CLASSIFICATION OF ITEMS OF NONCOMPLIANCE AND DEFECTS

Class A

Conditions which may pose a serious radiation hazard to the public health and safety.

l. An x-ray system having a malfunction such that inadvertent exposures could occur e.g., a system such that when the exposure switch is activated, not one but repeated exposures occur, or the timer fails to terminate exposure, or exposure initiated without utilizing the exposure switch.

2. A fluoroscopic x-ray system with an entrance exposure rate of greater than or equal to 25 R/min. , except:

   (a) During recording of fluoroscopic images, or

   (b) When an optional high level control is activated. If the control was manufactured after May 1995, the high level entrance exposure rate is limited to 20 R/min and any reading exceeding 25 R/min is also a Class A violation.

3. A fluoroscopic system such that the entire x-ray beam is not intercepted by the primary protective barrier.

4. A fluoroscopic system such that x-ray production is possible when the primary protective barrier is not in position to intercept the beam.

Class B

Certified Systems and Components Only

These are conditions that (1) would result in a large amount of unnecessary radiation exposure during a routine diagnostic x-ray examination, or (2) indicate other clearly defined items of noncompliance (certified systems and components only). These conditions may be determined in the field and calculated as in Reference 4 (the Routine Compliance Test Manual). For purposes of regulatory follow up, Class B conditions are divided into four groups according to the degree of health hazard presented by the conditions. The groupings are: Substantial Hazard, Moderate Hazard, Low Hazard, and Minimal Hazard (as compared to a fully compliant x-ray system).

Substantial Hazard

1. An exposure rate beyond the plane of the image receptor, due to transmission through the primary protective barrier of a fluoroscopic x-ray system (with the attenuation block in the useful beam) of

greater than or equal to 10 mR/hr for each R/min of entrance exposure rate at 10 cm from any accessible surface of the fluoroscopic imaging assembly.

2. An image-intensified fluoroscopic x-ray system such that the total misalignment of the edges of the x-ray field with the respective edges of the visible area of the visually defined field in the plane of the image receptor is greater than 10 percent of the SID.

3. A spot film device such that the total misalignment of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, exceeds 10 percent of the SID.

4. A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by greater than 10 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

5. Mobile radiographic systems where the illuminance of the light localizer is less than 96 lux at a 100 centimeter measurement distance.

Moderate Hazard

l. For radiographic x-ray systems:

   a. A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by greater than 5% of the SID and that the sum of the length and width differences without regard to sign be greater than 7% of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

   b. A radiographic x-ray system providing means to align the center of the x-ray field with respect to the center of the image receptor and the misalignment is greater than or equal to 5 percent of the SID.

   c. A radiographic x-ray system providing means for visually defining the perimeter of the x-ray field and the total misalignment of the edges of the visually defined field is greater than 5 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is indicated to be perpendicular to the axis of the x-ray beam.

   d. A coefficient of variation greater than or equal to 0.10 for a sample set of ten exposures as described in Reference 4.

e. A half-value layer more than 1/2 mm aluminum below the appropriate value listed in 21 CFR 1020.30 Table I.

f. Systems equipped with positive beam limitation where at SIDs for which the device is designed to operate, it does not either cause automatic adjustment of the x-ray field to the image receptor size in the plane of the image receptor within 5 seconds after insertion of the image receptor; or if adjustment is accomplished automatically in a time interval greater than 5 seconds, or manually, does not prevent the production of x-rays until such adjustment is made.

g. An average light localizer illuminance of less than 96 lux for stationary systems and between 96 and 144 lux for mobile systems, as measured with a Digiphot at a measurement distance of 100 centimeters or the maximum SID, whichever is greater.

h. A capacitor storage system such that the standby radiation is greater than or equal to 25 mR/hr.

i. A measured kilovoltage greater or less than the manufacturer's upper or lower accuracy limits:

(1) Measured kilovoltage greater than the indicated kilovoltage A measured kilovoltage more than 105 percent of the manufacturer's upper accuracy limit for indicated kilovoltage.

(2) Measured kilovoltage less than the indicated kilovoltage A measured kilovoltage that is less than 95 percent of the manufacturer's lower limit for indicated kilovoltage.

j. Intraoral dental systems capable of operation in the above 50 kVp range which exhibit a minimum source to skin distance less than 16 centimeters.

k. Intraoral dental systems capable of operation in the above 50 kVp range for which the field size at the cone tip is greater than or equal to 9 centimeters.

l. Dental radiographic systems in which it is possible to produce x-rays with the timer in the zero or off position.

m. Mammographic x-ray systems in which the edge of the x-ray field at the chest wall extends beyond the edges of the image receptor by more than 5 percent of the source to image receptor distance.

2. For fluoroscopic x-ray systems:

a. An image-intensified fluoroscopic x-ray system such that the total misalignment of the edges of the x-ray field with the respective edges of the visually defined field in the plane of the image receptor is equal to or greater than 6 percent, but less than 10 percent of the SID, and the sum, without regard to sign, of the misalignment along any two orthogonal dimensions intersecting at the center of the visible area of the image receptor is equal to or greater than 8 percent of the SID.

b. A nonimage-intensified fluoroscopic system such that any dimension of the x-ray field extends beyond the visible portion of the image receptor by greater than 8 percent of the SID.

c. For conditions described in 21 CFR 1020.32(d), if the maximum allowable entrance exposure rate is 5 R/min., test values of greater than or equal to 5.6 R/min., but less than 25 R/min. Correspondingly, for a maximum allowable rate of 10 R/min., test values of greater than or equal to 11.5 R/min. but less than 25 R/min. are included.

d. Half-value layer values which are more than 1/2 mm below the value specified in 21 CFR 1020.30 Table I.

e. An exposure rate due to transmission through the primary protective barrier of a fluoroscopic system with the attenuation block in the useful beam of greater than or equal to 4 mR/hr but less than 10 mR/hr for each R/min of entrance exposure rate at 10 cm beyond the plane of the image receptor.

f. A spot film device such that the total misalignment of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, exceeds 6 percent, but is less than 10 percent of the SID. The sum without regard to sign of the misalingment along any two orthogonal dimensions exceeds 7 percent of the SID.

g. Stationary fluoroscopes with a minimum source-to-skin distance of less than 35.2 centimeters.

h. Mobile fluoroscopes with a minimum source-to-skin distance of less than 27.2 centimeters or 18.1 centimeters when configured for surgical use (e.g. spacer removed).

i. For controls manufactured after May 1995, which have high level controls limited to 20 R/min, test values of greater than 21.5 R/min but less than 25 R/min.

j. Other similar situations.

Low Hazard

1. For radiographic x-ray systems:

   a. A coefficient of variation greater than or equal to 0.084 for a sample set of four exposures, or between 0.06 and 0.10 for a sample set of ten exposures as described in Reference 4.

   b. A linearity value of greater than or equal to 0.153. This value is based upon two sample sets of at least four exposures each, as described in Reference 4.

c. A radiographic x-ray system having indicated field size dimensions such that aperture adjustments result in x-ray field dimensions that differ from those of the image receptor by equal to or greater than 5 percent of the SID when the beam axis is intended to be perpendicular to the plane of the image receptor.

d. A stationary general purpose radiographic x-ray system (i.e., one equipped with stepless adjustment of the size of the x-ray field) such that the actual SID differs from the indicated SID by more than 5 percent of the indicated SID. These values are based on a test procedure using a direct measurement of the distance from the focal spot to the tabletop and from the tabletop to the film plane as described in Reference 4.

e. For stationary systems only, an average light localizer illuminance of between 96 and 144 lux as measured with a Digiphot.

f. A capacitor storage radiographic system such that the standby radiation is greater than 3.0 mR/hr, but less than 25 mR/hr.

g. Systems equipped with positive beam limitation devices which do not allow the field size to be reduced to a size less than that of the image receptor.

h. Systems equipped with positive beam limiting devices which do not provide for an automatic return to PBL from a reduced field size.

i. Mobile radiographic systems for which the minimum source to skin distance is less than 27.5 centimeters.

* j. Mammographic systems for which the edges of the x-ray field on any side extend beyond the edge of the image receptor by more than 5 percent of the SID. *

k. (1) When the maximum operating range is above 70 kVp; A half-value layer (HVL) between (0.15 + 0.04 x HVL) mm and 0.5 mm aluminum below the appropriate value listed in 21 CFR 1020.30 Table I.

(2) When the maximum operating range is 50 to 70 kVp: A half-value layer (HVL) between (0.08 + 0.04 x HVL) mm and 0.5 mm aluminum below the appropriate value listed in 21 CFR 1020.30 Table I.

(3) When the maximum operating range is less than 50 kVp: A half-value layer (HVL) between 0.1 mm and 0.5 mm aluminum below the appropriate value listed in 21 CFR 1020.30 Table I.

l. Systems equipped with positive beam limitation, which do not prevent the production of x-rays at SID's greater than 36 inches where the PBL device is not intended to operate.

2. For fluoroscopic x-ray systems:

   a. Fluoroscopic systems equipped with high level control which do not provide an audible indication of the activation of the high level control.

   b. Half-value layer (see item k(1) under radiographic systems).

* c. Systems which do not provide either continuous audible signal or termination of x-rays at the completion of a previously selected time interval. *

Class B

Uncertified Systems and Components Only

Other situations similar to those of Class B certified systems and components which in the judgement of the auditor constitute a defect as defined in 21 CFR 1003.2(b).

Class C

Certified Systems and Components Only

These are conditions that indicate test results exceeding the requirements of the standard but less than the values for Class B noncompliances for certified systems and components only. These may be determined in the field and calculated as in Reference 4.

l. For radiographic x-ray systems:

   a. A radiographic x-ray system having positive beam limitation where the x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, is such that either the length or the width of the x-ray field differs from that of the image receptor by 3.00 to 4.99 percent of the SID and that the sum of the length and width differences without regard to sign be between 4.00 and 6.99 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

   b. A radiographic x-ray system providing means to align the center of the x-ray field with respect to the center of the image receptor and misalignment is between 2.00 and 4.99 percent of the SID.

   c. A radiographic x-ray system providing means for visually defining the perimeter of the x-ray field and the total misalignment of the edges of the visually defined field is between 2.00 and 4.99 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is indicated to be perpendicular to the axis of the x-ray beam.

d. A radiographic x-ray system having indicated field size dimensions such that aperture adjustments result in x-ray field dimensions that differ from those of the image receptor by between 2.00 and 4.99 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

e. A stationary radiographic x-ray system providing means for stepless adjustment of the size of the x-ray field such that the actual SID is either larger or smaller than the indicated SID by between 2.00 and 4.99 percent. These values are based on a test procedure using direct measurement of the distance from the focal spot to the tabletop and from the tabletop to the film plane as described in Reference 4.

f. A coefficient of variation greater than 0.050 but less than 0.084. This value is based upon a sample set of four exposures. When a set of ten exposure values is made, the upper limit is reduced from 0.084 to 0.06 (see Reference 4).

g. Linearity value of greater than 0.100 but less than 0.152. This value is based upon two sample sets of at least four exposures each, as described in Reference 4.

h. (l) When the maximum operating range is above 70 kVp: A half-value layer (HVL) below the appropriate value listed in 21 CFR 1020.30 Table I but less than (0.15 + 0.04 X HVL) mm Al below the listed value.

(2) When the maximum operating range is 50 to 70 kVp: A half-value layer below the appropriate value listed in 21 CFR 1020.30 Table I but less than (0.08 + 0.04 X HVL) below the listed values.

(3) When the maximum operating range is less than 50 kVp: A half-value layer (HVL) below the appropriate value listed in 21 CFR l020.30 Table I but less than 0.1 mm Al below the listed value.

i. An average light localizer illumination greater than 144 but less than 160 lux as measured with a Digiphot.

j. A capacitor energy storage radiographic system such that the standby radiation is greater than 2.0 mR/hr but less than 3.0 mR/hr.

k. A measureable kilovoltage greater or less than manufacturer's upper or lower accuracy limits.

(l) Measured kilovoltage greater than indicated kilovoltage A measured kilovoltage ranging from the manufacturer's upper accuracy limit to a measured kilovoltage such that 95 percent of this value is greater than the upper accuracy limit.

Example: The indicated kilovoltage on the x-ray control is 100 kVp. If the manufacturer states an accuracy of $\pm$ 10 percent, the upper and lower accuracy limits would be 110 kVp and 90 kVp, respectively. In this case, a measured kilovoltage ranging from 110 kVp to 115.8 kVp would be a Class C noncompliance.

(2) Measured kilovoltage less than indicated kilovoltage A measured kilovoltage ranging from the manufacturer's lower accuracy limit to a measured kilovoltage such that 105 percent of this value is less than the lower accuracy limit.

Example: The indicated kilovoltage on the x-ray control is 100 kVp. If the manufacturer states an accuracy of ± 10 percent, the upper and lower accuracy limits would be 110 kVp and 90 kVp, respectively. In this case, a measured kilovoltage ranging from 90 kVp to 85.7 kVp would be a Class C noncompliance.

2. For fluoroscopic x-ray systems:

a. An image-intensified fluoroscopic x-ray system such that the total misalignment of the edges of the x-ray field with the respective edges of the visible area of the visually defined field in the plane of the image receptor is greater than 3 percent but less than 6 percent of the SID, and the sum, without regard to sign, of the misalignment along any two orthogonal dimensions intersecting at the center of the visible area of the image receptor is greater than 4 percent but less than 8 percent of the SID.

b. A nonimage-intensified fluoroscopic system such that any dimension of the x-ray field extends beyond the visible portion of the image receptor but by less than 8 percent of the SID.

* c. For conditions described in 21 CFR l020.32(d), if the maximum allowable entrance exposure rate is 5 R/min., test values of greater than 5.0 R/min., but less than 5.6 R/min. Correspondingly, if the maximum allowable entrance exposure rate is 10 R/min., test values of greater than 10.0 R/min. but less than 11.5 R/min. are included. *

d. Half-value layer (see h(1) under radiographic x-ray systems this section).

e. An exposure rate due to transmission through the primary protective barrier of a fluoroscopic system with the attenuation block in the useful beam of greater than 2.0 mR/hr but less than 4.0 mR/hr for each R/min. of entrance exposure rate at 10 cm beyond the plane of the image receptor.

f. A spot film device such that total misalignment of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, is greater than 3 percent but less than 6 percent of the SID. The sum without regard to sign of the misalignment along any two orthogonal dimensions is greater than 4 percent but less than 7 percent of the SID.

g. For controls manufactured after May 1995 which contain high level controls, where the maximum allowable entrance exposure rate is 20 R/min, test values greater than 20 R/min, but less than 21.5 R/min.

h. Stationary fluoroscopes with a minimum source-to-skin distance between 35.2 centimeters and 38 centimeters.

i. Mobile fluoroscopes with a minimum source-to-skin distance between 27.2 centimeters and 30 centimeters or between 18.1 centimeters and 20 centimeters when configured for surgical use (e.g. spacer removed).

j. Other similar situations.

Class C

Uncertified Systems and Components Only

Other situations similar to those of Class B certified systems and components which in the judgment of the auditor meet the definition of 21 CFR 1003.2(b).

Class D

All items which indicate a system in compliance.

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Class E

These items are minor functional noncompliances which may not be assembler related. They do not warrant a Notification letter by themselves, but may be included in a Notification letter issued because of other violations (similar to notification of Class C violations).

Minimal Hazard

1. For radiographic systems:

   a. Stationary systems where there are no means to indicate when the beam axis is perpendicular to the plane of the image receptor.

   b. Stationary systems where means are not provided to center the diagnostic source assembly over the image receptor.

   c. Systems where technique factors are not indicated at the operator's position.

   d. Systems which lack a warning label.

2. For fluoroscopic systems:

   a. No warning label present on the master x-ray control panel.

   b. Systems where the tube potential and tube current are not continuously indicated during x-ray exposure.

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