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Medical Fluoroscopic Equipment

(A) Fluoroscopic equipment shall meet the following standards:

(1) Unless the United States food and drug administration (FDA) has granted a variance for specific fluoroscopic equipment, the source-to-skin distance (SSD) for fluoroscopy equipment shall not be less than:

Unless there are FDA variances for specific fluoroscopy equipment, the source-to-skin distance shall meet the following requirements.

(a) Thirty-eight centimeters on stationary fluoroscopic equipment unless a particular procedure application prohibits that distance, in which case the SSD shall not be less than twenty centimeters;

Stationary fluoroscopic equipment shall have a means to limit the source-to-skin distance (SSD) to 38 centimeters using a component of the fluoroscopy equipment such as a spacer cone or tabletop. If a procedure prohibits the 38-centimeter SSD, the components of the stationary fluoroscopic equipment shall not allow less than a 20-centimeter SSD.

(b) Thirty centimeters on mobile fluoroscopic equipment unless a particular procedure prohibits that distance, in which case it shall not be less than twenty centimeters; and

Mobile fluoroscopic equipment shall have a means to limit the source-to-skin distance (SSD) to 30 centimeters using a component of the fluoroscopy equipment such as a spacer cone or tabletop. If a procedure prohibits the 30-centimeter SSD, components of the mobile fluoroscopic equipment shall not allow less than a 20-centimeter SSD.

(c) Nineteen centimeters for c-arm type fluoroscopic equipment having a maximum source-to-image distance (SID) less than forty-five centimeters unless a particular procedure prohibits that distance, in which case it shall not be less than ten centimeters. Such systems shall be used for extremity or dental purposes only;

Miniature fluoroscopic equipment (maximum source-to-image distance of 45 centimeters) shall have a means to limit the source-to-skin distance (SSD) to 19 centimeters using a component of the fluoroscopy equipment such as a spacer cone. If a procedure prohibits the 19-centimeter SSD, components of the miniature fluoroscopic equipment shall not allow less than a 10-centimeter SSD. Miniature fluoroscopic equipment can only be used for extremity or dental purposes.

(2) For c-arm fluoroscopic equipment equipped with a removable spacer cone, the spacer cone shall be attached to the x-ray source during use at all times unless it interferes with the clinical procedure;

If a c-arm fluoroscopic unit is equipped with a removable spacer cone, the spacer cone shall be attached to the x-ray source during use unless it interferes with the clinical

procedure.

(3) The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross-section of the useful beam at any SID and shall prevent further exposures when the primary barrier is not in the path of the entire x-ray beam;

Stationary fluoroscopic units usually have movable carriages with variable Source-to-Image Distances (SID) that house the image assembly that is fixed to the x-ray tube housing.

Mobile fluoroscopic units usually have a stationary image assembly with a fixed SID across from the x-ray tube (source) housing.

No matter the configuration, the fluoroscopic unit's image assembly shall be provided with a primary protective barrier that intercepts the entire cross-section of the x-ray beam passing through the collimating (beam limiting) device of the x-ray tube (source) housing at any SID capable on the fluoroscopic unit. This primary protective barrier shall prevent exposure if it is not in the path of the entire x-ray beam coming from the collimating device of the tube (source) housing.

(4) All fluoroscopic equipment shall provide intensified imaging. As used in this rule "intensified imaging" will include the use of digital image receptors;

All fluoroscopic equipment must provide intensified imaging. An image intensifier uses a photomultiplier tube or digital image receptor to amplify or brighten the fluoroscopic image.

(5) Fluoroscopic equipment shall meet the following field limitation specifications:

(a) For fluoroscopic equipment manufactured before June 10, 2006, the following applies:

(i) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three per cent of the SID. The sum of the excess length and the excess width shall be no greater than four per cent of the SID; and

For fluoroscopic equipment manufactured before June 10, 2006, the length and width of the x-ray field shall not exceed the visible area of the image receptor by more than 3 percent of the Source-to-Image Distance (SID).

For example: at a 30-inch source-to-image distance, when an 8 X 10-inch visual field is used, the x-ray field shall not be greater than 8.9 inches for the 8-inch dimension or 10.9 inches for the 10-inch dimension.

The sum of the excessive length and width of the x-ray field shall not be greater than 4 percent of the SID.

For example: at a 30-inch source-to-image distance, the sum of the

excess length and width of a given visual field size used can add to greater the 1.2 inches.

(ii) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor;

For fluoroscopic equipment manufactured before June 10, 2006, with rectangular x-ray fields used with circular image receptors, the error in alignment of x-ray field versus visual field shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(b) For fluoroscopic equipment with a circular image receptor manufactured on or after June 10, 2006, the maximum area of the x-ray field in the plane of the circular image receptor shall conform with one of the following requirements:

For fluoroscopic equipment with a circular image receptor manufactured on or after June 10, 2006, the maximum area of the x-ray field in the plane of the circular image receptor shall conform to one of the following:

(i) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to thirty-four centimeters in any direction, at least eighty per cent of the area of the x-ray field shall overlap the visible area of the image receptor; or

When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 centimeters in any direction:

At least 80 per cent of the area of the x-ray field shall overlap the visible area of the image receptor; or

(ii) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than thirty-four centimeters in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor shall not extend beyond the edge of the visible area of the image receptor by more than two centimeters;

When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 centimeters in any direction:

The x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor shall not extend beyond the edge of the visible area of the image receptor by more than 2 centimeters.

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(c) For fluoroscopic equipment with a rectangular image receptor manufactured on or after June 10, 2006, the following applies:

(i) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three per cent of the SID. The sum of the excess length and the excess width shall be no greater than four per cent of the SID; and

For fluoroscopic equipment with a rectangle image receptor manufactured on or after June 10, 2006, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three per cent of the SID.

For example: at a 30-inch source-to-image distance, when an 8 X 10-inch visual field is used, the x-ray field shall not be greater than 8.9 inches for the 8-inch dimension or 10.9 inches for the 10-inch dimension.

The sum of the excessive length and width of the x-ray field shall not be greater than 4 percent of the SID.

For example: at a 30-inch source-to-image distance, the sum of the excess length and width of a given visual field size used can add to greater the 1.2 inches.

(ii) The error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor;

For fluoroscopic equipment with a rectangle image receptor manufactured on or after June 10, 2006, the error in alignment of x-ray field versus visual field shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(d) If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the operator's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

"For X-ray Field Limitation System Failure;"

For fluoroscopy equipment where the size of the x-ray field automatically adjusts with the source-to-image distance or image receptor size, a capability may be provided for overriding the automatic adjustment in case of system failure.

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If an override of the automatic x-ray field adjustment is provided, a visible signal at the operator's position must indicate that the automatic x-ray field adjustment is being overridden.

The system failure switch to override the automatic x-ray field adjustment must be clearly labelled "For X-ray Field Limitation System Failure."

(e) Beam-limiting devices shall be provided with a means for stepless adjustment of the x-ray field; and

Fluoroscopy equipment shall have a beam-limiting device with a collimator which restrict the dimensions of the x-ray field. The beam-limiting device must have stepless adjustment for seamless movement of the collimator blades through all available x-ray field sizes.

Miniature c-arms are exempt from this paragraph [ref. paragraph (E) of this rule].

(f) Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five centimeters by five centimeters or less;

The stepless adjustment of the beam limiting device for fluoroscopy equipment shall, at the greatest source-to-image distance, provide continuous adjustment of x-ray field sizes from the maximum obtainable to an area of 5 centimeters by 5 centimeters or less.

Miniature c-arms are exempt from this paragraph [ref. paragraph (E) of this rule].

(6) Timers shall meet the following specifications:

(a) A means shall be provided to preset the cumulative on-time timer of the fluoroscopic tube. The maximum cumulative time of the timer shall not exceed five minutes without resetting;

The fluoroscopy equipment shall have a preset cumulative on-time timer to measure the fluoroscopy tube exposure on time. The maximum preset cumulative time of the on-time timer shall not exceed five minutes without resetting.

(b) The timer shall terminate the exposure or emit a signal audible to the operator when the exposure time reaches a maximum of five minutes. The signal shall continue to sound while x-rays are produced until the timer is reset;

The fluoroscopy equipment's preset cumulative on-time timer shall terminate the exposure or emit an audible signal to the operator when the exposure times reaches the maximum five minutes. The audible signal shall continue to sound during radiation exposure until the timer is reset.

(c) For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

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(i) A display of the fluoroscopic irradiation time at the operator's working position. This display shall function independently of the audible signal described in paragraph (A)(6)(c)(ii) of this rule. The following requirements apply:

For x-ray controls manufactured on or after June 10, 2006, there shall be a display of the fluoroscopic irradiation time at the operator's work position. This display shall function without regard to audible signal created from the passage of five minutes of exposure. See paragraph (A)(6)(c)(ii) of this rule.

(a) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six seconds;

For x-ray controls manufactured on or after June 10, 2006, when radiation is generated, the fluoroscopic irradiation time shall be continuously displayed in minutes and tenths of minutes and the time updated at least once every six seconds.

(b) The fluoroscopic irradiation time shall also be displayed within six seconds of termination of an exposure and remain displayed until reset; and

For x-ray controls manufactured on or after June 10, 2006, the fluoroscopic irradiation time shall also be displayed within six seconds of terminating the exposure and remained displayed until the time is reset.

(c) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure;

For x-ray controls manufactured on or after June 10, 2006, the display for the fluoroscopic irradiation time shall be able to be reset prior to beginning a new examination or procedure.

(ii) A signal audible to the operator shall sound for each passage of five minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two seconds;

For x-ray controls manufactured on or after June 10, 2006, a signal audible to the operator shall sound for each passage of five minutes of fluoroscopic irradiation time during an examination or procedure. The signal audible to the operator shall sound until manually reset, or if automatically reset, for at least 2 seconds during radiation exposure.

(7) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposure at any time, but means may be provided to

permit completion of any single exposure of the series in progress;

Fluoroscopy equipment when in fluoroscopy mode shall have a device (usually button or foot pedal) that requires continuous pressure by the operator to produce radiation.

When recording serial fluoroscopic images, the operator shall be able to stop the exposure at any time but may have means to complete any single exposure of the series in progress.

(8) Fluoroscopic systems shall meet the following air kerma rate limits:

Air kerma is the sum of the initial kinetic energy of all charged ionizing particles liberated by uncharged ionizing radiation in a given mass of air. The unit for air kerma is joules per kilogram which is given the special name of gray (Gy). To determine air kerma in Gy from exposure in units of roentgens (R) multiply exposure by the conversion factor 0.00876 Gy/R.

Air kerma rate is the air kerma per unit time.

(a) Fluoroscopic equipment provided with only automatic exposure rate control, or provided with both automatic exposure rate control and manual mode capabilities, shall not exceed an air kerma rate of eighty-eight milligray per minute (ten roentgens per minute exposure rate) in either mode at any combination of tube potential and current, at the measurement point specified in paragraph (C)(6) of this rule;

Fluoroscopic equipment with only automatic exposure rate control, or with both automatic exposure rate control and manual mode capabilities shall not exceed an air kerma rate of 88 milligray per minute (10 roentgens per minute exposure rate) in either mode at any combination of tube potential and current, at the following points of measurement:

- **For x-ray source below table, at 1 centimeter above the tabletop.**
- **For x-ray source above table, at 30 centimeters above the tabletop with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement.**
- **For c-arm type fluoroscopic equipment, at 30 centimeters from the input surface of the image receptor with the source positioned at any SID.**
- **For fixed SID lateral fluoroscopes attached to the x-ray table, at a point fifteen centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the table top is moveable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than fifteen centimeters to the centerline of the table.**

(b) Fluoroscopic equipment provided with only manual mode capabilities shall not exceed an air kerma rate of forty-four milligray per minute (five roentgens per minute exposure rate) at any combination

of tube potential and current, at the measurement point specified in paragraph (C)(6) of this rule; and

Fluoroscopic equipment with only manual mode capabilities shall not exceed an air kerma rate of 44 milligray per minute (5 roentgens per minute exposure rate) at any combination of tube potential and current, at the following points of measurement:

- **For x-ray source below table, at 1 centimeter above the tabletop.**
- **For x-ray source above table, at 30 centimeters above the tabletop with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement.**
- **For c-arm type fluoroscopic equipment, at 30 centimeters from the input surface of the image receptor with the source positioned at any SID.**
- **For fixed SID lateral fluoroscopes attached to the x-ray table, at a point fifteen centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the table top is moveable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than fifteen centimeters to the centerline of the table.**

(c) For fluoroscopic equipment that is provided with high-level control, and the high-level control is activated, the air kerma rate shall not exceed one hundred seventy-six milligray per minute (twenty roentgens per minute exposure rate) at any combination of tube potential and current, at the measurement point specified in paragraph (C)(6) of this rule;

Fluoroscopic equipment with high-level control, and high-level control activated, shall not exceed an air kerma rate of 176 milligray per minute (20 roentgens per minute exposure rate) at any combination of tube potential and current, at the following points of measurement:

- **For x-ray source below table, at 1 centimeter above the tabletop.**
- **For x-ray source above table, at 30 centimeters above the tabletop with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement.**
- **For c-arm type fluoroscopic equipment, at 30 centimeters from the input surface of the image receptor with the source positioned at any SID.**
- **For fixed SID lateral fluoroscopes attached to the x-ray table, at a point fifteen centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the table top is moveable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than fifteen centimeters to the centerline of the table.**

(i) For all fluoroscopy equipment that is provided with high-level control, special means of activation of high level control, such as manual pressure applied continuously by the operator, shall be required to avoid accidental use; and

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Fluoroscopy equipment with high-level control, must have a special means to activate high-level control that is different than activating the normal fluoroscopy mode to avoid accidental use.

(ii) A continuous signal audible to the operator shall indicate that high level control is being employed;

When fluoroscopy equipment is used in high level control a continuous audible signal must be activated during exposure to indicate to the operator that high-level control is being used.

(9) During fluoroscopy and cinefluorography the x-ray tube potential and current shall be continuously indicated;

During fluoroscopy and cinefluorography, the x-ray tube potential and current shall be continuously indicated usually on the control panel

(10) For undertable fluoroscopic equipment, a shielding device of at least 0.25 millimeter lead equivalent shall cover the bucky-slot;

Undertable fluoroscopic equipment must have a 0.25-millimeter lead equivalent shielding device (bucky-slot cover) covering the bucky-slot opening under the table during fluoroscopy. The buck-slot cover is usually connected to the bucky tray so moving the buck tray to the end of the table positions the bucky-slot cover to shield bucky-slot opening during fluoroscopy.

(11) For undertable fluoroscopic equipment, protective drapes, or other devices, at least 0.25 millimeter lead equivalent shall be provided between the patient and the individual operating the fluoroscopic equipment to intercept scattered radiation which would otherwise reach the fluoroscopist and others near the x-ray unit, except when such drapes or other devices would compromise the sterile field. Such devices shall not substitute for wearing required protective apparel;

Undertable fluoroscopy equipment must have protective drapes or other devices present between the patient and the individual operating the fluoroscopic equipment.

The only time these protective drapes or other devices can be removed for a fluoroscopy examination is if the protective drapes or devices compromise a sterile field.

These protective drapes or other devices between the patient and operator are in addition to wearing lead aprons, and lead gloves as required.

(12) Radiography using the fluoroscopic imaging assembly shall meet the following specifications:

(a) A means shall be provided between the source and the patient which will automatically limit the x-

ray field at the time the exposure is initiated to no more than the portion of the image receptor selected by the operator for spot films or radiographic images. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected such a mode of operation;

For radiography (spot film or radiographic imaging) using the fluoroscopic imaging assembly, there must be a means to automatically limit the x-ray field size at the time of the exposure to no more than the portion of the image receptor selected for the spot film and radiographic image.

If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected such a mode of operation.

(b) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three per cent of the SID when adjusted for full coverage of the selected portion of the image selector;

During radiography (spot film or radiographic imaging) using the fluoroscopic imaging assembly, neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the selected dimensions of the image receptor by more than three per cent of the source-to-image distance when adjusted for full coverage of the selected portion of the image selector.

For example: at a 30-inch source-to-image distance, when an 8 X 10-inch visual field is selected, the x-ray field shall not be greater than 8.9 inches for the 8-inch dimension or 10.9 inches for the 10-inch dimension.

(c) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two per cent of the SID; and

During radiography (spot film or radiographic imaging) using the fluoroscopic imaging assembly, the center of the x-ray field in the plane of the image receptor must be aligned with the center of the selected portion of the image receptor to within in two percent of the source-to-image distance. For example, at a 30-inch source-to-image distance, the centers must be aligned to within approximately ±0.9 inches.

(d) Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor. The minimum field size at the greatest SID shall not exceed five centimeters by five centimeters;

During radiography (spot film or radiographic imaging) using the fluoroscopic imaging assembly, the beam limiting device shall be able to reduce the x-ray field

size to a size smaller than the selected portion of the image receptor. The minimum size of the x-ray field at the greatest source-to-image distance shall not exceed 5 centimeters by 5 centimeters.

(13) Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the operator's working position the air kerma rate (AKR) and cumulative air kerma in accordance with the following requirements:

Fluoroscopic equipment manufactured on or after June 10, 2006, must display the air kerma rate and cumulative air kerma at the operator's work position in accordance with the following:

(a) When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in milligrays per minute shall be continuously displayed and updated at least once every second;

Fluoroscopic equipment manufactured on or after June 10, 2006, must display the air kerma rate at the operator's work position as follows: When the x-ray tube is activated and the number of images produced is greater than six images per second, the air kerma rate in milligrays per minute shall be continuously displayed and updated at least once every second.

(b) The cumulative air kerma in units of milligrays shall be displayed either within five seconds of termination of an exposure or displayed continuously and updated at least once every five seconds;

Fluoroscopic equipment manufactured on or after June 10, 2006, must display the cumulative air kerma at the operator's work position as follows: The cumulative air kerma in units of milligrays shall be displayed either within five seconds of termination of an exposure or displayed continuously and updated at least once every five seconds.

(c) The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma;

For fluoroscopic equipment manufactured on or after June 10, 2006, the display of the air kerma rate shall be clearly distinguishable from the display of the cumulative air kerma.

(d) The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope;

(i) For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference location shall be the respective locations specified in paragraph (C)(6)(a), (C)(6)(b) or (C)(6)(d) of this rule; or

For fluoroscopic equipment manufactured on or after June 10, 2006, the air kerma rate and cumulative air kerma shall represent the value for conditions of

free-in-air irradiation at the following reference locations:

- **For x-ray source below tabletop or cradle, at 1 centimeter above the tabletop or cradle.**
- **For x-ray source above table or cradle, at 30 centimeters above the tabletop with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement.**
- **For fixed SID lateral fluoroscopes attached to the x-ray table, at a point fifteen centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is moveable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than fifteen centimeters to the centerline of the table.**

(ii) For C-arm fluoroscopes, the reference location shall be fifteen centimeters from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin;

For c-arm fluoroscopic equipment manufactured on or after June 10, 2006, the air kerma rate and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at 15 centimeters from the isocenter toward the x-ray source along the beam axis or the location specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.

(e) Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure; and

For fluoroscopic equipment manufactured on or after June 10, 2006, the display of the cumulative air kerma shall be able to be reset prior to beginning a new examination or procedure.

(f) The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than plus or minus thirty-five per cent;

For fluoroscopic equipment manufactured on or after June 10, 2006, the displayed air kerma rate and cumulative air kerma shall not deviate from the actual measured values by more than plus or minus 35 percent.

(14) Fluoroscopic equipment manufactured on or after June 10, 2006 shall be equipped with means to display a last image hold (LIH) image following termination of the fluoroscopic exposure:

Fluoroscopic equipment manufactured on or after June 10, 2006 shall provide last image hold.

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Last image hold - means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

(a) For a LIH image obtained by retaining pre-termination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure;

For fluoroscopic equipment manufactured on or after June 10, 2006 with the last image hold image being obtained by retaining pre-termination fluoroscopic images, and the number of and method of combining images are selectable by the user, the selection must be indicated prior to initiation of the fluoroscopic exposure.

(b) For a LIH image obtained by initiating a separate radiographic exposure at termination of the fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure; and

For fluoroscopic equipment manufactured on or after June 10, 2006 with last image hold being obtained by initiating a separate radiographic exposure at termination of the fluoroscopic imaging:

- **The technique factors for the last image hold image shall be selectable prior to the fluoroscopic exposure, and**
- **The combination selected shall be indicated prior to initiation of the fluoroscopic exposure.**

(c) Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of the fluoroscopic exposure unless separate displays are provided.

For fluoroscopic equipment manufactured on or after June 10, 2006, means must be provided to clearly indicate to the user whether the displayed image is the last image held radiograph or fluoroscopy.

The display of the last image hold radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of the fluoroscopic exposure unless separate displays are provided.

(B) In addition to other applicable radiation safety rules adopted pursuant to Chapter 3748. of the Revised Code, handlers of fluoroscopic radiation-generating equipment shall comply with the following:

(1) Any individual who is in the room during the fluoroscopic procedure shall be adequately protected by standing behind a whole body protective barrier or shall be required to wear a protective lead apron of not less than 0.25 millimeter lead equivalent;

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All individuals who are in the room during fluoroscopic procedures shall be protected by standing behind a whole-body protective barrier or by wearing a protective lead apron of not less than 0.25-millimeter lead equivalent.

(2) Protective lead or lead equivalent gloves shall be used by individuals who are required to have their hands in or near the useful beam; and

Any individual who is required to place their hands in or near the useful beam shall wear protective lead equivalent gloves. In according with Ohio Administrative Code 3701:1-66-02(G)(3)(a), the protective gloves (material) must not be less than 0.5-millimeter lead equivalent.

(3) Handlers of fluoroscopic equipment used for interventional or cardiac procedures or on pediatric or pregnant patients shall maintain a record of:

Interventional procedure means an invasive procedure that utilizes radiation-generating equipment for diagnostic or therapeutic purposes. Generally, any fluoroscopic procedure in which an organ system is entered using a needle or catheter for diagnostic or therapeutic purposes. Common examples of these organ systems include the vascular, neurologic, spinal, hepatobiliary, gastric, urinary and reproductive systems.

Cardiac procedures mean all anatomic or physiological studies of intervention, both diagnostic and therapeutic, in which the heart or coronary arteries are entered via a systemic vein or artery using a catheter that is manipulated under fluoroscopic visualization.

Pediatric patients mean any patient that has not yet reached 18 years of age.

Pregnant patients mean any patient that is known to be pregnant.

(a) Cumulative air kerma or dose area product used for each examination, if the display of either is available on the fluoroscopic equipment; or

When the fluoroscopic equipment displays either the cumulative air kerma or dose area product, the handler shall maintain a record of the cumulative air kerma or dose area product for all interventional, cardiac, pediatric, or pregnant patient fluoroscopy procedures.

If neither the cumulative air kerma or dose area product are displayed on the fluoroscopic equipment, follow the requirements of paragraph (B)(3)(b) of this rule.

(b) The following items if the cumulative air kerma or dose area product is not displayed on the fluoroscopic equipment:

(i) Mode of operation such as high-level or pulsed mode;

(ii) Cumulative fluoroscopic exposure time; and

(iii) Number of radiographs and number of acquisitions.

When the fluoroscopic equipment does not display the cumulative air kerma or dose area product, the handler shall maintain a record of the mode of operation, total exposure time and number of radiographs and acquisitions for all interventional, cardiac, pediatric, or pregnant patient fluoroscopy procedures.

Mode of operation may include normal, high-level, pulsed, cine or automatic.

Cumulative (total) fluoroscopic exposure time.

Number of static images, digital or film.

(C) In addition to other applicable quality assurance requirements of Chapter 3701:1-66 of the Administrative Code, handlers of fluoroscopic equipment shall comply with the following:

(1) Handlers shall designate and utilize a radiation expert who shall develop in writing and perform fluoroscopic image quality evaluations appropriate for the fluoroscopic equipment including written procedures to include time intervals and system conditions for the evaluation of image quality;

A radiation expert is an individual defined in Ohio administrative Code 3701:1-66-01.

A radiation expert must be designated by the handler (facility) to:

- **Develop written procedures for the evaluation of image quality to include time intervals and system conditions appropriate for the fluoroscopic equipment being evaluated.**
- **Perform image quality evaluation appropriate for the fluoroscopic equipment.**

(2) On new installations or reinstallations of existing equipment prior to patient exposure, handlers shall utilize a radiation expert to perform the following:

New installation is the first time that new fluoroscopic equipment is installed in a specific location.

Re-installation of existing fluoroscopic equipment is when existing fluoroscopic equipment is removed from its current location in a facility and re-installed in the same location or another location in that facility.

(a) Radiographic device tests to determine compliance with allowable limits as specified in paragraph (A)(12) of this rule;

On new installation or reinstallation of existing equipment and prior to patient exposure, a radiation expert (medical physicist) designated in paragraph (C)(1) of this rule, must test radiography (spot film or radiographic imaging) device that use the fluoroscopic image assembly to ensure the primary x-ray beam is properly collimated, aligned and centered to the selected portion of the imaging receptor.

Also, in accordance with paragraph (C)(3) of this rule, after this initial evaluation, the radiation expert must perform this test annually thereafter.

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(b) Fluoroscopic image quality evaluations as specified in paragraph (C)(1) of this rule;

On new installation or reinstallation of existing equipment and prior to patient exposure, a radiation expert (medical physicist) designated in paragraph (C)(1) of this rule, must test the fluoroscopic image quality to ensure all test results are within the respective tolerance limits specified in the written procedures developed pursuant to paragraph (C)(1) of this rule.

Also, in accordance with paragraph (C)(3) of this rule, after this initial evaluation, the radiation expert must perform this test annually thereafter.

(c) Air kerma rate tests as specified in paragraph (C)(6) of this rule;

On new installation or reinstallation of existing equipment and prior to patient exposure, a radiation expert (medical physicist) designated in paragraph (C)(1) of this rule, must test the fluoroscopic air kerma rate (AKR), at the measurement point specified in paragraph (C)(6) of this rule, to ensure the AKR is within the maximum limit specified in paragraph (A)(8) of this rule.

Also, in accordance with paragraph (C)(3) of this rule, after this initial evaluation, the radiation expert must perform this test annually thereafter.

(d) High contrast and low contrast resolution evaluations in both fluoroscopic and radiographic modes;

On new installation or reinstallation of existing equipment and prior to patient exposure, a radiation expert (medical physicist) designated in paragraph (C)(1) of this rule, must test the high and low contrast resolution in both fluoroscopic and radiographic modes.

Also, in accordance with paragraph (C)(3) of this rule, after this initial evaluation, the radiation expert must perform this test annually thereafter.

(e) Five minute timer evaluations; and

On new installation or reinstallation of existing equipment and prior to patient exposure, a radiation expert (medical physicist) designated in paragraph (C)(1) of this rule, must test the five-minute timer.

Also, in accordance with paragraph (C)(3) of this rule, after this initial evaluation, the radiation expert must perform this test annually thereafter.

(f) Evaluation of the accuracy of technique factor indicators and integrated radiation dose displays;

On new installation or reinstallation of existing equipment and prior to patient exposure, a radiation expert (medical physicist) designated in paragraph (C)(1) of this rule, must evaluate the accuracy of the technique indicators and integrated radiation dose displays.

Also, in accordance with paragraph (C)(3) of this rule, after this initial evaluation,

the radiation expert must perform this test annually thereafter.

(3) After initial evaluations of fluoroscopic equipment have been performed, the test and evaluations in paragraph (C)(2) of this rule shall be performed by a radiation expert annually;

After initial evaluation of the fluoroscopy equipment, a radiation expert (medical physicist) must perform all test and evaluations in paragraph (C)(2) of this rule annually. This includes radiographic beam size evaluations, fluoroscopic image quality evaluations, air kerma rate, high and low contrast resolution, five-minute timer, and technique factor indicator and integrated radiation dose display accuracy.

Annually means at intervals not to exceed one year, plus or minus one month.

(4) After repair or replacement of any component of the fluoroscopic equipment which may alter the radiation output or image quality, prior to patient use, a radiation expert shall perform and document measurements of air kerma rates as specified in paragraph (C)(6) of this rule and image quality as specified in paragraph (C)(1) of this rule unless in the documented determination of a radiation expert, the repair or replacement will not cause a significant change in radiation output or significant degradation of image quality as specified in the quality assurance program;

A radiation expert shall perform and document, prior to patient use, measurements of air kerma rates and image quality after any repair or replacement of any component that may alter the radiation output or image quality of the fluoroscopic equipment, unless in the documented determination of a radiation expert, as part of the quality assurance program, the repair or replacement will not cause a significant change in radiation output or degradation of image quality.

(a) The radiation expert may designate qualified individuals to perform and document the measurements specified in paragraphs (C)(6) and (C)(1) of this rule;

The radiation expert may designate qualified individuals to perform and document air kerma rate and image quality measurements following the repair or replacement of any component of the fluoroscopic equipment. The measurements must be performed and documented, prior to patient use and in accordance with paragraphs (C)(6) and (C)(1) of this rule.

The radiation expert can either designate individuals by name and qualification, or a group of individuals by credentials. The radiation expert must document his/her qualification criteria in the quality assurance program as required by paragraph (C)(4)(b) of this rule.

(b) The radiation expert shall provide the criteria for qualifying these designees in the quality assurance program; and

The radiation expert shall provide the criteria that an individual or individuals must meet to perform air kerma rate and image quality measurements following post-repair or replacement of any component that may alter the radiation output or

image quality of the fluoroscopic equipment. These measurements must be made prior to patient use, and the radiation expert must document the qualifying criterion for the designees in the written quality assurance program.

(c) The radiation expert's approval of the designee's test results shall be documented within thirty days;

If a designee performs the post-repair or replacement measurements, the radiation expert must provide documented approval of the designee's measurements within 30 days. Electronic documentation is acceptable.

(5) The results of all tests performed in accordance with paragraphs (C)(2) to (C)(4) of this rule shall:

(a) Include the technique factors used in determining such results;

The documented record of the results of the tests required by paragraphs (C)(2) to (C)(4) of this rule must include the technique factors (kVp, mA, time, x-ray pulse or mAs) used for the testing/evaluation.

This applies to initial, annual, and after repair or replacement evaluations/testing of the following:

- **Spot film or radiographic imaging evaluations,**
- **Fluoroscopic image quality evaluations,**
- **Air kerma rate,**
- **High and low contrast resolution,**
- **Five-minute timer, and**
- **Accuracy of the technique factor indicators and integrated radiation dose display**.

(b) Include the name of the individual performing the measurements;

The documented record of the results of the test performed must include the name of the individual who performed the test.

(c) Include the date the measurements were performed; and

The documented record of the results of the test performed must include the date the test measurements were performed.

(d) Be maintained by the IRRP between inspections for review by the department;

The documented record of the results of the following tests must be kept by the Individual Responsible for Radiation Protection between inspections:

- **Spot film or radiographic imaging evaluations,**
- **Fluoroscopic image quality evaluations,**
- **Air kerma rate,**
- **High and low contrast resolution,**
- **Five-minute timer, and**
- **Accuracy of the technique factor indicators and integrated radiation dose display**.

Guidance in Bold Text

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(6) Compliance with air kerma rate allowable limits in paragraph (A)(8) of this rule shall be determined as follows:

(a) If the source is below the x-ray table, the air kerma rate shall be measured at one centimeter above the tabletop or cradle;

For x-ray sources below the table, compliance must be determined at one centimeter above the tabletop.

(b) If the source is above the x-ray table, the air kerma rate shall be measured at thirty centimeters above the tabletop with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement;

For x-ray sources above the table, compliance must be determined at 30 centimeters above the tabletop with the beam limiting device or spacer positioned as close as possible to this 30-centimeter measurement point.

(c) For c-arm type fluoroscopic equipment, the air kerma rate shall be measured at thirty centimeters from the input surface of the image receptor with the source positioned at any SID;

For c-arm x-ray sources, compliance must be determined at 30 centimeters from the surface of the image receptor with x-ray source (tube) positioned at any source-to-image distance.

(d) For fixed SID lateral fluoroscopes attached to the x-ray table, the maximum air kerma rate shall be measured at a point fifteen centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the table top is moveable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than fifteen centimeters to the centerline of the table;

For fixed source-to-image distance lateral fluoroscopes attached to the x-ray table, compliance must be determined at 15 centimeters from the centerline of the x-ray table with the end of the beam limiting device or spacer cone as close as possible to the 15-centimeter measurement point.

(e) For c-arm type fluoroscopic equipment having a SID less than forty-five centimeters, the air kerma rate shall be determined at the minimum SSD; and

For miniature c-arm having source-to-image distances less than 45 centimeters, compliance must be determined at the minimum source-to-skin distance.

(f) The maximum air kerma rate shall be determined with the kVp, mA and/or other selectable parameters adjusted to those settings which give the maximum air kerma rate. X-ray systems that

incorporate automatic exposure control shall have sufficient attenuative material placed in the useful beam to produce the maximum exposure rate of the system.

When determining the maximum air kerma rate, the kVp, mA and/or other selectable parameters must be set to give the maximum air kerma rate.

When determining the maximum air kerma rate of fluoroscopy equipment using automatic exposure control, there must be enough attenuative material in the beam to produce the maximum exposure rate from the fluoroscopic unit.

(D) Handlers of mobile fluoroscopic equipment shall not be required to comply with the requirements of paragraphs (A)(10), and (A)(11) of this rule and paragraph (H) of rule 3701:1-66-02 of the Administrative Code.

Mobile fluoroscopic equipment is not required to comply with the following requirements:

- **Paragraph (A)(10) of this rule regarding a Bucky slot cover;**
- **Paragraph (A)(11) of this rule regarding protective drapes; and**
- **Rule 3701:1-66-02(H) regarding structural shielding.**

(E) Handlers of c-arm fluoroscopic equipment having a maximum SID less than forty-five centimeters shall not be required to comply with the requirements of paragraphs (A)(5)(e), (A)(5)(f), (A)(10), (A)(11), and (A)(12) of this rule and paragraph (H) of rule 3701:1-66-02 of the Administrative Code. In addition, if a radiation expert has specified in the registrant's quality assurance program that an individual is unlikely to receive a total effective dose equivalent of greater than two millirem in any one hour or one hundred millirem in a year, the handler shall not be required to comply with the requirements of paragraph (B)(1) of this rule.

Miniature c-arm fluoroscopic equipment is not required to comply with the following requirements:

- **Paragraph (A)(5)(e) of this rule regarding beam-limiting devices having step-less adjustment of the x-ray field;**
- **Paragraph (A)(5)(f) of this rule regarding step-less adjustment at the maximum source-to-time distance.**
- **Paragraph (A)(10) of this rule regarding a Bucky slot cover;**
- **Paragraph (A)(11) of this rule regarding protective drapes;**
- **Paragraph (A)(12) of this rule regarding radiographic beam alignment; and**
- **Rule 3701:1-66-02(H) regarding structural shielding.**

(F) All individuals operating fluoroscopic equipment, and individuals likely to receive an annual effective dose equivalent in excess of one millisievert (one hundred millirem) from participating in fluoroscopic procedures, shall receive at least two hours of radiation protection training specific to fluoroscopy in addition to the training required by rule 3701:1-38-10 of the Administrative Code prior to performing or participating in fluoroscopic procedures. Additionally, each individual shall receive one hour of re-training whenever the individual receives in excess of thirty per cent of the allowable occupational dose measured over one calendar year.

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All individuals operating fluoroscopic equipment must receive at least 2 hours of radiation protection training specific to fluoroscopy prior to performing or participating in fluoroscopic procedures.

All individuals likely to receive an annual effective dose equivalent in excess of 1 mSv (100 mrem) from participating in fluoroscopic procedures shall receive at least 2 hours of radiation protection training specific to fluoroscopy prior to performing or participating in fluoroscopic procedures.

This includes but not limited to:

- **Radiologic technologists, radiologists;**
- **Surgery personnel: physicians, nurses, and anesthesiologists; and**
- **Speech Therapist.**

In addition, if an individual receives in excess of thirty per cent of the allowable occupational dose (5rem) measured over one calendar year, the individual must receive one hour of retraining.

Because of the many variables which contribute to exposure an individual may receive from participating in fluoroscopic procedures, the radiation expert must justify those individuals that are not required to receive the training. Appropriate justification from a radiation expert would be documented in the written quality assurance program and include at least, but limited to, the following:

- **Results from a survey of the radiation levels in the areas surrounding the fluoroscopic unit, as performed by a radiation expert (medical physicist) [please reference rule 3701:1-38-14(A) of the Administrative Code]; and**
- **Based on the results of this survey along with the application of use and occupancy factors, a determination by the radiation expert, of which individuals are unlikely to receive an annual effective dose equivalent in excess of 1 mSv (100 mrem) in a year.**

(G) The training required by paragraph (F) of this rule shall be approved by the registrant's designated radiation expert, and be specific to the type of fluoroscopic equipment used. Documentation of receiving the training required by paragraph (F) of this rule shall be retained by the registrant and be available for review upon inspection. At a minimum, training topics shall include, but not be limited to:

The radiation expert designated by your facility must approve the 2-hour fluoroscopy training specific to the fluoroscopy type used at the facility. The facility's designated radiation expert can approve fluoroscopy training that occurred at another facility if s/he obtains the receipt of training documents that include all the topics listed below for review at the Ohio Department of Health inspection.

The training must include the following topics:

(1) Principles and operation of the fluoroscopic equipment to be used;

The training must include the principles and operation of the fluoroscopic equipment.

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(2) Fluoroscopic and radiographic outputs of each mode of operation, including high-level control options clinically used;

The training must include a description of each mode of operation.

(3) Dose management, including dose reduction techniques for fluoroscopic equipment;

The training must include dose reduction techniques.

(4) Safe operating procedures of each piece of fluoroscopic equipment that may be used by each individual.

The training must include a review of the safe operating procedures, which are part of the written quality assurance program pursuant to the requirements of rule 3701:1-66-04(B)(4) of the Administrative Code.

(5) Units of measurement and dose, including dose-area product values and air kerma;

The training must include units of measurement and dose, including dose-area product values and air kerma.

(6) Radiation protection methods for patient and staff;

The training must include radiation protection principles: time, distance, shielding.

(7) Basic properties of radiation; and

The training must include a description of the basic properties of radiation.

(8) Biological effects of radiation.

The training must include a description of the biological effects of radiation.

(H) Fluoroscopic equipment used for radiation therapy procedures is regulated pursuant to rule 3701:1-67-09 of the Administrative Code.

Fluoroscopic equipment used for radiation therapy procedures is regulated pursuant to Ohio Administrative Code 3701:1-67-09.

(I) Computed tomography scanners equipped with fluoroscopic capabilities are regulated pursuant to rule 3701:1-66-10 of the Administrative Code.

Computed tomography scanners equipped with fluoroscopic capabilities are mainly used for image guidance procedures and are regulated pursuant to Ohio Administrative Code 3701:1-66-10.