PART IX

VERTICALLY MOUNTED CASSETTE HOLDER

FORM FD 3261

REPRINTED
APRIL 2000

ROUTINE COMPLIANCE TESTING

VERTICALLY MOUNTED CASSETTE HOLDER

RADIOGRAPHIC SYSTEMS

(Teat 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-cm^3 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 cm^3 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-rat 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

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 was developed in section 5.12, and while viewing the radiographic image locate the outside edges of the image of the focal-spot assembly. Measure the minimum separation of the outside 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 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 be 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 cm^2 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 cm^2 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 ling 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, $\overline{E_1}$:

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

   Record the value of $\overline{E_1}$ at Result 1.

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

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

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

   Record the value of C_1, at Result 2.

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

3. Calculate the average exposure per mAs, $\overline{X_1}$, as follows:

$$\overline{X_1} = \overline{E_1} / mAs_1$$

   Record the value of $\overline{X_1}$ at Result 3.

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

$$\overline{E_2} = \frac{1}{n} \sum_{i-1}^{n} x_1$$

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

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

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

   Record the value of C_2 at Result 5.

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

Calculate the average exposure per mAs, $\overline{X_2}$, follows:

$$\overline{X_2} = \overline{E_2} / mAs_2$$

Record the value of $\overline{X_2}$ at Result 6.

B. LINEARITY

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

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

where $\overline{X_1}$ and $\overline{X_2}$ are 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:

   Actual HVL = (0.923 x 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:

   Percent timer inaccuracy = maximum deviation x 100/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:

   SID = ((225.19/(Item 44-6.35)) + Item 42 + 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:

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

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

   Record these values at Results 20 and 21.

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

   horizontal difference = Result 18 - Result 20

   vertical difference = Result - 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:

$$\text{percent vertical difference} = \left| \frac{\text{Result 23} \times 100}{\text{SID}} \right|$$

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

   SID' = (Result 17 - data item 42 - data item 42 - data item 43 - 4.6) cm.

   Record SID' at Result 28.

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

   Percent horizontal misalignment = Result 26 x 100/SID'

   Percent vertical misalignment = Result 27 x 100/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:

   HCF = data item 58/data item 60

   VCF = data item 59/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:

   CHD = HCF x data item 52 x (Result 17/(Result 17 - data item 43)).

   CVD = VCF x data item 53 x (Result 17/(Result 17 - data item 43)).

   Record at Results 37 and 38.

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

   Horizontal difference = CHD - Result 35.

   Vertical difference = CVD - Result 36.

   Percent difference (horizontal) = (horizontal difference x 100)/Result 17.

   Percent difference (vertical) = (vertical difference x 100)/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:

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

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, $\overline{E}_1$ = _____ mR
2. Coefficient of variation, C_1 = _____
3. Average exposure/mAs, $\overline{X}_1$ = _____ mR/mAs
4. Average exposure, $\overline{E}_2$ = _____ mR
5. Coefficient of variation, C_2 = _____
6. Average exposure/mAs, $\overline{X}_2$ = _____ mR/mAs
7. Coefficient of linearity, L = _____

BEAM QUALITY

Normalized Exposure

8. N_4 = _____ at 4.5 mm Al
9. N_3 = _____ at 3.5 mm Al
10. N_2 = _____ at 2.5 mm Al
11. N_1 = _____ at 1.5 mm Al

    N_0 = 1.00 at 0.00 mm Al

12. Observed HVL = _____ mm Al at _____ kVp
13. Actual HVL = _____mm Al at _____ kVp

TIMER ACCURACY

14. Indicated time setting = _____ seconds
15. Maximum deviation from indicated setting = _____ seconds
16. Percent timer inaccuracy = _____ percent

SID DETERMINATION

17. Measured SID = _____ cm

X-RAY FIELD/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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

VERTICALLY MOUNTED CASSETTE HOLDER RADIOGRAPHIC SYSTEMS FIELD TEST RECORD

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

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

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

REGIONAL REVIEW *(NAME)*:

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

Test Procedure

1. VC [ ] (11–13)

Component Certification Information

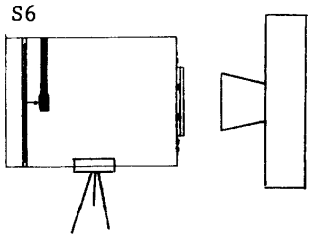
2. Indicate the status of each as follows:

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

[ ] (14) Beam Limiting Device
[ ] (15) High Voltage Generator
[ ] (16) Vertical Cassette Holder
[ ] (17) Tube Housing Assembly
[ ] (18) Tube Housing Assembly with Beam Limiting Device
[ ] (19) Other *(Specify)*
[ ] (20) X-ray Controls

3. Means To Center Diagnostic Source Assembly To The Image Receptor [ ] (21) Y—YES N—NO X—NOT APPLICABLE

Test Setup



MDH (Pulse Exposure)
4.5 mm Al

Technique Factors

4. Timer mode of operation during testing [ ] (22)
M—manually set time or mAs
P—phototimer

5. [ ].[ ] kVp (23–25) Capacitor discharge equipment-use maximum mAs for kV selected.
6. [ ].[ ] mA (26–28)
7. [ ] . [ ] sec (29–32) OR [ ].[ ] pulses (33–35)
8. [ ].[ ] mAs (36–38)

Beam Quality:

9. [ ].[ ] mR (39–43) @ 4.5 mm Al
10. [ ].[ ] mR (44–48) @ 3.5 mm Al
11. [ ].[ ] mR (49–53) @ 2.5 mm Al
12. [ ].[ ] mR (54–58) @ 1.5 mm Al

13. Technique Factors Indicated Before Exposure [ ] (59) Y—YES N—NO

14. Exposure Terminated After Preset Time Interval, Preset mAs, Or Preset Radiation Exposure To Image Receptor [ ] (60) Y—YES N—NO

15. Warning Label Present [ ] (11) Y—YES N—NO

16. MDH Threshould Setting, 0.5-3 phase, 0.2–1 phase [0].[ ] (12)

Reproducibility

17. [ ].[ ] mR (13–17)
18. [ ].[ ] msec (18–21)
19. [ ].[ ] mR (22–26)
20. [ ].[ ] msec (27–30)
21. [ ].[ ] mR (31–35)
22. [ ].[ ] msec (36–39)
23. [ ].[ ] mR (40–44)
24. [ ].[ ] msec (45–48)

Card No. *(9-10)*: 11

FORM FDA 3261 (2/83)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

VERTICALLY MOUNTED CASSETTE HOLDER RADIOGRAPHIC SYSTEMS FIELD TEST RECORD

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

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

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

REGIONAL REVIEW *(NAME)*

11

Reproducibility (Continued)

25. [49] . [53] mR	Data Here If Any Of Items 17, 19, 21 And 23 Differ By More Than 10 Percent Of Largest Value	26. [54] [57] msec	
27. [58] . [62] mR		28. [63] [66] msec	
29. [67] . [71] mR		30. [72] [75] msec	
31. [11] . [15] mR		32. [16] [19] msec	
33. [20] . [24] mR		34. [25] [28] msec	
35. [29] . [33] mR		36. [34] [37] msec	

12

Linearity

37. [38] [40] mA

If Change In mA Causes a kVp Shift, Readjust kVp Setting to Value Selected at Item 5 Above

38. [45] . [49] mR

39. [53] . [57] mR

40. [58] . [62] mR

41. [66] . [70] mR

SID Determination

42. Distance from Base of Test Stand To Face of Vertical Cassette Holder [41] . [44] cm

43. Distance from Face of Vertical Cassette Holder to Image Receptor [50] . [52] cm

44. Outside Separation of Image of Focal Spot Strips [63] . [65] cm

X-Ray Field/Image Receptor Size Comparison (Fixed Collimation Only)

45. Image Receptor Horizontal Dimension [11] . [13] inches OR [14] . [16] cm

46. Image Receptor Vertical Dimension [17] . [19] inches OR [20] . [22] cm

47. X-Ray Field Image Horizontal Dimension [23] . [25] cm

48. X-Ray Field Image Vertical Dimension [26] [28]

13

Actual Versus Indicated Field Size

49. Beam Limiting Device Numerically Indicates Field Size [29] Y–YES N–NO

50. Indicated Field Horizontal Dimension [30] . [32] in OR [33] . [35] cm

51. Indicated Field Vertical Dimension [36] . [38] in OR [39] . [41] cm

52. Light Field Horizontal Dimension [42] . [44] cm

53. Light Field Vertical Dimension [45] . [47]

FORM FDA 3261 (2/83)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

VERTICALLY MOUNTED CASSETTE HOLDER RADIOGRAPHIC SYSTEMS FIELD TEST RECORD

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

REGIONAL REVIEW *(NAME)*

13

Illuminance

54. ____ total − ____ ambient = [48][50] fc

55. ____ total − ____ ambient = [51][53] fc

56. ____ total − ____ ambient = [54][56] fc

57. ____ total − ____ ambient = [57][59] fc

X-Ray Field/Light Field Alignment and Size Comparison

58. X-Ray Field Horizontal Dimension [60][62] cm

59. X-Ray Field Vertical Dimension [63][65] cm

60. Light Field Horizontal Dimension [66][68] cm

61. Light Field Vertical Dimension [69][71] cm

62. Horizontal Misalignment [72][73] cm

63. Vertical Misalignment [74][75] cm

X-Ray Field/Image Receptor Centers Comparison

64. Centers Misalignment [11][12] cm

14

Standby Radiation: (Capacitor discharge equipment only)

65. [13] X-Not Applicable

66. [14][18] mR

67. [19] min [20][21] sec

REMARKS

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