PART V

DENTAL RADIOGRAPHIC SYSTEMS

FORM FDA 2785

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ROUTINE COMPLIANCE TESTING

DENTAL RADIOGRAPHIC SYSTEMS

(Test Procedure DRA - Use Form FDA 2785)

1.0 GENERAL GUIDANCE

1.1 This procedure is applicable to dental systems designated for use with intraoral image receptors.

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 SPECIFIC GUIDANCE

2.1 Some dental x-ray controls are provided with a manual line voltage compensator. In accordance with the user instructions, this compensator is to be used before each exposure to adjust the incoming line voltage to the proper value. This is usually done by adjusting the line voltage to a mark or a specific voltage range on an x-ray control meter face.

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 to 1,800 heat units.

3.0 PRETEST CHECKLIST

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

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 the Center for guidance.

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

3.4 Record 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 dental radiographic test record. Thus, test records for three dental tube housing assemblies with a common x-ray control would be identified as follows: "G12345" - general

information; "DR12345A" - dental; "DR12345B" dental - and "DR12345C" - dental.

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 Dental Field Test Record.

3.7 Record the manufacturer's name and model number and serial number as listed on the identification label for the tube housing assembly tested at item 3.

4.0 INITIAL SETUP (see figure on test record)

4.1 Place the test stand on a stable, horizontal surface suitable for supporting the test stand and other test equipment (e.g., a table, countertop, and so forth).

4.2 Attach the spacer assembly, positioned out of the beam, to the top of the test stand.

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

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

4.5 Insert the beam defining assembly (BDA), lead side up, into slot 1.

4.6 If the maximum operable kVp control setting is greater than 70, set 4.5 mm of aluminum on top of the BDA.

4.7 If the maximum operable kVp control setting is between 50 to 70, set 3.0 mm of aluminum on top of the BDA.

5.0 BEAM QUALITY

5.1 If the maximum operable kVp control setting is greater than 70, set the kVp to a value over 70. Record at item 4.

5.2 If the maximum operable kVp control setting is between 50 and 70, set the kVp to the maximum value. Record at item 4.

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

5.4 If only mAs is selectable; choose a value commonly used and record at item 7. Leave items 5 and 6 blank.

NOTE: Remote control stations often have duplicate indication of technique factors that may of may not agree with the indication at the master control panel. The technique to be recorded should be that which is indicated at the panel where technique factor selection is made.

5.5 Center the tubehead above the test stand so that the position indicating device (PID) is pointing downward approximately 3 inches above and perpendicular to the BDA.

NOTE: The top of the spacer assembly is approximately 3 inches above the BDA and can be used in positioning the PID.

5.6 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 x-ray monitor by switching the function selector to HOLD and then back to MEASURE.

5.7 Make an exposure and record the reading (exclusive of the minus sign) and the corresponding aluminum thickness at item 8.

IMPORTANT!

It is critical to use the values of filtration called for in steps 5.8(a) and 5.8(b). Data taken with filtration inappropriate for the selected kVp, as specific in these steps, may result in false noncompliance.

5.8 a. If the selected tube potential is greater than 70 kVp, place aluminum at Slot 1 to obtain totals of 3.5, 2.5, and 1.5 mm and make an exposure for each total.

b. If the selected tube potential is in the 50- to 70- kVp range, place aluminum at Slot 1 to obtain totals of 2.0, 1.5, and 1.0 mm and make an exposure for each total.

5.9 For each total, record the exposure and the corresponding aluminum thickness at items 9 through 11.

6.0 REPRODUCIBILITY AND LINEARITY

6.1 Remove the remaining aluminum filters.

6.2 Reset the x-ray monitor function selector to HOLD and then back to MEASURE. The x-ray monitor display should read -0.00

6.3 Make an exposure at the selected technique factors. Do not record the resultant reading. Without changing technique factors or the x-ray monitor settings, make an additional exposure. The reading will not have a minus sign present. Record this reading of exposure at item 12. Switch the mode selector to PULSE DURATION and record this time reading at item 13.

6.4 a. Make three additional exposures, with the exposure readings being recorded at items 14, 16, and 18, and time readings at items 15, 17, and 19. All variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement.

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, take 6 additional exposures. Record the exposure and the time readings at items 20 through 31. Do not reset the x-ray monitor between readings.

6.5 For systems manufactured before May 1994 if the unit under test either does not allow specific of tube current, or if only mAs is selectable, then omit procedural steps 6.6 through 6.9, enter an asterisk in the first column of item 32 on the Field Test Record, and state in the Remarks that mA is fixed, or only mAs is selected, whichever is appropriate.

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

a. (1) If tube current selection is in fixed stations, select an adjacent tube current station and record the indicated value at item 32.

(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 32.

b. (1) If the tube current or mAs is in fixed steps, select an adjacent setting and record the mAs product at item 32.

(2) If the tube current or mAs is continuous (i.e. not in discrete steps), select a second setting not differing from the first by more than a factor of 2, and record the mAs product at item 32.

6.7 The change in the tube current or mAs may cause in tube potential. If manual compensation is available, readjust the tube potential to its original value, and continue with step 6.8. However, if the kVp cannot be compensated back to its original setting, enter an asterisk in the first column of item 33, skip procedural steps 6.8 and 6.9 and state in the Remarks that the kVp could not be compensated.

6.8 Make an exposure at the selected technique factors. Record this reading at item 33.

6.9 While varying technique factors between each measurement as in step 6.4, make three additional exposures. Record the exposure readings at items 34, 35, and 36.

6.10 Remove the beam-defining assembly and insert the focal-spot assembly, brass strips up, into Slot 1.

6.11 Reposition the spacer assembly <u>in</u> the beam.

6.12 Set the x-ray monitoring mode selector to EXPOSURE and the function selector to MEASURE.

6.13 Insert the slide assembly, grid side <u>down</u>, into Slot 5.

6.14 Insert a plastic cassette containing a sheet of direct-print paper into the slide assembly and center a plastic cassette containing a sheet of direct-print paper on top

of the spacer assembly.

6.15 Position the tubehead above the center of the test stand with the PID pointing downward. Bring the PID down until it is perpendicular to and in firm contact with the cassette located on top of the spacer assembly.

6.16 Make several exposures to obtain approximately 600 mR. Both sheets of direct-print paper should then provide a satisfactory image.

6.17 Carefully raise the tubehead a few inches. Remove both cassettes and develop the direct-print paper by exposure to fluorescent light. (Refer to page LINA-1 for proper development technique.)

7.0 X-RAY FIELD SIZE AT MINIMUM SOURCE-TO-SKIN DISTANCE

7.1 Refer to the direct-print image from the cassette that was on top of the spacer assembly.

7.2 Is the field circular or rectangular? Record at item 37.

7.3 Measure to the nearest millimeter the apparent diameter if the image is circular or a diagonal if the image is rectangular. Record at item 38.

8.0 MINIMUM SOURCE-TO SKIN DISTANCE

8.1 Refer to the direct-print paper from the cassette that was in the slide assembly.

8.2 Measure to the nearest millimeter the minimum separation of the outside edges of the image of the focal-spot strips. Record at item 39.

9.0 FUNCTION REQUIREMENTS

9.1 If multiple tubeheads are controlled by a single exposure switch, is there a preindication of which tubehead has been selected, both at the control panel and at the selected tubehead? Record at item 40.

9.2 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 41.

9.3 Are the technique factors visible at the operator's position? Record at item 42.

9.4 Is exposure terminated after a preset time interval, preset mAs, preset number of pulses, or preset radiation exposure? Record at item 43.

> 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 exposure occur or termination of exposure will not occur until release of the exposure switch.

10.0 MECHANICAL TIMER FUNCTION REQUIREMENTS

IMPORTANT!

This section is applicable only to systems having a mechanical rather than electronic exposure timer. The mechanical timer will always have a zero time position while the electronic timer does not have a zero time position. If the system being tested has an electronic timer, record as "x" at items 44 and 45 in Functional Requirements.

10.1 At the controls, select the lowest available kVp and tube current setting and an exposure time of 1 second.

10.2 Set the x-ray monitor mode selector to PULSE DURATION. Reset the MDH instrument by switching the function selector to HOLD and then back to MEASURE.

10.3 Depress the exposure switch for the full duration of the selected exposure time. Record for future reference the exposure time reading from the MDH.

10.4 Depress the exposure switch momentarily, releasing it before the timer can terminate the exposure.

10.5 Reset the MDH instrument by switching the function selector to HOLD and then back to MEASURE.

10.6 Depress the exposure switch for the full duration of the selected exposure time. Compare the exposure time reading from the MDH with the value obtained in step 10.3.

10.7 Did the timer reset either to zero or to the initial setting after the first incomplete exposure? Record at item 44.

10.8 Set the timer to the "zero" of "off" position, if possible.

10.9 Attempt to make an exposure with the timer in this position, using the x-ray monitor to determine if an exposure has actually occurred.

10.10 Was it possible to make an exposure with the timer in the "zero" or "off" position? Record at item 45.