PART IV

MOBILE RADIOGRAPHIC SYSTEMS

FORM FDA 2783

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ROUTINE COMPLIANCE TESTING

MOBILE RADIOGRAPHIC SYSTEMS

(Test Procedure MRA - Use Form FDA 2783)

1.0 GENERAL GUIDANCE

1.1 This procedure is applicable to mobile and portable radiographic x-ray systems that are battery, capacitor, or direct-line powered. A standby radiation test applicable to capacitor energy storage equipment is included.

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 then continue with the next appropriate section.

2.0 SPECIFIC GUIDANCE

2.1 Some battery powered mobile x-ray systems incorporate a battery charge compensator. For the purpose of reproducibility testing, the battery range switch should be considered as a fourth technique factor to be left in the same position for all four exposures measurements.

2.2 On equipment with line voltage compensator be sure the indicator is in the proper region before performing any compliance test that depends on electrical power (e.g., exposure output, light illuminance, and so forth).

2.3 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

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.

3.0 PRETEST CHECKLIST

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

3.2 Connect the 6-cm^3 ionization chamber to the electrometer. Set the mode selector switch to EXPOSURE RATE and the function selector 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.

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

3.4 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 Mobile Radiographic Field Test Record.

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

3.6 Complete items 1 and 2 of the Field Test Record.

3.7 Determine if the unit is full-wave rectified (F), half-wave rectified (H), or capacitor-discharged (C), and record at item 3.

4.0 INITIAL SETUP (see figure on test record)

4.1 Position the mobile or portable radiographic x-ray system near some stable horizontal surface suitable, for supporting the test stand and other test equipment (e.g., a table, countertop, and so forth.)

4.2 Assemble the test stand with the spacer assembly positioned out of the beam. Place the test stand on the horizontal surface and position the diagnostic source assembly over the test stand with the x-ray axis aimed vertically downward.

4.3 Insert the slide assembly into Slot 6 of the test stand, grid side up and insert a plastic cassette containing a sheet of direct-print paper into the slide assembly.

4.4 Insert the ion chamber assembly through the lower chamber mounting hole in the test stand and secure with the retaining ring.

4.5 Set the Pulse - Fraction Threshold on the MDH instrument to 0.2.

4.6 Center the diagnostic source assembly over the test stand such that the probable axis of the x-ray beam is approximately perpendicular to, and centered on the slide assembly grid.

NOTE: In most cases, a light localizer will be the means provided for visual definition. If so, turn on the light localizer and center the source assembly over the test stand by centering the light field on the slide assembly grid. Using a piece of white paper in the slide assembly will make visualization of the light field easier during setup. Remove it when the setup is complete. Some mobile systems have a timer that shuts off the light localizer after a short period of "ON" time; therefore, work as rapidly as possible and avoid excessive "ON" time.

4.7 Lower the diagnostic source assembly until the beam-limiting device comes into firm contact with the spacer assembly, or until any spacer bars on the beam limiting device are even with the top of the spacer assembly.

4.8 If the capability is provided for adjustment of the filtration present in the useful beam, adjust for minimum filtration that will allow an exposure.

4.9 Adjust the beam-limiting device such that the visually defined field is approximately 4" x 6" at the slide assembly grid with the 6" dimension along the long axis of the test stand. 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 shield by the stand.

4.10 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. Again, avoid disturbing the slide assembly or the test stand.

NOTE: One method of checking if the outer edge of the metal marker is on the edge of the light field is as follows:

a) Set the corner of a sheet of white paper on top of the metal marker.

b) Note the edge of the light field on the paper. Move the metal marker so that the outer edge is in line with the image of the light field on the white paper.

c) Set a corner of the white paper on the metal marker so that approximately 1/4" of the marker extends on each side of the triangle formed by the corner of the paper. The bright outline of the light field should be co-linear with the edge of the metal marker. If it is not, adjust accordingly.

d) Remove the white paper.

4.11 Insert the focal-spot assembly, brass side up, into Slot 1 of the test stand.

4.12 Set 4.5 mm of aluminum on top of the focal-spot assembly.

5.0 BEAM QUALITY

5.1 Set the peak tube potential to a value commonly used, provided that the value exceeds 70 kVp. Record at item 4.

5.2 (a) If independently selectable, choose values of tube current and exposure time commonly used; record at items 5 and 6. Leave item 7 blank.

(b) If only mAs is selectable, choose a value commonly used and record at item 7. Leave items 5 and 6 blank.

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

5.3 Set the x-ray monitor mode selector to PULSE EXPOSURE. The x-ray monitor display should read -0.00. If any other display is present, reset the instrument by

switching the function selector to HOLD and then back to MEASURE.

5.4 Without changing technique factors or the x-ray monitor settings, make an exposure. Record the exposure reading at item 8.

5.5 Place aluminum at slot 1 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 9, 10, and 11.

5.6 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 12.

5.7 Is exposure terminated after preset time interval, preset mAs, preset number or pulses, or preset radiation exposure to image receptor? Record at item 13.

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

6.0 REPRODUCIBILITY AND LINEARITY

6.1 Remove the filtration present at Slot 1. Take care not to disturb the test setup.

6.2 Reset the x-ray monitor by switching the function selector to HOLD and then back to MEASURE. Make an exposure. Do not record the resultant reading . Make a second exposure. Record this reading of exposure at item 14. Switch the mode selector to PULSE DURATION and record the time at item 15.

6.3 (a) Make three additional exposures, record the exposure readings at items 16, 18, and 20 and the time readings at items 17, 19, and 21. All variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. DO NOT reset the x-ray monitor between readings.

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

(b) If any two readings differ by more than 10 percent of the highest mR reading, make 6 additional exposures and record the exposure and the time readings at items 22 through 33. Do not reset the x-ray monitor between readings.

6.4 If the unit under test either does not allow specific selection of tube current, or if only mAs is selectable, omit Steps 6.5 through 6.8, and enter an asterisk in the first column of item 34 on the Field Test Record and state in the Remarks that mA is fixed or only mAs is selectable, whichever is appropriate.

6.5 Use step a. for equipment manufactured prior to May 1994 and step b. for equipment manufactured on and after May 1994.

a. 1. If tube current selection is in fixed stations, select an adjacent tube current station and record the indicated value at item 34.

2. If tube current selection is continuous (i.e., not in discrete steps), select a second tube current not differing from the first by more than a factor of 2. Record at item 34.

b. 1. If the tube current or mAs selection is in fixed stations, select an adjacent setting and record the mAs product at item 34.

2. If tube current or mAs selection is continuous (i.e., not in discrete steps), select a second setting not differing from the first by more than a factor of 2. Record the mAs product at item 34.

6.6 The change in tube current or mAs product may cause a change in tube potential. If manual compensation is available, readjust the tube potential to its original value, and continue with Steps 6.7 and 6.8. However, if the kVp cannot be compensated back to its original setting, enter an asterisk in the first column of item 35, skip procedural Steps 6.7 and 6.8, and state in the Remarks that the kVp could not be compensated.

6.7 Make an exposure at the selected technique factors. Record this reading at item 35.

6.8 While varying the technique factors between each measurement as in Step 6.3, make three additional exposures. Record the exposure readings at item 36, 37, and 38.

6.9 Sum the exposures in Items 8 through 38. If the sum is 1R or greater, then the direct-print paper should provide a satisfactory image. Make additional exposures, if required, to obtain at least 1R to the 6-cm^3 ion chamber.

6.10 Remove the plastic 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.)

7.0 ILLUMINANCE OF LIGHT LOCALIZER

7.1 Remove the test stand from the horizontal test surface.

7.2 Raise the diagnostic source assembly to a source to image receptor distance of 42.5 inches (108 cm above the test surface, as measured by the rule attached to the source assembly. (If no rule is provided, use the tape in the test kit and estimate the location of the focal spot.) Open the beam-limiting device to an approximate field size of 10" x 10".

7.3 Set the photometer on the test surface. Turn on the light localizer. 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. Record this illuminance at item 39.

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

7.4 Repeat the measurements at or near the center of the other three quadrants of the light field and record uncorrected illuminance at items 40, 41, and 42.

8.0 X-RAY FIELD/LIGHT FIELD ALIGNMENT

8.1 Refer to the direct-print paper from the cassette exposed during the beam quality and reproducibility tests.

8.2 While viewing the radiographic image on the direct-print paper, note the location of the edges of the images of the meal strips. On each side of the indicated x-ray field, measure the misalignment between the apparent edge of the x-ray field and the outside edge of the image of the metal strip to the nearest millimeter. (The image of the metal strip may be reconstructed to 0.5" x 1.5", if necessary.) The length misalignment may be considered to be the sum of the misalignment of the two short edges of the x-ray field with the outside edges of the metal strips as measured above. See Figure 1. Record the length misalignment at item 43.

8.3 The width misalignment is determined similarly for both longer edges of the field. Record the width misalignment at item 44.

8.4 While still viewing the radiographic image on the direct-print paper, locate the outside edges of the image of the focal-spot assembly. Measure the minimum separation of the outside edges to the nearest millimeter and record at item 45.

9.0 STANDBY RADIATION FROM CAPACITOR ENERGY STORAGE EQUIPMENT

9.1 Perform this test only if the equipment under test is of the capacitor energy storage type.

9.2 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.

9.3 Open the beam-limiting device fully.

9.4 Position the window of the ionization chamber on the x-ray beam axis as close as possible to and parallel with the face of the beam-limiting device. It may be most convenient to rotate the beam-limiting so that it faces upward and to place the ion chamber on the beam-limiting device face.

9.5 Adjust the kVp setting to its maximum value.

9.6 Charge the capacitors fully.

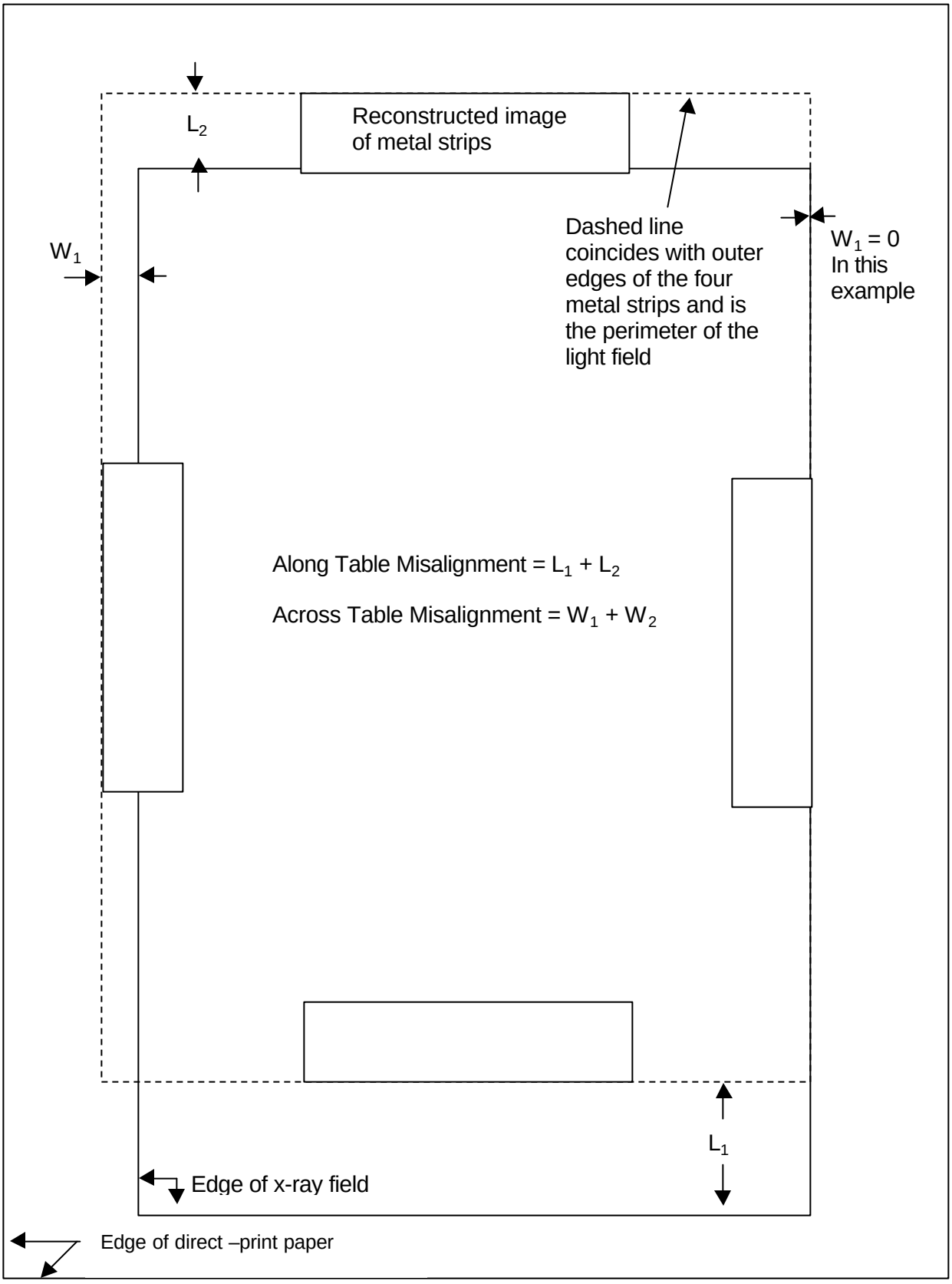
L2
Reconstructed image of metal strips
W1
Dashed line coincides with outer edges of the four metal strips and is the perimeter of the light field
W1 = 0 In this example
Along Table Misalignment = L1 + L2
Across Table Misalignment = W1 + W2
L1
Edge of x-ray field
Edge of direct –print paper

Figure 1

9.7 Set the x-ray monitor 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 periodically necessary to recharge the capacitors to full charge by manually activating the "charge" switch when the tube potential drops by more than 5 kV.

9.8 Record the exposure measurement at item 46 and the time measurement at item 47.

9.9 If no discernible exposure occurs during the 2-minute interval, record 00.0 at item 46.