CALCULATION TECHNIQUES UNDERTABLE X-RAY SOURCE FLUOROSCOPIC AND SPOT-FILM SYSTEMS

(Test Procedure UFA - Form FDA 2786)

A. Minimum Source to Skin Distance

1. Refer to data item 42 of the Field Test Record. The minimum source to skin distance (min SSD) is calculated as follows:

 $\min \text{ SSD} = \frac{218.06 - 1.61}{(\text{data item } 42 - 6.35)}$

Record the min SSD at Result 1.

B. Fluoroscopic X-Ray Field/Image Receptor Alignment

1. Refer to data items 8 through 15 of the Field 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 12 - (data item 8 x 2.54)) cm.Misalignment 2/1 = (data item 13 - (data item 9 x 2.54)) cm.Misalignment 3/2 = (data item 14 - (data item 10 x 2.54)) cm.Misalignment 4/3 = (data item 15 - (data item 11 x 2.54)) cm.

Record the results at Results 2 through 5. 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.

 Refer to Result 1, minimum SSD. Calculate the source to image receptor distance (SID) as follows:

SID = (min SSD + 18.41) cm.

Record at Result 6.

- 3. Calculate the following misalignments:
 - a. (1/4 + 3/2) misalignment = misalignment 1/4 + misalignment 3/2. Record at Result 7.
 - b. Percent (1/4 + 3/2) misalignment = (Result 7) x 100/SID Record at Result 8.
 - c. (2/1 + 4/3) misalignment = misalignment 2/1 + misalignment 4/3 Record at Result 9.

- d. Percent (2/1 + 4/3) Misalignment =(Result 9) x 100/SID Record at Result 10.
- e. Total misalignment = Result 7 + Result 9 Record at Result 11.

f. Percent total misalignment = (Result 7 + Result 9) x 100/SID Record at Result 12.

- 4. Repeat the calculations of steps 1 through 3 for data items 16 through 23 and record at Results 13 through 23.
- C. Fluoroscopic Entrance Exposure Rate
 - 1. Automatic mode: Refer to data item 29.

 $EER = ((data item 29) \times (result 1 + 3.5)2)/(result 1 + 1.0)2$ Record the EER at Result 24.

2. Manual mode: Refer to data item 34.

EER = ((data item 34) x (result 1 + 3.5)2)/(result 1 + 1.0)2 Record the EER at Result 25.

3. The applicable EER limit(s) can be determined from one of the tables below for equipment manufactured before May 1995, otherwise, the limit is 10 R/min.

Mode of Equipment	Without High-Level Control(HLC)	With High-Level Control (HLC)*
Automatic	10 R/min	5 R/min
Manual	5 R/min	5 R/min

*EER without activating HLC

Dual Fluoroscopic Technique Factor Control Mode Equipment

	Manual		Automatic	Automatic	
Mode Selected	Without HLC	Mode With HLC*	Mode With HLC*	Both Modes With HLC*	
Automatic	10 R/min	10 R/min	5 R/min	5 R/min	
Manual	10 R/min	5 R/min	10 R/min	5 R/min	

*EER without activating HLC

4. First determine from data item 26 on the Field Test Record whether the system is a

dual or single mode. Then refer to the proper table and using data items 29, 30, 34 and 35, on the Field Test Record select the applicable EER limit(s).

- D. <u>Primary Barrier Transmission</u>
 - 1. Refer to data items 39. Record at Result 26.
 - 2. Refer to data items 40 and 41 on the Field Test Record. Calculate the primary barrier transmission (PBT) as follows:

PBT = ((data item 40/data item 41) x 3600)/Result 26

Record PBT at Result 27.

NOTE: This test is done in automatic mode only if the response to data item 26 on the Field Test Record is "A - automatic only."

- E. Beam Quality
 - 1. Refer to data items 44, 46, 48, 50, and 52 on the Field Test Record. Divide each exposure reading by its corresponding exposure time (data items 45, 47, 49, 51, and 53) to yield the exposure rate in each case. Record the exposure rates, R4 through R0, at Results 28-32.
 - 2. Divide each exposure rate, R4 through R1, by R0, the exposure rate for zero filtration. Record the resultant quotients, N4 through N1, at Results 33-36. N0 will, of course, always equal exactly 1.000.
 - 3. On semilog 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 (including the zero filtration data) 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 the kVp at Result 37.
 - 4. To determine the actual HVL, corrections for geometry effects and instrument energy dependence must be made.
 - a. Actual HVL = (1.247 x HVLobs) 0.432

This equation does not represent a universal correction to the observed HVL. However, it is applicable to observed HVL's of the limits specified in the X-ray Performance Standard. For extremely large observed HVL's, this equation underestimates the actual HVL. The intent of this equation is to enable accurate compliance determinations for x-ray beams with marginal observed HVL's.

b. Record the value of the actual HVL and the kVp at Result 38.

F. Reproducibility

1. Refer to data items 66, 68, 70 and 72 on the Field Test Record. Calculate the average exposure, \overline{E} as follows:

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

where the Xi's are the data items (66, 68, 70, and 72). Record \overline{E} at Result 39. (Note: If ten measurements have been made during the test, data item 66, 68, 70, 72, 74, 76, 78, 80, 82, and 84 would be used in the calculation and n = 10 in the equation.)

2. Calculate the coefficient of variation (C) as follows:

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

where the Xi's are the data items (66, 68, 70, and 72) and \overline{E} is the average exposure. Record C at Result 40. (Note: If ten measurements have been made during the test, data items 66, 68, 70, 72, 74, 76, 78, 80, 82 and 84 would be used in the calculation and n = 10 in the equation.)

- G. X-Ray Field Spot-Film Size Comparison
 - 1. Refer to Result 1 (min SSD). Calculate the distance from the focal spot to the slide assembly, SID', as follows:

SID' = (min SSD + 35.95) cm.

Record the SID' at Result 41.

2. Refer to Result 1 (min SSD) and data item 65 on the Field Test Record. Calculate the distance from the focal spot to the spot-film plane, SID", as follows:

SID'' = (min SSD + data item 65) cm.

Record SID" at Result 42.

- 3. Along-table comparison:
- a. Refer to data item 63 on the Field Test Record. Calculate the x-ray field dimension along-table at the spot-film plane (CAL) as follows:

CAL = ((SID" x data item 63)/SID')cm

Record CAL at Result 43.

b. Refer to data item 61 on the field Test Record. If the selected spot-film dimension along-table is recorded in inches, multiply item 61 by 2.54 to convert to centimeters. Record the selected spot-film dimension along table

at Result 44.

c. Calculate the along-table difference as follows:

Along-table difference = (CAL - Result 44) cm.

Record at Result 45.

d. Calculate the percent along-table difference as follows:

Percent along-table difference = (result 45 x 100)/SID"

Record at Result 46.

- 4. Across-table Comparison:
 - a. Refer to data item 64 on the Field Test Record. Calculate the x-ray field dimension across-table at the spot-film plane (CAC) as follows:

CAC = ((SID'' x data item 64)/SID')cm

Record CAC at Result 47.

- b. Refer to data item 62 on the Field Test Record. If the selected spot-film dimension across-table is recorded in inches, multiply item 62 by 2.54 to convert to centimeters. Record the selected image spot-film dimension across-table at Result 48.
- c. Calculate the across-table difference as follows:

Across-table difference = (CAC - Result 48) cm.

Record at Result 49.

d. Calculate the percent across-table difference as follows:

Percent across-table difference = (result 49 x 100)/SID"

Record at Result 50.

- 5. Sum of along and across-table differences:
 - a. Refer to Results 45 and 49. Sum the absolute value of each Result and record the sum at Result 51.
 - b. Refer to Results 46 and 50. Sum the absolute value of each Result and record the sum at Result 52.

RESULTS RECORD UNDERTABLE X-RAY SOURCE FLUOROSCOPIC AND SPOT-FILM SYSTEMS

(Test Procedure UFA - Form FDA 2786)

Field Test Serial No.

Minimum Source to Skin Distance

1. Minimum SSD = ____cm.

Fluoroscopic X-Ray Field/Image Receptor Alignment

- 2. Misalignment 1/4 = ____cm.
- 3. Misalignment 2/1 =____cm.
- 4. Misalignment 3/2 =____cm.
- 5. Misalignment 4/3 =____cm.
- 6. SID = ____cm.
- 7. (1/4 + 3/2) Misalignment = ____cm.
- 8. Percent (1/4 + 3/2) Misalignment = ____%.
- 9. (2/1 + 4/3) Misalignment = _____cm.
- 10. Percent (2/1 + 4/3) Misalignment = ____%.
- 11. Total Misalignment = ____cm.
- 12. Percent Total Misalignment = ____%.
- 13. Misalignment 1/4 =____cm.
- 14. Misalignment 2/1 =____cm.
- 15. Misalignment 3/2 =____cm.
- 16. Misalignment 4/3 =____cm.
- 17. SID = _____cm.
- 18. (1/4 + 3/2) Misalignment = _____cm.
- 19. Percent (1/4 + 3/2) Misalignment = ____%.

- 20. (2/1 + 4/3) Misalignment = _____cm.
- 21. Percent (2/1 + 4/3) Misalignment = ____%.
- 22. Total Misalignment = ____cm.
- 23. Percent Total Misalignment = ____%.

Fluoroscopic Entrance Exposure Rate

Automatic Mode

24. Entrance Exposure Rate = _____R/min.

Manual Mode

25. Entrance Exposure Rate = _____R/min.

Primary Barrier Transmission

- 26. Entrance Exposure Rate = _____R/min.
- 27. Primary Barrier Transmission = ____(mR/hr)/(R/min)

Beam Quality

Exposure Rate

- 28. R4 = _____mR/s at 4.5 mm Al.
- 29. R3 = _____mR/s at 3.5 mm Al.
- 30. R2 = _____mR/s at 2.5 mm Al.
- 31. R1 = _____mR/s at 1.5 mm Al.
- 32. R0 = _____mR/s at 0.0 mm Al.

Normalized Exposure Rate

- 33. N4 = _____at 4.5 mm Al.
- 34. N3 = _____at 3.5 mm Al.
- 35. N2 = _____at 2.5 mm Al.
- 36. N1 = _____at 1.5 mm Al.

N0 = 1.0 at 0.0 mm Al.

- 37. HVLobs = _____mm AI at _____kVp
- 38. Actual HVL = _____mm Al at _____kVp

Reproducibility

- 39. Average Exposure, $\overline{E} = _$ mR.
- 40. Coefficient of Variation, C = _____.

X-Ray Field - Spot-Film Size Comparison

- 41. Distance from Focal Spot to Slide Assembly, SID' = _____cm.
- 42. Distance from Focal Spot to Spot-Film Plane, SID" = _____cm.

Along-Table Comparison

- 43. X-ray Field Dimension Along-Table at Spot-Film Plane = _____cm.
- 44. Selected Spot-Film Dimension Along-Table = _____cm.
- 45. Along-Table Difference = ____cm.
- 46. Percent Along-Table Difference = ____%.

Across-Table Comparison

- 47. X-Ray Field Dimension Across-Table at Spot-Film Plane = _____cm.
- 48. Selected Spot-Film Dimensions Across-Table Width = _____cm.
- 49. Across-Table Difference = ____cm.
- 50. Percent Across-Table Difference = ____%.

Sum Along + Across-Table Differences

- 51. Along + Across-Table Difference = _____ cm.
- 52. Percent Along + Percent Across-Table Difference = ____%.