PART VI

ABOVETABLE

X-RAY SOURCE

FLUOROSCOPIC

AND

SPOT-FILM

SYSTEMS

FORM FDA 3069
ROUTINE COMPLIANCE TESTING

ABOVETABLE X-RAY SOURCE

FLUOROSCOPIC AND SPOT-FILM SYSTEMS

(Test Procedure AFA - Use Form FDA 3069)

1.0 GENERAL GUIDANCE

1.1 This procedure is applicable to general purpose radiographic/fluoroscopic systems having a common abovetable x-ray source and manual, automatic, or both manual and automatic adjustment of technique factors during fluoroscopy. The SID may be fixed or variable. This procedure must be used in conjunction with the Routine Compliance Testing procedure for Abovetable x-ray Source Radiographic Systems. It is intended as a supplement to that procedure.

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

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

2.0 PRETEST CHECKLIST

2.1 Record the five digits, which appear preprinted on the general information test record, in the appropriate block for each page of the abovetable x-ray source fluoroscopic test record. Since this test is performed in conjunction with an abovetable radiographic test, add the same letter designator as on the radiographic test record. Thus, test records for an abovetable radiographic/fluoroscopic system would be identified as follows: "GI12345" - general information; "AR12345A" - radiographic; and "AF12345A" - fluoroscopic.

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

2.3 Check the certification status of the image intensifier or, if the system was manufactured prior to 4/26/77, the fluoroscopic imaging assembly. Record at item 2.

3.0 INITIAL SETUP

3.1 Set the system up for fluoroscopic operation. If spot-filming capability is provided, load the undertable image receptor (UTIR)/spot-film device with a commonly used size of spot-film cassette (preferably an empty one).
3.2 Set the cumulative timer to the maximum position.

3.3 Move the UTIR/spot-film device to the park position and swing any compression device out of the path of the beam.

3.4 Place the slide assembly on the table such as to intercept the fluoroscopic x-ray field. Place paper beneath the slide assembly, if needed, to protect the table surface.

3.5 On the top of the slide assembly, center copper attenuators totaling 0.1 inch in thickness.

3.6 Turn the TV monitor on and allow time for warmup.

3.7 If a remote control console is not provided or is not located in a shielded area, put on a lead apron and position any available scatter shields in place.

4.0 SURVEYOR PROTECTION TEST

NOTE: a) If the remote control console is located in a shielded area, omit this section and record "N" in item 3.

b) This is not a compliance test. The purpose of this test is to determine the radiation exposure level at any unshielded area occupied by the surveyor while making fluoroscopic exposures.

c) Abovetable source systems are capable of producing high levels of tabletop scatter radiation. Therefore, if the fluoroscopy exposure switch is provided with a cable, move the switch as far away as possible from the table.

d) The GM Meter is a sensitive instrument, but is extremely energy dependent. It is intended as a qualitative indication. Any quantitative measurements of radiation exposure should be made using the 100-cm$^2$ ionization chamber.

4.1 If possible, set the fluoroscopic technique factor control made to "Manual."

4.2 Set the x-ray control to approximately 90 kVp and 2 mA.

4.3 Fully open the beam-limiting device.

4.4 Make several short exposures and with the GM meter scan the console work area. Note the greatest GM meter deflection. (Refer to page GM-1 for instructions on the proper use of the GM meter.)

4.5 If the meter indication is greater than 15 for the Model 251B instrument and 150 for the TBM-1 instrument make followup measurements with the 100-cm$^2$ ionization chamber. If these followup measurements exceed 50 mR/hr, stop all further testing.
Record at item 3 that the system is hazardous and explain in the Remarks.

4.6 If the GM meter indication is less than 15 for the Model 251B instrument and 150 for the TBM-1 instrument, record "N" in item 3.

5.0 TRACKING TEST

NOTE: For systems designed to operate at a fixed SID or a set of discrete SIDs, skip to section 6.0.

5.1 Lower the source assembly such that the end of the beam limiting is as close as possible to a point 30 centimeters above the tabletop.

5.2 Adjust the beam-limiting device so that all blades are fully visible on the TV monitor.

5.3 Depress the exposure switch. Raise the source assembly through the entire range of SIDs, to assure that the system is tracking properly. Because of nonlinearities in the system, the collimator blades may wiggle slightly as the SID changes. However, if the system is tracking properly, the blades should remain relatively fixed, regardless of the SID. If the blades are not tracking properly, the amount by which they have to be adjusted to become visible on the TV monitor is an indication of the relative misalignment at the SID. Record the worst case SID for future reference.

5.4 Does the beam-limiting device properly track the image receptor? Record at item 4.

6.0 FLUOROSCOPIC X-RAY FIELD/IMAGE RECEPTOR ALIGNMENT

6.1 Change the equipment setup to the following (see figure on test record):

a) Center the test stand without the spacer assembly beneath the diagnostic source assembly.

b) Place the slide assembly, grid side up, on top of the test stand.

c) Insert the 6-cm$^3$ ionization chamber through the top mounting hole of the test stand and secure with the retaining ring.

d) Center 0.1 inch of copper attenuators on the base of the test stand.

e) Set the x-ray monitor mode selector to EXPOSURE.

6.2 Set the fluoroscopic technique factor control to "Manual."

6.3 a) If the answer to the tracking question (data item 4) is "No," set the source assembly to the suspected worst case SID. Lock the vertical movement. Using the test kit measuring tape, measure the distance from the source to the tabletop. Record at item 5. Unless the focal-spot location is marked on the tube housing, estimate the focal-spot or source location as being in a plane halfway down the housing end cap from the axial centerline of the housing assembly. Check to assure the beam-limiting device is fully open.
and continue with the next step in the test procedure.

b) If the answer to the tracking question (data item 4) is "Yes," skip to step 6.11.

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

6.5 With the fluoroscopic technique factors at 90 kV and 2 mA, make an exposure. If the grid image is not readable, it may be necessary to increase the mA. Read the dimensions of the grid image to the nearest tenth of an inch.

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

6.6 Record the values in order from 1/4 to 4/3 at items 6 through 9.

6.7 If the accumulated exposure is 1.0 R or greater, then the direct-print paper should provide a satisfactory image. Make additional exposure as required to obtain a total of 1.0 R.

6.8 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.)

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

6.10 Record the values in order from 1/4 to 4/3 at items 10 through 13.

6.11 Select an SID at which the system will operate in fluoroscopic mode. If already at the suspected worst case SID from Step 6.3, maintain this SID. Lock the vertical movement. Measure the distance from the source to the tabletop. Record at item 14. Check to assure the beam-limiting device is fully open.

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

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

6.14 With the fluoroscopic technique factors at 90 kV and 2 mA, make an exposure. If the grid image is not readable, it may be necessary to increase the mA. Read the dimensions of the grid image to the nearest tenth of an inch.

NOTE: See lines 1/4, 2/1, 3/2, and 4/3 of Figure 1. For future reference, observe that 1/4 passes between the slide
assembly quadrant numbers 1 and 4, and so forth, and each

Along Table Direction

Across Table Direction

Figure 1
small division of the grid represents 0.1 inch.

6.15 Record the values in order from 1/4 to 4/3 at items 15 through 18.

6.16 If the accumulated exposure is 1.0 R or greater, then the direct-print paper should provide a satisfactory image. Make any additional exposure required to obtain a total of 1.0 R.

6.17 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.)

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

6.19 Record the values in order from 1/4 to 4/3 at items 19 through 22.

**FLUOROSCOPIC TECHNIQUE FACTOR CONTROL**

Are the fluoroscopic technique factors manually controlled, automatically controlled, or are both manual and automatic fluoroscopic technique factor controls provided? Record at item 23.

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

**7.0 ENTRANCE EXPOSURE RATE-MANUAL MODE**

7.1 Remove the slide assembly from the test setup.

7.2 Lower the source assembly to the lowest SID position that allows fluoroscopic operation. If the source assembly can be lowered further than the top of the test stand, the test setup will have to be changed as follows.

   a) Remove the test stand from beneath the source assembly.

   b) Reverse the 6-cm³ 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.

   c) Lower the source assembly such that the end of the beam-limiting device is as close as possible to the ion chamber.

   d) Center 0.1 inch of copper attenuators on the tabletop beneath the source assembly.

7.3 Measure the distance from the source to tabletop. Record at item 24.
7.4 If testing a dual-field image intensifier, select the mode of least magnification (e.g., the 9" mode). Check to be sure that the beam-limiting device is fully open.

7.5 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.

7.6 Many systems do not yield their maximum entrance exposure rate at maximum tube potential or tube current: therefore, check the exposure rate at various kVp and mA settings to establish worst-case 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 25 and 26, respectively. Record the maximum exposure rate at item 27.

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

7.7 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.

7.8 If the high-level exposure rate exceeds the low-level rate, record "Y" in item 28. Otherwise, record "N" in item 28.

7.9 Is there a continuous audible signal upon activation of the high level control? Record at item 29. If special means of activation or continuous manual pressure are not provided for the high-level control, explain the operation of the high-level control in the REMARKS section.

NOTE: The EER requirements do not apply for the recording of fluoroscopic images. For x-ray controls manufactured after May 19, 1995, the EER requirements do not apply to the recording of fluoroscopic images when operating in a pulsed mode. In addition, the recording mode is not considered high-
level control and therefore, no audible signal is required. The Center is looking into the record mode uses and would need manufacturer justification for any unit that could operate only in a record mode.

8.0 ENTRANCE EXPOSURE RATE - AUTOMATIC

8.1 If not already done, remove the slide assembly from the test setup.

8.2 Again, if the source assembly can be lowered further than the top of the test stand, the test setup will have to be changed.
   a) Remove the test stand from beneath the source assembly.
   b) 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.
   c) Lower the source assembly such that the end of the beam-limiting device is as close as possible to the ion chamber.
   d) Center 0.1 inch of copper attenuators on the tabletop beneath the source assembly.

8.3 If not already done, measure the distance from the source to the tabletop. Record at item 24.

8.4 If testing a dual-field image intensifier, select the mode of least magnification (e.g., the 9" mode). Check to be sure that the beam-limiting device is fully open.

8.5 Center a 1/8" thick lead sheet on top of the copper attenuators.

8.6 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.

8.7 Check the exposure rate at various kVp and mA settings to establish worst case technique factors. Observe the indicated tube potential and tube current during exposure.

8.8 Record the indicated tube potential and tube current at items 30 and 31, respectively.

8.9 Record the maximum exposure rate at item 32.

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

8.10 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.

8.11 If the high-level exposure rate exceeds the low-level rate, record "Y" in item 33. Otherwise, record "N" in item 33.

8.12 Is there a continuous audible signal upon activation of the high-level control? Record at item 34. If special means of activation or continuous manual pressure are not provided for the high-level control, explain the operation of the high-level control in the REMARKS section.

NOTE: For x-ray controls manufactured after May 19, 1995, the EER requirements do not apply to the recording of fluoroscopic images when operating in a pulsed mode. In addition, the recording mode is not considered high-level control and therefore, no audible signal is required. The Center is looking into the record mode uses and would need manufacturer justification for any unit that could operate only in a record mode.

9.0 X-RAY FIELD/SPOT-FILM SIZE COMPARISON

9.1 Remove all equipment (including the test stand) from the table.

9.2 Position the UTIR/spot-film device in place for spot filming.

9.3 Partially withdraw the spot-film cassette from the tray or tunnel.

9.4 Measure to the nearest millimeter the distance from the top of the cassette to tabletop surface and record at item 35.

NOTE: If the system is equipped with a concave tabletop, measure both the vertical distance from the top of the cassette to any reference point on the tabletop, and the distance from that reference
point to the center of the tabletop surface. Subtract the second measurement from the first, and record the difference at item 35. See figure 2.

9.5 Maintain the x-ray source at the same position used for entrance exposure rate measurements; i.e., a source-to-table distance corresponding to item 24.

9.6 Position the spot-film cassette for an exposure, and select a four-on-one format. If a four-on-one format is not available, select any format, which results in a spot-film size smaller than the diameter of the image intensifier.

9.7 Record the dimensions of the selected spot-film size, in the plane of the spot-film cassette, at items 36 and 37. Since two four-on-one formats may be provided, be careful to record the dimension of the format actually selected. Also, dimensions are recorded as along and across the table.

9.8 Turn on the light localizer and measure to the nearest millimeter the dimensions of the light field at the surface of the table. Record the dimensions at items 38 and 39.
$C = A - B = \text{DISTANCE FROM TOP OF FILM CASSETTE TO BASE OF TEST STAND.}$

RECORD VALUE OF $C$ AT ITEM 35

FIGURE 1: HOW TO DETERMINE DISTANCE FROM TOP CASSETTE TO BASE OF TEST STAND FOR CONCAVELY CURVED TABLE TOP.
Verify that:

1. An "N" answer for data item 4 has resulted in data at data items 5 through 13.

2. A "Y" answer for data item 4 has resulted in data at data items 14 through 22, but not 5 through 13.

3. The values for the "x-ray Field Dimension" are at least 2½ times those in the "Image Dimension" column for data items 6 through 13 and 15 through 22.

4. If data item 23 is marked "M," data is recorded at items 25 through 29.

5. If data item 23 is marked "A," data is recorded at data items 30 through 34.

6. If data item 23 is marked "B," data is recorded at data items 24 through 33.

7. If data items 28 or 33 are marked "Y," the high level control exposure rate is provided in Remarks.
CALCULATION TECHNIQUES
ABOVE-TABLE X-RAY SOURCE
FLUOROSCOPIC AND SPOT-FILM SYSTEMS

(Test Procedure AFA - Form FDA 3069)

A. FLUOROSCOPIC X-RAY FIELD/IMAGE RECEPTOR ALIGNMENT

1. Refer to data items 6 through 13 of the test record. Calculate the misalignment between the x-ray field and the visible dimension of the image receptor as follows:

   Misalignment 1/4 = Data item 10 - (Data item 6 x 2.54)
   Misalignment 2/1 = Data item 11 - (Data item 7 x 2.54)
   Misalignment 3/2 = Data item 12 - (Data item 8 x 2.54)
   Misalignment 4/3 = Data item 13 - (Data item 9 x 2.54)

   Record at Results 1-4. 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 misalignment.

2. Determine the distance from the source to the center of the x-ray field image, SID:

   SID = (Data item 5 - 41.2) Centimeters

   Record this value at Result 5.

3. Calculate the following misalignments:

   a. (1/4 + 3/2) Misalignment = Result 1 + Result 3
      Record the (1/4 + 3/2) Misalignment at Result 6.

   b. Percent (1/4 + 3/2) Misalignment = (Result 6 x 100)/SID
      Record at Result 7.

   c. (2/1 + 4/3) Misalignment = Result 2 + Result 4
      Record the (2/1 + 4/3) Misalignment at Result 8.

   d. Percent (2/1 + 4/3) Misalignment = (Result 8 x 100)/SID
      Record the percent (2/1 + 4/3) misalignment at Result 9.

   e. Total Misalignment = (Result 6) + (Result 8)
      Record the total misalignment at Result 10.

   f. Percent Total Misalignment + (Result 10 x 100)/SID
Record the percent total misalignment at Result 11.

4. Repeat the calculations of steps 1 through 3 for data items 14 through 22 and record at Results 12 through 22.

B. FLUOROSCOPIC ENTRANCE EXPOSURE RATE

1. Manual Mode:

Refer to data items 27 and 24. Calculate the entrance exposure rate (EER) in R/min as follows:

\[ EER = (\text{data item 27}) \times \left( \frac{(\text{data item 24-31.3})}{(\text{data item 24-30})^2} \right) \]

Record this value at Result 23.

2. Automatic Mode:

Refer to data items 32 and 24. Calculate the entrance exposure rate (EER) in R/min as follows:

\[ EER = (\text{data item 32}) \times \left( \frac{(\text{data item 24-31.3})}{(\text{data item 24-30})^2} \right) \]

Record this value at Result 24.

C. MINIMUM SSD DETERMINATION

1. Refer to data item 24. The minimum SSD is determined as follows:

\[ \text{Minimum SSD} + (\text{Data item 24 - 31.3}) \text{ cm} \]

Record this value at Result 25.

D. X-RAY FIELD/SPOT FILM SIZE COMPARISON

1. Calculate the SID for the spot-film sizing using data items 24 and 35 as follows:

\[ \text{SID} = \text{Data item 24} + \text{Data item 35} \]

Record the SID at Result 26.

2. Refer to data items 36 and 37 and record at Results 27 and 28.

3. Refer to data items 38 and 39 and calculate the x-ray field dimensions in the plane of the image receptor, using the Along Table Correction Factor (ALCF) and Across Table Correction Factor (ACCF) determined during testing of the Radiographic portion of the system (Above table Source Radiographic Systems Results 25 and 26).
CAL = Data item 38 x ALCF x Result 26/(Result 26 - Date item 35)

CAC = Data item 39 x ACCF x Result 26/(Result 26 - Data item 35)

Record the calculated dimension along the across table as Results 29 and 30.

4. Calculate the difference between the dimensions of the x-ray field and the dimensions of the image receptor as follows:

   Along Table Difference = CAL - Data item 36

   Across Table Difference = CAC - Data item 37

Record the results at Results 31 and 32.

5. Calculate the percent along and across table differences:

   % Along Table Difference = Result 31 x 100/Result 26

   % Across Table Difference = Result 32 x 100/Result 26

Record at Results 33 and 34.

6. Calculate the percent total difference, and record at Result 35.

   % Total Difference = abs (Result 33) + abs (Result 34)
<p>| | | | | | | | | | | | | | | | | | | | |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 1. | 1/4 Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 2. | 2/1 Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 3. | 3/2 Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 4. | 4/3 Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 5. | SID = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 6. | (1/4 + 3/2) Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 7. | % (1/4 + 3/2) Misalignment = | % |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 8. | (2/1 + 4/3) Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 9. | % (2/1 + 4/3) Misalignment = | % |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 10. | Total Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 11. | Percent Total Misalignment = | % |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 12. | 1/4 Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 13. | 2/1 Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 14. | 3/2 Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 15. | 4/3 Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 16. | SID = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 17. | (1/4 + 3/2) Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 18. | % (1/4 + 3/2) Misalignment = | % |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 19. | (2/1 + 4/3) Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 20. | % (2/1 + 4/3) Misalignment = | % |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| 21. | Total Misalignment = | cm |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>22.</td>
<td>Percent Total Misalignment = __________ %</td>
</tr>
<tr>
<td>23.</td>
<td>Manual Mode EER = __________ R/min</td>
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<tr>
<td>24.</td>
<td>Automatic Mode EER = __________ R/min</td>
</tr>
<tr>
<td>25.</td>
<td>Minimum SSD = __________ cm</td>
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<tr>
<td><strong>ENTRANCE EXPOSURE RATE</strong></td>
<td></td>
</tr>
<tr>
<td>26.</td>
<td>SID = __________ cm</td>
</tr>
<tr>
<td>27.</td>
<td>Film Dimension Along Table = __________ cm</td>
</tr>
<tr>
<td>28.</td>
<td>Film Dimension Across Table = __________ cm</td>
</tr>
<tr>
<td>29.</td>
<td>X-ray Field Dimension Along Table = __________ cm</td>
</tr>
<tr>
<td>30.</td>
<td>X-ray Field Dimension Across Table = __________ cm</td>
</tr>
<tr>
<td>31.</td>
<td>Along Table Difference = __________ cm</td>
</tr>
<tr>
<td>32.</td>
<td>Across Table Difference = __________ cm</td>
</tr>
<tr>
<td>33.</td>
<td>% Along Table Difference = __________ %</td>
</tr>
<tr>
<td>34.</td>
<td>% Across Table Difference = __________ %</td>
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<tr>
<td>35.</td>
<td>% Total Difference = __________</td>
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Entrance Exposure Rate (Continued)

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<th>AUTO</th>
<th>30.</th>
<th>31.</th>
<th>32.</th>
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<td></td>
<td>Kvp</td>
<td>mA</td>
<td>R/min</td>
</tr>
<tr>
<td>28</td>
<td>28</td>
<td>31</td>
<td></td>
</tr>
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</table>

33. Is a high level control present? Y—YES  N—NO

34. Continuous Audible Signal Upon Activation of High Level Control Y—YES N—NO X—N/A

X-Ray Field/Spot Film Size Comparison

35. TABLETOP to SPOT-FILM PLANE Distance cm

36. Film Dimension Along Table cm

37. Film Dimension Across Table cm

38. Light Field Along Table cm

39. Light Field Across Table cm

REMARKS
PART VII

PEAK KILOVOLTAGE DETERMINATION
RADIOGRAPHIC SYSTEMS

FORM FDA 3068

REPRINTED APRIL 2000
ROUTINE COMPLIANCE TESTING

PEAK KILOVOLTAGE DETERMINATION

RADIOGRAPHIC SYSTEMS

(Test Procedure KVA - Use Form FDA 3068)

1.0 GENERAL GUIDANCE

1.1 This kVp test procedure is applicable to single and three phase, stationary and mobile radiographic, medical and dental x-ray equipment with a tungsten target. It is not applicable to capacitor discharge or fluoroscopic x-ray equipment.

1.2 The kVp test procedure is intended to be performed in conjunction with an Abovetable Radiographic (ARA), Mobile Radiographic (MRA), or Dental Radiographic (DRA) Field Test.

1.3 This test is only valid for reproducible systems. If it is suspected that the system under test has a reproducibility noncompliance, this test should not be performed.

1.4 Record the five digits, which appear preprinted on the general information test record, into the box in the upper right hand corner of the peak kilovoltage determination test record. Since this test is performed in conjunction with abovetable radiographic, dental radiographs, or mobile radiographic tests, add the same letter designator as on the radiographic test record. Thus, test records for an abovetable radiographic/undertable fluoroscopic system would be identified as follows: "GI12345" - general information; "AR12345A" - radiographic; "KV12345A" - peak kilovoltage; and "UF12345B" - fluoroscopic.

1.5 Connect the 6-cm$^3$ ionization chamber to the electrometer. Set the x-ray monitor mode selector to EXPOSURE RATE and the function selector to MEASURE. Allow the electronics 10 seconds to stabilize. After 10 seconds, the exposure rate reading should be less than 4 mR/min. If it is not, the instrument may be defective and CDRH should be contacted.

2.0 TEST SETUP

2.1 Attach the spacer assembly, positioned out of the beam, to the top of the test stand. Insert the beam-defining assembly, lead side up, into Slot 1 of the test stand.

2.2 (a) **Non-Dental Equipment**: Using the light localizer, center the test stand underneath the source assembly. Lower the source assembly until the face of the beam-limiting device is in firm contact with the spacer assembly. Lock the vertical movement. Turn on the light localizer and adjust the beam-limiting device such that the visually defined field is approximately 3" x 3" at the beam-defining assembly. The field should be centered on the 2" x 2" aperture of the beam-defining assembly.

(b) If the filtration present in the useful beam is adjustable, adjust to the value used during the radiographic field test.
2.3 **Dental Equipment:** Center the tube head above the beam-defining assembly so that the PID is pointing downward approximately 3 inches (height of spacer assembly) above and perpendicular to the beam-defining assembly. For kVp setting of 70 kVp or lower, center a total of 3.5 mm of aluminum on the beam-defining assembly. Tape the aluminum in place. For 90 kVp, fixed, omit the 3.5 mm of Al.

2.4 Insert the 6-m$^3$ ion chamber through the top mounting hole of the test stand, and set the x-ray monitor mode selector to EXPOSURE and the function selector to HOLD.

### 3.0 COPPER TRANSMISSION DATA

3.1 Enter the code for the appropriate test procedure at item 1.

3.2 **Non-Dental Equipment:** The kVp setting tested must be in the range of 71-90 kVp, and must be identical to the kVp used during beam quality measurements. Record at item 2.

3.3 **Dental Equipment:** The kVp setting must be 70 kVp or lower when there is a range of kVp settings available. Record at Item 2.

3.4 (a) If independently selectable, choose values of tube current and exposure time that will result in at least 100 mR at the chamber position when there is no copper absorber in the beam (3.5 mm of aluminum for dental equipment tested at 70 kVp or lower). To accomplish this condition, a test exposure as described in step 3.5 may be required. Record tube current and exposure time at items 3 and 4. Leave item 5 blank.

(b) If only mAs is selectable, choose a value that will result in a least 100 mR at the chamber position when there is no copper absorber in the beam (3.5 mm of aluminum for dental equipment tested at 70 kVp or lower). To accomplish this condition, a test exposure as described in step 3.5 may be required. Record the mAs at item 5. Leave items 3 and 4 blank.

3.5 The x-ray monitor display should read 0.00. If any other display is present, reset the instrument by switching the function selector to MEASURE and then back to HOLD. Make an exposure at the selected technique factors as soon as possible after switching the function selector to MEASURE. Since there is a slow upward drift in the exposure value in MEASURE, switch back to HOLD as soon as possible after exposure and record the exposure reading at item 6.

3.6 Consult Table 1 (kVp versus copper absorber thickness) for the appropriate thickness of copper absorbers for completing the test. If the kVp setting selected for the test is not provided as part of Table 1, select the closest kVp in the table and the associated thickness of copper absorbers.
Table 1. Copper absorber thickness to be used at each data item number during the test procedure as a function of equipment type and kVp setting.

<table>
<thead>
<tr>
<th>Copper Thickness (mm)</th>
<th>kVp</th>
<th>Item 7</th>
<th>Item 8</th>
<th>Item 9</th>
<th>Item 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>65</td>
<td>0.46</td>
<td>0.87</td>
<td>1.00</td>
<td>1.26</td>
<td></td>
</tr>
<tr>
<td>70</td>
<td>0.46</td>
<td>0.87</td>
<td>1.00</td>
<td>1.54</td>
<td></td>
</tr>
<tr>
<td>90</td>
<td>0.80</td>
<td>1.26</td>
<td>2.00</td>
<td>2.54</td>
<td></td>
</tr>
<tr>
<td>Non-Dental:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>71</td>
<td>0.46</td>
<td>0.87</td>
<td>1.00</td>
<td>1.67</td>
<td></td>
</tr>
<tr>
<td>80</td>
<td>0.54</td>
<td>1.00</td>
<td>1.33</td>
<td>2.13</td>
<td></td>
</tr>
<tr>
<td>90</td>
<td>0.67</td>
<td>1.33</td>
<td>1.67</td>
<td>2.67</td>
<td></td>
</tr>
</tbody>
</table>

NOTE: Six copper sheets are included in the test kit, with approximate thickness in millimeters of 0.13 (2 each), 0.33, 0.54, 1.0, and 2.0 - the exact thickness of each sheet is stamped on the sheet. Using various combinations of these thickness, total copper thickness millimeters of approximately 0.13, 0.26, 0.33, 0.46, 0.54, 0.67, 0.80, 0.87, 1.0, 1.16, 1.26, 1.33, 1.46, 1.54, 1.67, 1.80, 1.87, 2.0, 2.13, 2.26, 2.33, and 2.46 can be achieved.

3.7 Center the copper absorber(s) corresponding to the smallest thickness (item 7) on the beam-defining assembly.

3.8 Set the x-ray monitor back to MEASURE. As soon as possible after switching the function selector to MEASURE, make an exposure.

3.9 Switch back to HOLD as soon as possible after the exposure and record the exposure reading and selected copper thickness at item 7.

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

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

b. Stationary anode tubes: Wait 30 seconds between exposures of less than 900 heat units and 60 seconds between exposures of 900 of 1800 heat units.

3.10 Repeat the procedure of steps 3.8 and 3.9 for each thickness of copper absorber with the largest thickness last. Record the exposure reading and the selected copper thickness at items 8, 9, and 10, respectively.

Note: For the last copper thickness, quickly check that the resultant exposure value is less than 2 percent of the 0.0-mm Cu exposure; i.e., data item 6. If it is not, repeat the last exposure with sufficient copper to satisfy this condition.
1) If this test is performed in conjunction with a Non-Dental Radiographic Field Test, data item 2 (kVp) is identical to the peak tube potential for beam quality and is in the range of 71-90 kVp.

2) If this test is performed in conjunction with a Dental Field Test, data item 2 (kVp) is 70 kVp or less, or 90 kVp, fixed.

3) The mAs has been adjusted such that at least 100 mR is obtained at the chamber location for data item 6.

4) The copper absorber thickness used for the test are appropriate for the equipment tested and the selected kVp.

5) The exposure value at data item 10 is less than 2 percent of the exposure value at data item 6.
PEAK KILOVOLTAGE DETERMINATION

CALCULATION TECHNIQUE

(Test Procedure KVA - Form FDA 3068)

1. Refer to data items 6, 7, 8, 9, and 10 on the Field Test Record. Divide each exposure by the exposure for 0.0 mm Cu; i.e., data item 6 on the Field Test Record. Record the four resultant quotients, \( N_1 \) through \( N_4 \), at Results 1, 2, 3, and 4.

2. On semilog paper, plot the four normalized exposures along the logarithmic scale with the corresponding thickness of copper absorbers along the linear axis. Draw a smooth curve fit to the points and determine the 8 and 2 percent transmission values as those thickness of copper that would yield normalized exposures of 0.08 and 0.02, respectively. Record the copper thickness values at Results 5 and 6.

3. Refer to Results 5 and 6. Calculate:

\[ A = (\text{Result 6} - \text{Result 5}) \]

Record at Result 7.

4. Select the proper equation, based on the type of compliance test performed, and calculate the measured kVp:

   a. Non-Dental Equipment

   \[
   \text{Measured } kVp = \exp \left( \frac{11.6 - \ln(A)}{2.54} \right)
   \]

   b. Dental Equipment, 70 kVp or lower

   \[
   \text{Measured } kVp = \exp \left( \frac{12.52 - \ln(A)}{2.77} \right)
   \]

   c. Dental Equipment, 90 kVp, fixed

   \[
   \text{Measured } kVp = \exp \left( \frac{10.424 - \ln(A)}{2.31} \right)
   \]

   Record the measured kVp at Result 8.

5. Select the proper equation, based on the type of compliance test performed and calculate the actual kVp:

   a. Non-Dental Equipment

   \[
   \text{Actual kVp} = (1.065 - (0.026 \times HVL_{\text{obs}})) \times \text{measured kVp}
   \]
where $HVL_{obs}$ is the observed half-value layer during the Non-Dental radiographic field test.

b. Dental Equipment, 70 kVp or lower

Actual kVp = measured kVp

c. Dental Equipment, 90 kVp, fixed

Actual kVp = $(1.08 - (0.009 \times HVL_{act.})) \times$ measured kVp

Where $HVL_{act.}$ is the actual half-value layer calculated from the Dental Radiographic Field Test.

6. Refer to data item 2 on the Field Test Record and record as Result 10. Calculate the percent deviation from the indicated kVp setting as follows:

$$Percent \ Deviation = \left(\frac{Indicated \ kVp - Actual \ kVp}{Indicated \ kVp}\right) \times 100$$

Record Percent Deviation at Result 11.
RESULTS RECORD

PEAK KILOVOLTAGE DETERMINATION

(Test Procedure KVA - Form FDA 3068)

Field Test
Serial No. ______

Normalized Exposures

\[ N_0 = 1.0 \]

1. \( N_1 = \) __________
2. \( N_2 = \) __________
3. \( N_3 = \) __________
4. \( N_4 = \) __________

8% and 2% Transmission Copper Thicknesses

5. _____ mm Cu @ 8%
6. _____ mm Cu @ 2%

Difference in 8% and 2% Copper Thickness

7. \( A = \) _____. _____ mm Cu

<table>
<thead>
<tr>
<th>Measured kVp</th>
<th>Actual kVp</th>
<th>Indicated kVp</th>
<th>Percent Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. _____ kVp</td>
<td>9. _____ kVp</td>
<td>10. _____ kVp</td>
<td>11. _____ %</td>
</tr>
</tbody>
</table>
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PEAK KILOVOLTAGE DETERMINATION FIELD TEST RECORD

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

Card No.
(P-10)

Test Procedure:

1. KV

Technique Factors:

2. kVp

3. mA

4. sec OR pulses

5. mAs

Copper Transmission Data:

MDH (Exposure Mode)

6. at least 100mR

7. 31

8. 35

9. 43

10. less than 2% of item 6

REMARKS

Copper Thicknesses (mm)

<table>
<thead>
<tr>
<th>kVp</th>
<th>Item 7</th>
<th>Item 8</th>
<th>Item 9</th>
<th>Item 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental:</td>
<td>65</td>
<td>0.46</td>
<td>0.87</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>70</td>
<td>0.46</td>
<td>0.97</td>
<td>1.00</td>
</tr>
<tr>
<td>Non Dental:</td>
<td>70</td>
<td>0.46</td>
<td>0.97</td>
<td>1.00</td>
</tr>
<tr>
<td></td>
<td>80</td>
<td>0.94</td>
<td>1.00</td>
<td>1.33</td>
</tr>
<tr>
<td></td>
<td>90</td>
<td>0.67</td>
<td>1.33</td>
<td>1.67</td>
</tr>
</tbody>
</table>

CHECK IF CONTINUATION SHEET USED

FORM FDA 3068 (10/80)

PART VII

KV-8

04/1/2000
SUPPLEMENT TO PEAK KILOVOLTAGE DETERMINATION PROCEDURE

ROUTINE COMPLIANCE TESTING

PEAK KILOVOLTAGE DETERMINATION

RADIOGRAPHIC SYSTEMS

(Test Procedure KVB - Use Form FDA 3068)

1.0 GENERAL GUIDANCE

INSTRUCTIONS FOR USING THE MINI-X/TIME KVP METER

The MINI-X kVp/Time meter is a self contained, non-invasive kVp meter that can measure x-ray tube potential with an accuracy of ± 2.0%. Since it employs a digital similar to the MDH 1015, the kVp can be determined almost instantaneously during an exposure. Since this involves a departure from the copper filtration method in the compliance test procedures, the following procedure should be used instead:

1.1 This kVp test procedure is applicable to single and three phase, stationary and mobile radiographic, medical and dental x-ray equipment with a tungsten anode. It is not applicable to capacitor discharge x-ray equipment.

1.2 The kVp test procedure is intended to be used in conjunction with an above table Radiographic (ARA), Mobile Radiographic (MRA), or Dental Radiographic (DRA) Field Test.

1.3 This test is only valid for reproducible systems. If it is suspected that the system under test has a reproducibility noncompliance, this test should not be performed.

1.4 Record a "B" at data item 1.

1.5 Record the five digits, which appear preprinted on the general information test record, into the box in the upper right hand corner of the peak kilovoltage determination test record. Since the test is performed in conjunction with above table radiographic, dental radiographic, or mobile radiographic tests, add the same letter designator as on the radiographic test record. Thus test records for an above table radiographic/undertable fluoroscopic system would be identified as follows: "GI12345" - general information; "AR12345A" - radiographic; "KV12345A" - peak kilovoltage; and "UF12345B" - fluoroscopic.

1.6 Turn on the kVp meter with the ON/OFF button (labeled "Ω/Ω•"). Make sure that the meter is set in the mode to measure the kVp.

1.7 The meter is equipped to measure the exposure time in a manner similar to the MDH 1015. If the display has a "." at the end of the liquid crystal display (LCD), then the meter is in the exposure time mode and has to be switched to the kVp mode. Push the button labeled "kVp/Time" once and the "." should disappear. The meter is now ready to measure kVp.
2.0 TEST SETUP AND PROCEDURE

2.1 Place the kVp meter on the table underneath the diagnostic source assembly (DSA).

2.2 Make sure that the x-ray beam axis is perpendicular to the kVp meter.

2.3 If testing a dental x-ray system, go directly to step 2.7.

2.4 The blades of the beam-limiting device should be open wide enough so that the detectors are completely within the x-ray field.

2.5 If the x-ray system is equipped with a light localizer, turn it on. On top of the kVp meter, there is a circle labeled "SENSOR AREA". This is the portion of the meter where the radiation detectors that measure the kVp are located. Position the kVp meter in the light field so that the detector area is in the center of the x-ray field. Make sure that the DSA is perpendicular to the face of the kVp meter.

2.6 If the filtration in the beam-limiting device is adjustable, adjust it to the value used during the radiographic field test.

2.7 Dental Systems: Center the tube head above the circle labeled "SENSOR AREA" so that the end of the cone is in contact with the surface of the kVp meter.

2.8 Select the kVp that was used during the BEAM QUALITY test. It must exceed 45 for an accurate measurement. Record at data item 2.

2.9 a) If independently selectable, choose values of tube current and exposure time that will result in a least 25 mR to the detector. An exposure time setting of 0.100 seconds or greater and an mA of approximately 100 or greater should be sufficient.

b) If only mAs is selectable, then a value of 10 mA or greater should be sufficient.

2.10 After the exposure is made, the LCD display on the kVp meter blinks for several seconds and stops. The reading the remains after the blinking stops is the measured kVp value.

2.11 Record the kVp reading at data item 7. As an example, the data could be entered as "102.40."

NOTE: The following notes pertain to specific error codes that the kVp meter might display. The display codes have the following meanings:

Er. 1 Low signal.

The detector signal is too low. Increase mA or decrease the distance between MINI-X and the tube.
Er. 2 High signal.
The detector signal is too high. Decrease mA or increase the distance between MINI-X and the tube.

Er. 3 Low kVp.
The measured kVp is lower than 45 kV.

Er. 4 High kVp.
The measured kVp is higher than 155 kV.

Er. 5 Short exposure time.
The exposure time is too short, MINI-X cannot calculate a correct kVp-value.

Er. 6 No exposure time can be calculated.
Incorrect calculation of exposure time due to a false trigger of the timer. Try with a longer exposure time or a different mA - setting.

If the MINI-X at any time indicates an error that will not disappear after appropriate changes, it would be advised to try a longer exposure time, shorter SID, or higher mA.
PART VIII

MAMMOGRAPHIC SYSTEMS

FORM FDA 3070

REPRINTED APRIL 20000
ROUTINE COMPLIANCE TESTING

MAMMOGRAPHIC SYSTEMS

(Test Procedure MAA - Use Form FDA 3070)

1.0 GENERAL GUIDANCE

1.1 This procedure is applicable to any mobile or stationary special purpose mammographic x-ray system.

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

2.0 PRETEST CHECKLIST

2.1 Turn on the main power to the x-ray system and have it oriented for a craniocaudal view (i.e., x-ray beam in a direction from the head to the feet).

2.2 Connect the 6-cm³ ionization chamber to the electrometer. Set the x-ray monitor mode selector switch to EXPOSURE RATE and the function selector switch to MEASURE. Allow the electronics 10 seconds to stabilize. After 10 seconds, the exposure rate reading should be less than 4 mR/min. If it is not, the instrument may be defective and the CDRH should be contacted.

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

2.4 Enter the five digits, which appear preprinted on the General Information Test Record, and a unique letter designator, in the appropriate block on each page of the Mammographic Systems Field Test Record.

2.5 Verify that the assembler's report, FDA 2579, is correctly prepared. If it is not, write the correct information above the incorrect information.

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

2.7 Check the certification status of each component to determine if the components are: certified without a variance (C), certified with a variance (V), not certified (N), or not present (X). Record this data at item 2.

2.8 Determine the image receptor size most commonly used with the system. Select the correct cone or aperture for this image receptor.

2.9 (a) If the SID is adjustable, adjust it to the maximum for which the above beam-limiting device - image receptor combination is designated. Record the SID at item 3.

(b) If the SID is fixed, record the design SID at item 3.
2.10 Record at item 4, whether or not the beam-limiting device was manufactured after October 1977.

2.11 If possible, have the x-ray technician retract to remove from the x-ray beam any existing breast compression device.

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

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

b. Stationary anode tubes: Wait 30 seconds between exposures of less than 900 heat units and 60 seconds between exposures of 900 to 1,800 heat units.

**3.0 BEAM QUALITY**

**Test Setup (see figures on test record)**

Note: If a BENT test stand is available, complete steps a), b), and c). If not, then place the electrometer directly on the image receptor support device (IRSD) and skip to step d).

a) Place the BENT test stand on the image receptor support deviation (IRSD).

b) Secure the 6-cm$^3$ ion chamber to the BENT test stand.

c) Center the ion chamber and test stand in the x-ray field using the alignment means provided on the system and secure with tape.

CAUTION: Be sure not to disturb the ionization chamber position during the following exposures. Most of these systems have a severe x-ray field intensity gradient (heel effect), so that chamber movement between exposures may substantially affect the readings.

d) Place the cardboard support over the ion chamber such that the chamber is centered in the cardboard support.

e) If the maximum operable kVp control setting is less than 50, set 1.5 mm of aluminum on the cardboard support.

f) If the maximum operable kVp control setting is between 50 and 70, set 3.0 mm of aluminum on the cardboard support.
Test Procedure

3.1 Whenever a manual mode of operation for exposure termination (manually set time or mAs) is provided, select this mode of operation over the automatic control mode (phototimer). Record the mode of operation used during testing at item 5.

3.2 (a) If the maximum operable kVp control setting is less than 50, set the kVp to the maximum value. Record at item 6.

(b) If the maximum operable kVp control setting is 50 or greater, set the kVp to a value between 50 and 60. Record at item 6.

3.3 (a) If testing in the phototimed mode, select a commonly used value of tube current and record at item 7. Leave items 8 and 9 blank.

(b) If independently selectable, choose a combination of tube current and exposure time not to exceed the anode’s heat loading specifications. Record at item 7 and 8. Leave item 9 blank.

(c) If only the mAs is selectable, choose a value not to exceed the anode’s heat loading specifications. Record at item 9. Leave items 7 and 8 blank.

3.4 If the capability is provided for adjustment of the filtration present in the useful beam, adjust for the minimum filtration that will allow an exposure. Be sure that the compression device is in the x-ray beam.

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

MANUALLY SET TIMER OR mAs MODE

3.6 Make an exposure and record the reading (exclusive of the minus sign) and the corresponding aluminum thickness at item 10.

3.7 (a) If the kVp setting is less than 50, place aluminum on top of the cardboard support to obtain totals of 1.0, 0.75, 0.5, and 0.25 mm. For each total, make an exposure and record the exposure and the corresponding aluminum thickness at items 11 through 14.

(b) If the kVp setting is 50 or greater, place aluminum on top of the cardboard support to obtain totals of 2.0, 1.5, 1.0 and 0.5 mm. For each total, make an exposure and record the exposure and the corresponding aluminum thickness at items 11 through 14.

3.8 Skip to 3.11

PHOTOTIMER MODE
3.9 Make an exposure and record the reading (exclusive of the minus sign) and the corresponding aluminum thickness at item 10.

3.10 (a) If the kVp setting is less than 50, transpose aluminum from the top of the cardboard support to the cardboard support to the bottom such that totals of 1.0, 0.75, 0.5, and 0.25 mm end up between the source and ion chamber. For each total, make an exposure and record the exposure and the corresponding aluminum thickness at items 11 through 14.

(b) If the kVp setting is 50 or greater, transpose aluminum from the top of the cardboard support to the bottom such that totals of 2.0, 1.5, 1.0, and 0.5 mm end up between the source and ion chamber. For each total, make an exposure and record the exposure and the corresponding aluminum thickness at items 11 through 14.

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

3.12 Are the technique factors visible at the operator's position? Record at item 16.

3.13 Is exposure terminated after a preset time interval, preset mAs, preset number of pulses, or preset radiation exposure? Record at item 17.

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

4.0 REPRODUCIBILITY AND LINEARITY

Test Setup (same as BEAM QUALITY without cardboard support or Al filters)

Test Procedure

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

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

4.2 If phototiming has been selected, place an aluminum filter with a nominal thickness of 2 mm on the test stand so as to cover the entire sensitive area of the phototimer detector.

4.3 (a) If the system is single-phase, set the x-ray monitor Pulse Fraction Threshold
4.4 Set the x-ray monitor mode selector to PULSE EXPOSURE and the function selector to MEASURE. The display should indicate -0.00. If any other reading is present, reset the monitor by switching the function selector to HOLD and then back to MEASURE.

4.5 Make an exposure. DO NOT record the resultant reading. Without resetting the x-ray monitor, make another exposure. The reading will now have no minus sign present. Record the exposure reading at item 19. Switch the mode selector to PULSE DURATION and record this time reading at item 20. DO NOT reset the x-ray monitor.

NOTE: If testing in the phototimed mode, the exposure item recorded by the x-ray monitor should be greater than 0.1 and less than 1.0 seconds. If the exposure time is outside this range, adjust the aluminum attenuator thickness accordingly, verify its placement, and repeat steps 4.4 and 4.5.

4.6 (a) Make three additional exposures with the exposure readings being recorded at items 21, 23, and 25 and the time readings at items 22, 24, and 26. DO NOT reset the x-ray monitor.

(b) If any two exposure readings differ by more than 10 percent of the higher exposure reading, make an additional 6 exposures. Record the exposure readings at items 27, 29, 31, 35, and 37, and the time readings at items 28, 30, 32, 34, 36, and 38.

4.7 If testing in the phototimed mode, or if the system either does not allow specific selection of tube current, or it only mAs is selectable, then omit steps 4.8 through 4.11 and enter an asterisk in the first column of item 39 on the Field Test Record, and state in Remarks than mA is fixed, mAs is selected, or the system is phototimed only.

4.8 (a) If tube selection is in fixed stations, select an adjacent tube current station and record the indicated value at item 39.

(b) If the 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 at item 39.

4.9 The change in tube current may cause a change in the indicated tube potential. If manual compensation is available, readjust the tube potential to its original value, and continue with steps 4.10 and 4.11. However, if the kVp cannot be compensated back to its original setting, enter an "*" in the first column of item 40, skip steps 4.10 and 4.11 and state in the Remarks that the kVp could not be compensated.
4.10 Make an exposure at the selected technique factors. Record this reading at item 40.

4.11 While varying technique factors between each measurement as described is step 4.1, make three additional exposures. Record the exposure readings at items 41, 42, and 43. It is not necessary to reset the x-ray monitor between exposures.

5.0 X-RAY FIELD/IMAGE RECEPTOR ALIGNMENT

Test Setup

a. Remove all equipment from the image receptor support device (IRSD).

b. Have the x-ray technique position an image receptor for an exposure using the alignment means provided (e.g., lightfield, cassette guides, and so forth). The developed image will be used to evaluate the x-ray field alignment.

c. Place two plastic cassettes containing direct print paper in an overlapping pattern over the image receptor such that the cassettes extend at least 2 inches beyond three edges of the image receptor. These edges should correspond to the chest wall and adjacent side wall edges (see Figure 1).

d. Place metal markers on top of the plastic cassettes to identify the patient side or chest wall edge of the image receptor.

e. Place the slide assembly on top of the plastic cassettes, grid side down, and align one long edge with the chest wall edge of the image receptor (See c., Figure 1).

f. Set the electrometer on the IRSD. Position the ion chamber in the center of the image receptor.

Test Procedure

5.1 Maintain the technique factors used for beam quality testing. If photo timing has been selected, retain the aluminum filter used in reproducibility testing.

5.2 Set the function selector on the x-ray monitor to EXPOSURE. Make an exposure and check the reading. Make any additional exposures needed to obtain 3 R at the ion chamber.

5.3 Have the technician process the mammographic image receptor.

5.4 Develop the direct print paper in each cassette. (Refer to page LINA-1 for proper development technique.)
a) Image receptor positioned for an exposure on the image receptor support device.

b) Two plastic cassettes with direct print paper positioned over image receptor.

c) Slide assembly, grid side down, positioned over the plastic cassettes.
5.5 Refer to the developed mammographic image obtained from the technician. Using this image and the direct print paper images, reconstruct the geometric relationship in effect during the exposure.

NOTE: The metal marker images identify the chest wall edge of the image receptor. The other edges are identified with respect to this edge as right and left edges (see Figure 2).

5.6 Measure to the nearest millimeter, the maximum x-ray field excess at the chest, right and left edges of the image receptor. The measurement direction should be perpendicular to the image receptor edges. Record the results at items 44, 45, and 46. For any edge where the x-ray field is smaller than the image receptor, record 0.00 at the corresponding item number. Figure 3 shows an example where the x-ray field excess occurs only at the chest wall edge.

6.0 ILLUMINANCE OF LIGHT LOCALIZER

6.1 If the SID is variable, set the diagnostic source assembly to a source to detector distance of 39.25 inches (100 cm or the maximum SID whichever is less). Open the beam-limiting device to the indicated image receptor size.

6.2 Set the photometer on the cassette holder. (Refer to page PHOTO-1 for proper use of the photometer.) Turn on the localizer. At or near the center of one quadrant of the light file, determine the illuminance by subtracting the ambient light level from the corresponding light level when the light localizer is engaged. Do not move the photometer between measurements. Record this illuminance in the REMARKS section.

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

6.3 Repeat the measurements at or near the center of the other three quadrants of the light field and record in the REMARKS section in the following format (example):

\[ \text{ILLUM } 17 + 18.15 + 16 + 15.4 = 16.6 \text{ fc} \]
FIGURE 3

- Developed x-ray film
- Excessive x-ray field at chest wall edge
- Overlapping direct print paper
MAMMOGRAPHIC SYSTEMS

FILED TEST RECORD EDIT CHECKS

(Test Procedure MAA - Use Form FDA 3070)

Verify that:

1. SID has been entered at data item 3.

2. If data item 5 is marked "P," the exposure times at data items 20, 22, 24, and 26 are greater than 100 milliseconds.

3. If data item 6 (kVp) is less than 50, the aluminum filters used at data items 10 through 14 correspond to 1.5, 1.0, 0.75, and 0.25 mm, respectively.

4. If data items 6 (kVp) is between 50 and 70 kVp, the aluminum filters used at data items 10 through 14 correspond to 3.0, 2.0, 1.5, 1.0, and 0.5 mm, respectively.

5. If the difference between any two of data items 19, 21, 23, and 25 is greater than 10 percent of the largest value, an additional 6 exposures have been entered for reproducibility at data items 27 through 38.

6. If data item 5 is marked "P," data is not present at data items 39 through 43.
CALCULATION TECHNIQUES

MAMMOGRAPHIC SYSTEMS

(Test Procedure MAA - Form FDA 3070)

A. REPRODUCIBILITY AND LINEARITY

1. Refer to data items 19, 21, 23, and 25 of the Field Test Record. Calculate the average exposure $\overline{E}_1$, as follows:

$$ \overline{E}_1 = \frac{1}{n} \sum_{i=1}^{n} X_i $$

where the $X_i$'s are the data items referred to above. Record the value of $\overline{E}_1$ at Result 1. If item exposure measurements have been taken, data items 19, 21, 23, 27, 29, 31, 33, 35, and 37 would be used in the calculation and n=10 in the equation.

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

$$ C_1 = \frac{1}{E_1} \left( \sum_{i=1}^{n} \left( X_i - \overline{E}_1 \right)^2 / (n - 1) \right)^{1/2} $$

where the $X_i$'s are the data items 19, 21, 23, and 25. Record the value of $C_1$ at Result 2. If ten exposure measurements have been taken, data items 19, 21, 23, 25, 27, 29, 31, 33, 35, and 37 would be used in the calculation and n=10 in the equation.

NOTE: If testing in the phototimed mode, or if the system either does not allow specific selection of tube current, or if only mAs is selectable, skip the following calculations.

3. Refer to data items 7, 8, and 9 of the Field Test Record and compute the mAs, if data item 9 is blank, by multiplying data item 7 by data item 8. If data item 8 is given as pulses, convert to time in seconds by dividing the pulses by 120. The average exposure rate per mAs, $\overline{X}_1$, is given by:

$$ \overline{X}_1 = \frac{\overline{E}_1}{\text{mAs}} $$

Record the value of $\overline{X}_1$ at Result 3.

4. Refer to data items 40, 41, 42, and 43 of Field Test Record and calculate the average exposure, $\overline{E}_2$, as follows:

$$ \overline{E}_2 = \frac{1}{n} \sum_{i=1}^{n} X_i $$

where the $X_i$'s are the data items 40, 41, 42, and 43. Record $\overline{E}_2$ at Result 4.

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

$$ C_2 = \frac{1}{E_2} \left( \sum_{i=1}^{n} \left( X_i - \overline{E}_2 \right)^2 / (n - 1) \right)^{1/2} $$
where the $X_i$’s are the data items 40, 41, 42, and 43. Record the value of $C_2$ at Result 5.

6. Refer to data items 8 and 39 of Filed Test Record and compute the mAs by multiplying data item 39 by data item 8. If data item 8 is given as pulses convert to time in seconds by dividing the pulses by 120. The average exposure rate per mAs, $\overline{X}_2$, is given by:

$$\overline{X}_2 = \frac{E_2}{mAs}$$

Record the value of $\overline{X}_2$ at Result 6.

7. Refer to Results 3 and 6 and calculate the coefficient of linearity, $L$, by:

$$L = \frac{\overline{X}_1 \cdot \overline{X}_2}{(\overline{X}_1 + \overline{X}_2)}$$

where $\overline{X}_1$ and $\overline{X}_2$ are the average exposure per mAs recorded at Results 3 and 6. Record at Result 7.

B. BEAM QUALITY

1. Refer to data items 10 through 14 on the Field Test Record and convert to normalized exposure ratios by dividing each of them by Results 8 through 12, respectively. Plot the six normalized exposure ratios on semilog paper, with the corresponding thickness of aluminum absorber along the linear axis. Draw a smooth curve fit to the six points and determine the half-value layer (HVL) as that thickness of aluminum absorber which would yield a normalized exposure ratio of 0.50. Record the HVL and selected kVp (data item 6 on the Field Test Record) at Result 13.

2. Refer to Table 1 and determine the minimum acceptable HVL for the indicated kVp. Record the minimum acceptable HVL at Result 14.
Table 1. Minimum acceptable HVL

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<th>kVp</th>
<th>HVL</th>
<th>kVp</th>
<th>HVL</th>
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</table>

C. TIMER ACCURACY

1. Refer to data item 8 on the Field Test Record, if this item is blank, omit the timer accuracy computation. Otherwise, record data item 8 on the Field Test Record at Result 15 on the Results Record (i.e., indicate time setting), and, if necessary, convert to time in seconds by dividing by 120. Refer to data items 20, 22, 24, and 26 (28, 30, 32, 34, 36, 38) on the Field Test Record and choose the one value that has the largest deviation from the indicated time setting. Calculate this deviation as the absolute value of the measured time subtracted from the indicated time. Record that deviation at Result 16.

2. Calculate the percent timer inaccuracy as follows:

   \[ \text{Percent Timer Inaccuracy} = \left( \frac{\text{Maximum deviation}}{\text{Indicated time setting}} \right) \times 100. \]

   Record the percent timer inaccuracy at Result 17.

D. X-RAY FIELD/IMAGE RECEPTOR ALIGNMENT

1. Refer to data item 3 on the Field Test Record. If necessary, convert data item 3 (SID) to centimeters by multiplying by 2.54. Record the SID at Result 18.

2. Refer to data items 44, 45, and 46 on the Field Test Record. Calculate the x-ray field excess in percent SID as follows:
x-ray field excess in percent SID = (data items 44, 45, or 46/SID) x 100.

Record the x-ray field excess in percent SID at Result 19.

3. Refer to data item 4 on the Field Test Record and record at Result 20. If "yes", the x-ray field may not exceed the image receptor, except at the chest wall edge.
RESULTS RECORD

MAMMOGRAPHIC SYSTEMS

(Test Procedure MAA - Form FDA 3070)

FIELD TEST
SERIAL NO.________

REPRODUCIBILITY AND LINEARITY

1. Average Exposure, $\bar{E}_1 = \text{_______ mR}$
2. Coefficient of Variation, $C_1 = \text{_______}$
3. Average Exposure Ratio, $\bar{X}_1 = \text{_______ mR/mAs}$
4. Average Exposure, $\bar{E}_2 = \text{_______ mR}$
5. Coefficient of Variation, $C_2 = \text{_______}$
6. Average Exposure Ratio, $\bar{X}_2 = \text{_______ mR/mAs}$
7. Coefficient of Linearity, $L = \text{_______}$

BEAM QUALITY

8. $N_5 = \text{_______ at ________ mm Al}$
9. $N_4 = \text{_______ at ________ mm Al}$
10. $N_3 = \text{_______ at ________ mm Al}$
11. $N_2 = \text{_______ at ________ mm Al}$
12. $N_1 = \text{_______ at ________ mm Al}$

No. = 1.000 at 0 mm Al
13. HVL = ________ mm Al at ________ kVp
14. Minimum Acceptable HVL = ________ mm Al

TIMER ACCURACY

15. Indicated Time Setting = ________ sec.
16. Maximum Deviation from Indicated Setting = ________ sec.
17. Percent Timer Inaccuracy = ________ %
X-RAY FIELD RECEPTOR ALIGNMENT

18. SID = ________ cm.

19. X-ray field excess in percent SID. ________ ________ ________ cm
    chest right left

20. Beam Limiting device manufactured after October 1977: yes no (circle)
Reproducibility (Continued)

Data here, if any of items 14, 16, 18 and 20 differ by more than 10 percent of the largest value.

Linacuity

If change in mA causes a kVp shift, readjust kVp (if possible) to value selected at item 4 above.

Illuminance (uncorrected; SID = 42.5" (106 cm))

X-Ray Field/Light Field Alignment:

Minimum Source To Skin Distance

Outside Separation of Image of Focal Spot Strips

Standby Radiation: (Capacitor discharge equipment only)

REMARKS

CHECK IF CONTINUATION SHEET USED
PART IX

VERTICALLY MOUNTED CASSETTE HOLDER

FORM FD 3261

REPRINTED APRIL 2000
ROUTINE COMPLIANCE TESTING

VERTICALLY MOUNTED CASSETTE HOLDER

RADIOGRAPHIC SYSTEMS

(Tests Procedure VCA - Use Form FDA 3261)

1.0 GENERAL GUIDANCE

1.1 This Procedure is applicable to stationary radiographic x-ray systems employing a vertically mounted cassette holder designed for one or more image receptor sizes at a fixed SID. The procedure does not apply to systems equipped with positive beam-limitation.

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

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

2.0 PRETEST CHECKLIST

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

2.2 Connect the 6-cm³ chamber to the electrometer. Set the x-ray monitor mode selector switch to EXPOSURE RATE and the function selector switch to MEASURE. Allow the electronics 10 seconds to stabilize. After 10 seconds, the exposure rate should be less than 4 mR/min. If it is not, the instrument may be defective and you should contact CDRH for guidance.

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

2.4 Record the five digits, which appear preprinted on the general information test record, and unique letter designator in the appropriate block on each page of the Vertically Mounted Cassette Holder Radiographic Systems field test record.

2.5 Verify that the assembler's report, FD 2579, is correctly prepared. If it is not, write the correct information above the incorrect information.

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

2.7 Indicate the certification status of each component at item 2.
3.0 INITIAL SETUP

3.1 If applicable, are means provided to center the diagnostic source assembly to the image receptor? This can be met by tubestand detents, light localizer or other similar devices. Record at item 3.

3.2 Place a loaded film cassette into the cassette holder. If film is not available, use direct-print paper in the following manner: note that most vertically mounted cassette holders have a front panel that is usually etched or otherwise marked with the useable film size(s). Position a plastic cassette containing a sheet of direct-print paper precisely in the center of a selected film size marking and tape into place. If the holder does not have a front panel, then tape the plastic cassette to an empty film cassette and load the cassette into the holder.

NOTE: If the system is phototimed only, then film must be used, since sufficient exposure for the direct-print paper images cannot be obtained.

3.3 If the system does not have a variable aperture collimator but uses cones or fixed apertures, select the appropriate collimator for the selected film size and center the x-ray source to the image receptor.

NOTE: In order to assure that the x-ray field will be large enough to image both brass strips of the focal-spot assembly and yet be small enough to "fit" on the direct-print paper in the slide assembly, use the following film size/collimator:

a. For a 72" SID use a 14" x 17" size if possible, but no less than 10" x 12".

b. For a 40" SID, use a 10" x 12" or smaller size.

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

a) Mount the right side of the test stand onto the tripod so that the MDH holes are on top. Follow the tripod setup procedure in Appendix B of the test procedures manual.

b) Position the test stand and tripod assembly so that the test stand is centered in the x-ray beam. For a 72" SID, position the test stand such that the based of the stand is approximately 100 centimeters from the plane of the image receptor. For a 40" SID, position the test stand as close as possible to the end of the cone or BLD, but leave enough space to insert the aluminum filters.

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

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

e) Position the 6 cm³ chamber in hole ”D" of the test stand and secure with the retaining ring.
3.5 If the system has a variable aperture collimator with light localizer perform the following additional steps:

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

   b) Turn on the light localizer and center the test stand by centering the light field on the slide assembly grid. A piece of white paper in the slide assembly makes visualization of the light field easier during setup. Remove it when the setup is complete.

   c) Adjust the beam limiting device so that the light field is approximately 7" x 9" at the slide assembly with the longer dimension parallel to the long dimension of the slide assembly. Using a piece of white paper, at the "top" of the test stand, check all edges of the light field against those of the opening in the top of the test stand to make sure that the light field is not shielded by the stand and passes through the opening in the top of the test stand.

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

3.6 Quickly recheck the alignment of the source assembly, test stand, and image receptor. Make any necessary adjustments. If the system has a variable aperture collimator, check the metal marker strips to assure that they are still aligned with the light field.

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

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

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

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

   b. Stationary anode tubes: wait 30 seconds between exposures of less than 900 heat units and 60 seconds between exposures of 900 to 1800 heat units.

   If a loaded film cassette is used at step 3.2 set the technique factors to commonly used values and make an exposure. Have the x-ray technologist process the film for you. If a readable image is not obtained at these technique factors, adjust the
technique factors appropriately and repeat the exposure with another film. Set the developed film aside for later determination of the centers alignment and continue with the next step.

4.0 BEAM QUALITY

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

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

4.3 a) If independently selectable, choose a value of tube current and exposure time commonly used, record at items 6 and 7. Leave item 8 blank.
   b) If only mAs is selectable, choose a value commonly used, record at item 8. Leave items 6 and 7 blank.

NOTE: For capacitor discharge systems, the maximum selectable mAs for the selected peak tube potential shall be used.

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

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

MANUALLY SET THE TIMER OR mAs MODE

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

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

4.8 Skip to 4.11.

PHOTOTIMER MODE

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

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

4.11 Are the technique factors indicated before the exposure? Record at item 13.
4.12 Is the exposure terminated after a preset time interval, preset mAs, or preset radiation exposure to the image receptor? Record at item 14.

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

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

5.0 REPRODUCIBILITY AND LINEARITY

Test Setup (Same as BEAM QUALITY expect all aluminum filters removed unless testing in phototimer mode, then all aluminum filters transposed to slot 7.)

Test Procedure

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

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

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

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

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

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

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

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

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

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

a. If tube current selection is in fixed stations, select an adjacent tube current station and record the indicated value at item 37. If tube current selection is continuous (i.e., not in discrete steps), select a second tube current not differing from the first by more than a factor of 2. Record at item 37.

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

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

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

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

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

5.12 Remove the cassette from the slide assembly and develop the direct-print paper be exposure to fluorescent light. (Refer to page LINA-1 for proper development technique). If a readable image has not been obtained, a new cassette with fresh direct-print paper should be inserted and exposed with sufficient radiation to produce an image.

6.0 ADDITIONAL EXPOSURES TO VERTICAL CASSETTE

Should you chose to use a plastic cassette containing direct-print paper taped to the vertical cassette holder (step 3.2), a total exposure of 8 to 10 R to the ion-chamber when testing at 72” SID, or 3 to 4 R when testing at 40” SID is necessary to provide a readable image on the direct-print paper. If the total exposure to the ion chamber
(step 5.11) is greater than 8 R (3 R for 40" SID) skip to 6.2. However, if the total exposure to the ion chamber is less than 8 R (3 R for 40" SID), perform step 6.1.

6.1 Make additional exposures as required to obtain at least 8 R (3 R for 40" SID) to the ion chamber. Check the anode cooling curves to ensure that the rated anode limits are not exceeded.

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

7.0 SID DETERMINATION

7.1 With the test stand still in position, measure to the nearest millimeter the distance from the base of the test stand to the front panel of the vertical cassette holder. Record at item 42. If the vertical cassette holder does not have a front panel, then load a film cassette into the holder and measure the distance from the base of the test stand to the film cassette. Record the distance at item 42, record 00.0 at item 43, and skip steps 7.2, 7.3, and 7.4.

7.2 Place a film cassette into the cassette tray.

7.3 Partially insert the cassette tray.

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

Note: If the vertical cassette is a closed system (automatic feed and processing) such that steps 7.2 to 7.4 cannot be performed, consult the users’ information of product literature to determine the distance called for in 7.4 and record at item 43. If the distance called for in 7.4 and record at item 43. If the distance still cannot be determined, enter 4.0 cm at item 43.

7.5 Take the developed direct-print paper that has been in the slide assembly and while viewing the radiographic image locate the outside edges of the image of the focal-spot assembly. Measure the minimum separation of the outside edge to the nearest millimeter and record at item 44.

7.6 Remove the test stand and other test equipment.

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

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

8.1 Record the dimensions of the selected image receptor (step 3.3) at items 45 and 46.

8.2 Take the developed direct print-paper that has been in the slide assembly and reconstruct the outline of the x-ray field using a straight edge and pencil or pen.
8.3 Measure to the nearest millimeter the dimensions of the x-ray field image on the direct-print paper. Record the dimensions at items 47 and 48.

9.0 ACTUAL VERSUS INDICATED FIELD SIZE

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

9.2 Manually adjust the beam-limiting device for an indicated field size; for example, 14 x 17 inches. Record the indicated field size at items 50 and 51.

9.3 Turn on the light localizer and measure to the nearest millimeter the dimension of the light field at the surface of the cassette holder. Record the dimensions at items 52 and 53. If the cassette holder does not have a front panel, load a film cassette into the holder, and measure the dimensions of the light field at the surface of the film cassette. Record the dimensions at items 52 and 53.

10.0 ILLUMINANCE OF LIGHT LOCALIZER

10.1 Turn on the light localizer.

10.2 Set the photometer against the cassette holder and hold into place. (Refer to page PHOTO-1 for proper user of the photometer.) At or near the center of one quadrant of the light field, determine the illuminance by subtracting the ambient light level from the corresponding light level when the light localizer is engaged. Do not move the photometer between measurements, and be careful not to cover or shade the detector element with your hand or body. Record this illuminance at item 54.

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

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

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

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

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

11.3 Measure the dimensions of the x-ray field image on the direct-print paper, to the nearest millimeter. Record the x-ray field dimensions at items 58 and 59.
11.4 Measure the light field dimensions by measuring the distance from the outside edges of the image of the marker strips, which define the edge of the light field in each direction. Record the light field dimensions at items 60 and 61.

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

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

**12.0 X-RAY FIELD/IMAGE RECEPTOR CENTERS COMPARISON**

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

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

12.3 Refer now to the film or direct-print paper that was positioned at the cassette holder (step 3.2). Draw diagonals from opposite corners of the film or direct-print paper to define the center of the film (or paper).

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

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

**13.0 STANDBY RADIATION FROM CAPACITOR DISCHARGE EQUIPMENT**

13.1 Perform this test only if the equipment under test is of the capacitor discharge type. If it is not, mark item 65 with an "X" and leave items 66 and 67 blank.

13.2 Set the x-ray monitor function selector to OFF. Connect the 100 cm² ionization chamber to the electrometer. Set the function selector to HOLD. Set the mode selector to EXPOSURE.

13.3 Use the largest beam-limiting opening possible (largest cone if multiple apertures available).

13.4 Position the face of the 100 cm² chamber on the x-ray beam axis as close as possible to and parallel with the face of the beam-limiting device. Note that the chamber and electrometer may have to be taped into place.

13.5 Adjust the kVp to its maximum setting.

13.6 Charge the capacitors fully.
13.7 Set the x-ray monitor function selector to MEASURE and using a stopwatch, without engaging the exposure switch, measure the standby radiation emission for 2 minutes. Because of the long time period required for this measurement, it may be necessary to periodically recharge the capacitors to full charge by manually activating the "charge" switch when the tube potential drops by more than 5 kV.

13.8 Record the exposure measurement at item 66 and the time measurement at item 67. If no discernible exposure occurs during the 2-minute interval, record 00.000 at item 66.
Vertically Mounted Cassette Holder

Radiographic Systems

Field Test Record Edit Checks

(Test Procedure VCA - Form FDA 3261)

Verify that:

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

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

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

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

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

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

7. For reproducibility, if only four values are entered (data items 17 through 25), no two exposures differ by more than 10 percent of the highest value.

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

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

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

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

12. If data item 65 is blank, then values for exposure and time are entered at data items 66 and 67, respectively.

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

VERTICALLY MOUNTED CASSETTE HOLDER

RADIOGRAPHIC SYSTEMS

(Test Procedure VCA - Form FDA 3261)

A. REPRODUCIBILITY

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

   a. Using the following equation, substituting n=4 or n=10, as appropriate, calculate the average exposure, \( \bar{E}_i \):
      \[
      \bar{E}_i = \frac{1}{n} \sum_{i=1}^{n} X_i
      \]
   Record the value of \( \bar{E}_i \) at Result 1.

   b. Calculate the coefficient of variation, \( C_1 \), as follows:
      \[
      C_1 = \frac{1}{\bar{E}_i} \left( \sum_{i=1}^{n} \left( X_i - \bar{E}_i \right)^2 / (n - 1) \right)^{1/2}
      \]
      where n=4 or n=10, depending on the number of exposures.
   Record the value of \( C_1 \) at Result 2.

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

3. Calculate the average exposure per mAs, \( \bar{X}_I \), as follows:
   \[
   \bar{X}_I = \frac{\bar{E}_i}{mAs_i}
   \]
   Record the value of \( \bar{X}_I \) at Result 3.

4. Refer to data items 38 to 41, calculating the average exposure, \( \bar{E}_2 \), as follows:
   \[
   \bar{E}_2 = \frac{1}{n} \sum_{i=1}^{n} X_i
   \]
   Record the value of \( \bar{E}_2 \) at Result 4.

5. Calculate the coefficient of variation, \( C_2 \), as before:
   \[
   C_2 = \frac{1}{\bar{E}_2} \left( \sum_{i=1}^{n} \left( X_i - \bar{E}_2 \right)^2 / (n - 1) \right)^{1/2}
   \]
   Record the value of \( C_2 \) at Result 5.
6. For controls manufactured before May 1994 refer to data items 7 and 37 on the Field Test Record and compute the mAs by multiplying the exposure time in 7 by the tube current in 37. For controls manufactured on or after May 1994, data item 37 should be in mAs units already.

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

$$\bar{X}_2 = \frac{E_2}{\text{mAs}_2}$$

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

B. LINEARITY

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

$$L = \frac{\bar{X}_1 - \bar{X}_2}{\bar{X}_1 + \bar{X}_2}$$

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

C. BEAM QUALITY

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

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

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

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

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

D. TIMER ACCURACY

1. Refer to the time setting of data item 7, and if left blank, omit the timer accuracy calculation. Otherwise, record it at Result 14 as the indicated time setting.
2. Refer to data items 18, 20, 22, and 24, and if ten exposures were made, to data items 26, 28, 30, 32, 34, and 36 also. Choose the one value, which has the maximum deviation from the indicated time setting. Calculate the maximum deviation as the absolute value of the measured time from the indicated time. Record the deviation at Result 15.

3. Calculate the timer inaccuracy as follows:

   \[
   \text{Percent timer inaccuracy} = \frac{\text{maximum deviation} \times 100}{\text{indicated timer setting}}.
   \]

   Record the percent timer inaccuracy at Result 16.

E. SID DETERMINATION

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

   Calculate the SID as follows:

   \[
   \text{SID} = \frac{225.19}{\text{(Item 44 - 6.35)}} + \text{Item 42} + \text{Item 43}
   \]

   Record the SID at Result 17.

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

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

2. Refer to data items 44, 47, and 48 and calculate the x-ray field size at the image receptor:

   \[
   \text{Calculate horizontal dimension} = \text{Item 47} \times \text{SID} \times \frac{\text{(Item 44 - 6.35)}}{\text{(Item 44 x 35.46)}}
   \]

   \[
   \text{Calculate vertical dimension} = \text{Item 48} \times \text{SID} \times \frac{\text{(Item 44 - 6.35)}}{\text{(Item 44 x 35.46)}}
   \]

   Record these values at Results 20 and 21.

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

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

   \[
   \text{vertical difference} = \text{Result} - \text{Result 21}.
   \]

   Record at Results 22 and 23, respectively.

   If Result 22 is negative, calculate the percent difference:

   \[
   \text{Percent horizontal difference} = \left| \frac{\text{Result 22} \times 100}{\text{SID}} \right|
   \]
Record at Result 24 (If Result 22 is negative, record 0.00 at Result).

If Result 23 is negative, calculate the percent difference:

percent vertical difference = \[ \frac{|\text{Result 23} \times 100|}{\text{SID}} \]

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

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

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

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

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

Record SID' at Result 28.

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

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

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

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

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

\[ \text{HCF} = \frac{\text{data item } 58}{\text{data item } 60} \]

\[ \text{VCF} = \frac{\text{data item } 59}{\text{data item } 61} \]

Record the HCF at Result 31 and the VCF at Result 32.

H. X-RAY FIELD/IMAGE RECEPTOR CENTERS COMPARISON

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

2. Calculate the center misalignment as a percent of the SID (Result 17):

\[ \text{percent centers misalignment} = \frac{\text{Result } 33 \times 100}{\text{Result } 17} \]

Record the percent center misalignment at Result 34.

I. ACTUAL VERSUS INDICATED FIELD SIZE
1. Refer to data items 50 and 51, the indicated field horizontal and vertical dimensions. Convert to centimeters, if necessary, before recording at Results 35 and 36. Refer to data items 52 and 53 and calculate the x-ray field horizontal and vertical dimensions as follows:

\[ \text{CHD} = \text{HCF} \times \text{data item 52} \times \frac{\text{Result 17}}{\text{Result 17} - \text{data item 43}} \]

\[ \text{CVD} = \text{VCF} \times \text{data item 53} \times \frac{\text{Result 17}}{\text{Result 17} - \text{data item 43}} \]

Record at Results 37 and 38.

2. Calculate the horizontal and vertical differences and the percent differences.

\[ \text{Horizontal difference} = \text{CHD} - \text{Result 35} \]

\[ \text{Vertical difference} = \text{CVD} - \text{Result 36} \]

\[ \text{Percent difference (horizontal)} = \frac{\text{horizontal difference} \times 100}{\text{Result 17}} \]

\[ \text{Percent difference (vertical)} = \frac{\text{vertical difference} \times 100}{\text{Result 17}} \]

Record at Results 39-42.

J. ILLUMINANCE OF LIGHT LOCALIZER

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

\[ \text{avg. ill.} = \frac{(\text{SID} - \text{data item 43})^2 \times (\text{data item 54} + \text{data item 55} + \text{data item 56} + \text{data item 57})}{(108)^2 \times 4} \]

Record at Result 43.

K. STANDBY RADIATION

Refer to data items 66 and 67 on the Field Test Record and calculate the standby radiation as follows:

\[ \text{Standby radiation} = \frac{\text{data item 66}}{\text{data item 67 in seconds}} \times 3600 \text{ mR/hr.} \]

Record value at Result 44.
RESULTS RECORD

VERTICALLY MOUNTED CASSETTE HOLDER

RADIOGRAPHIC SYSTEMS

(Test Procedure VCA - Form FDA 3261)

Field Test
Serial No. ______

REPRODUCIBILITY AND LINEARITY

1. Average exposure, $\bar{E}_1 = \text{_______ mR}$

2. Coefficient of variation, $C_1 = \text{_______}$

3. Average exposure/mAs, $\bar{X}_1 = \text{_______ mR/mAs}$

4. Average exposure, $\bar{E}_2 = \text{_______ mR}$

5. Coefficient of variation, $C_2 = \text{_______}$

6. Average exposure/mAs, $\bar{X}_2 = \text{_______ mR/mAs}$

7. Coefficient of linearity, $L = \text{_______}$

BEAM QUALITY

Normalized Exposure

8. $N_4 = \text{_______ at 4.5 mm Al}$

9. $N_3 = \text{_______ at 3.5 mm Al}$

10. $N_2 = \text{_______ at 2.5 mm Al}$

11. $N_1 = \text{_______ at 1.5 mm Al}$

$N_0 = 1.00 \text{ at 0.00 mm Al}$

12. Observed HVL = _______ mm Al at _______ kVp

13. Actual HVL = _______ mm Al at _______ kVp

TIMER ACCURACY

14. Indicated time setting = _______ seconds

15. Maximum deviation from indicated setting = _______ seconds

16. Percent timer inaccuracy = _______ percent

PART IX

VC-17

04/1/2000
SID DETERMINATION

17. Measured SID = _______ cm

X-RAY FIELD/IMAGE RECEPTOR SIZE COMPARISON (Fixed Collimation Only)

18. Image receptor horizontal dimension = _______ cm
19. Image receptor vertical dimension = _______ cm
20. Calculated horizontal dimension = _______ cm
21. Calculated vertical dimension = _______ cm
22. Horizontal dimension difference = _______ cm
23. Vertical dimension difference = _______ cm
24. Percent difference horizontal dimension = _______ percent
25. Percent difference vertical dimension = _______ percent

X-RAY FIELD/LIGHT FIELD ALIGNMENT AND SIZE COMPARISON

26. Total horizontal misalignment = _______ cm
27. Total vertical misalignment = _______ cm
28. SID' = _______ cm
29. Percent horizontal misalignment = _______ percent
30. Percent vertical misalignment = _______ percent
31. HCF = _______
32. VCF = _______

X-RAY FIELD/IMAGE RECEPTOR CENTERS COMPARISON

33. Centers misalignment = _______ cm
34. Percent centers misalignment = _______ percent

ACTUAL VERSUS INDICATED FIELD SIZE

35. Indicated field horizontal dimension = _______ cm
36. Indicated field vertical dimension = _______ cm
37. CHD = _______ cm
38. CVD = _______ cm
39. Horizontal difference = _______ cm
40. Vertical difference = _______ cm
41. Percent difference (horizontal) = _______ percent
42. Percent difference (vertical) = _______ percent

ILLUMINANCE OF LIGHT LOCALIZER
43. Average illuminance = _______ footcandles

STANDBY RADIATION
44. Standby radiation = _______ mR/hr
### Illuminance

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<tr>
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### X-Ray Field/Light Field Alignment and Size Comparison

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<th>58. X-Ray Field</th>
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<tr>
<td></td>
<td>Horizontal Dimension</td>
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<th>60. Light Field</th>
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<td>Vertical Dimension</td>
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<tr>
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<td>72 cm</td>
<td>74 cm</td>
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### X-Ray Field/Image Receptor Centers Comparison

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### Standby Radiation: (Capacitor discharge equipment only)

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<tr>
<td></td>
<td>14 mR</td>
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### REMARKS