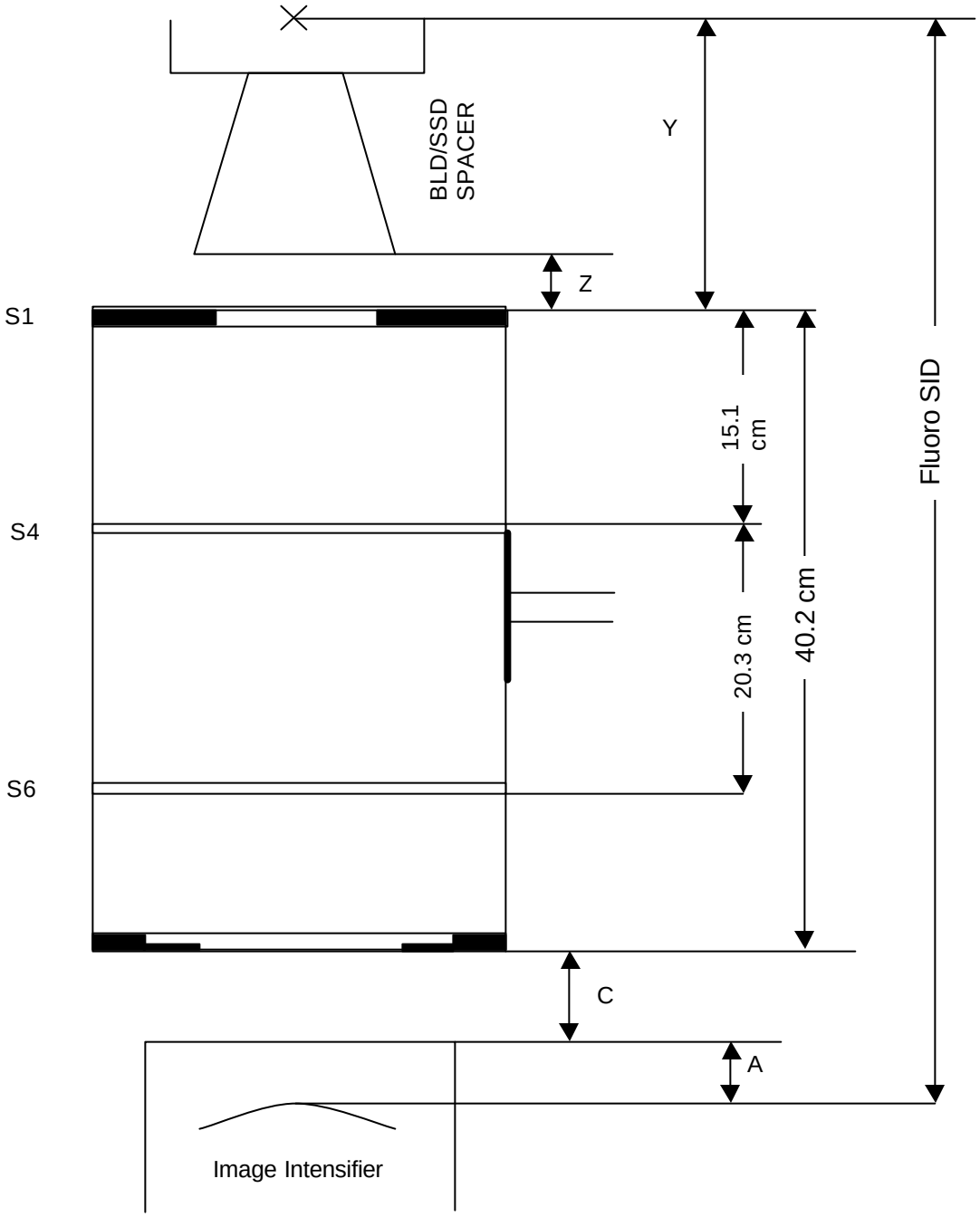
Record at Result 65

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

Record at Result 66.

$$\text{Percent } (\Delta L + ?W) = \text{percent } ? L + \text{percent } ? W$$

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.

Figure 4