PART VI

ABOVETABLE X-RAY SOURCE FLUOROSCOPIC AND SPOT-FILM SYSTEMS

FORM FDA 3069

REPRINTED
April 2000

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 ion 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 form 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

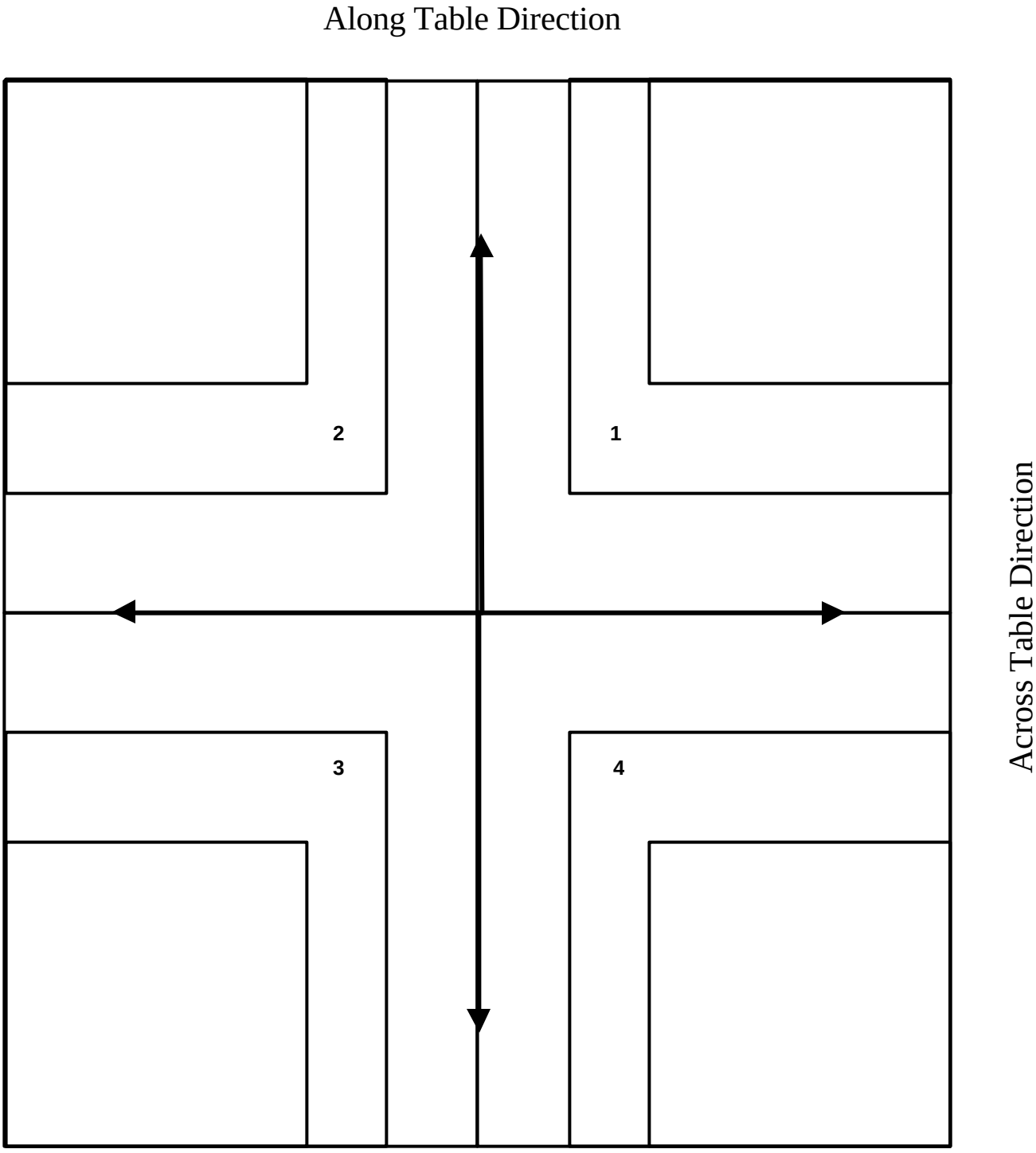

Figure 1

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-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.

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 May19, 1995, the EER requirements do not apply to the recording of fluoroscopic images when operating in a pulsed mode. In addition, the recording mode is not considered high-

level control and therefore, no audible signal is required. The Center is looking into the record mode uses and would need manufacturer justification for any unit that could operate only in a record mode.

8.0 ENTRANCE EXPOSURE RATE - AUTOMATIC

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

9.0 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 = DISTANCE FROM TOP OF FILM CASSETTE TO BASE OF TEST STAND.

RECORD VALUE OF C AT ITEM 35

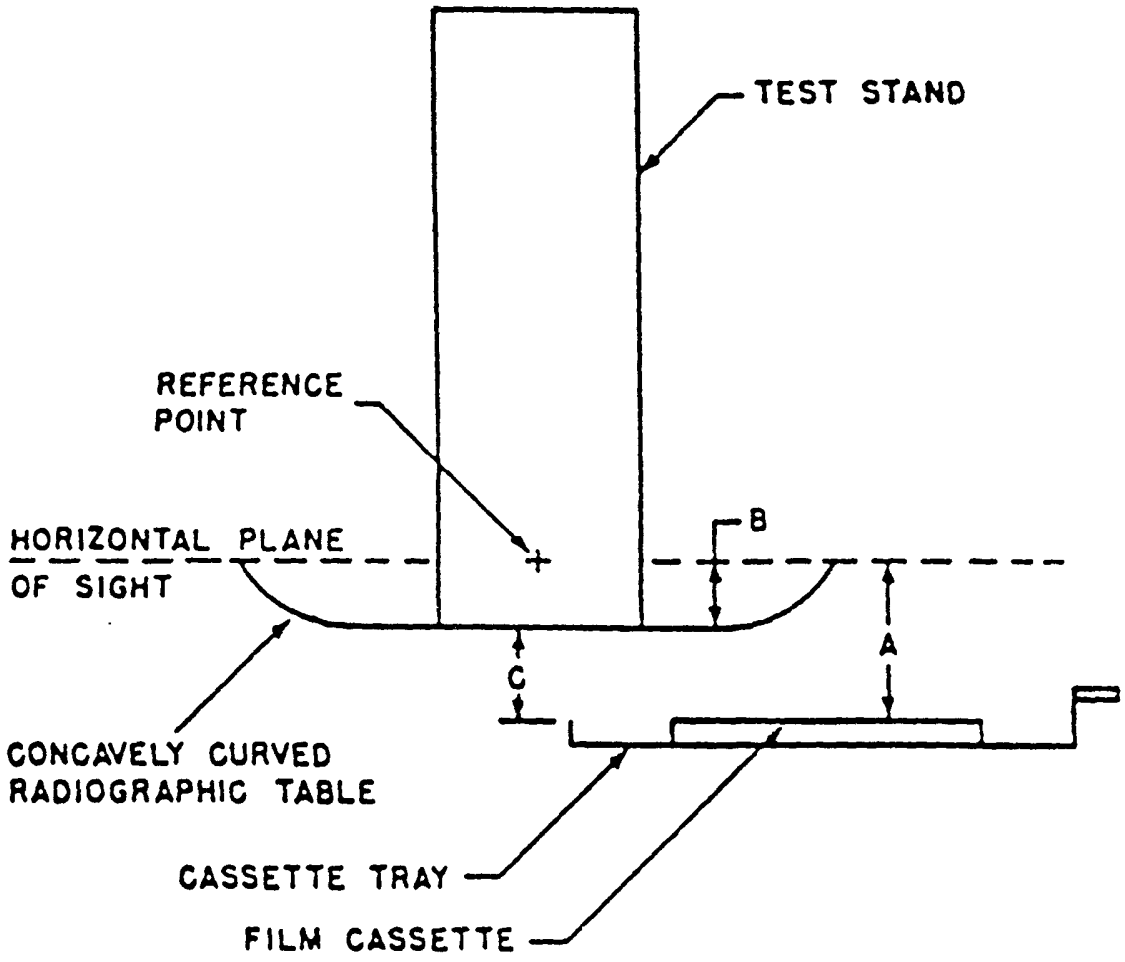

FIGURE 1: HOW TO DETERMINE DISTANCE FROM TOP CASSETTE TO BASE OF TEST STAND FOR CONCAVELY CURVED TABLE TOP.