Ohio Administrative Code

Rule 3701:1-66-07 Medical fluoroscopic equipment.

Effective: December 13, 2024

(A) Fluoroscopic equipment will 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 will not be less than:

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

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

(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 prevents that distance, in which case it will not be less than ten centimeters. Such systems will be used for extremity or dental purposes only;

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

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

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

(5) Fluoroscopic equipment will 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 will 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 will be no greater than four per cent of the SID; and

(ii) For rectangular x-ray fields used with circular image receptors, the error in alignment will 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 will conform with one of the following obligations:

(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 will 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 will not extend beyond the edge of the visible area of the image receptor by more than two centimeters;

(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 will 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 will be no greater than four per cent of the SID; and

(ii) The error in alignment will 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 will indicate whenever the automatic field adjustment is overridden. Each such system failure override switch will be clearly labeled as follows:

"For X-ray Field Limitation System Failure;"

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

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

(6) Timers will meet the following specifications:

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

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

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

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

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

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

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

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

(7) X-ray production in the fluoroscopic mode will 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 will 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;

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

(a) Fluoroscopic equipment provided with only automatic exposure rate control, or provided with both automatic exposure rate control and manual mode capabilities, will 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;

(b) Fluoroscopic equipment provided with only manual mode capabilities will 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

(c) For fluoroscopic equipment that is provided with high-level control, and the high-level control is activated, the air kerma rate will 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;

(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, will be needed to avoid accidental use; and

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

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

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

(11) For undertable fluoroscopic equipment, protective drapes, or other devices, at least 0.25 millimeter lead equivalent will 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 will not substitute for wearing obligated protective apparel;

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

(a) A means will 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 will 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 will 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;

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

(d) Means will 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 will not exceed five centimeters by five centimeters;

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

(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 will be continuously displayed and updated at least once every second;

(b) The cumulative air kerma in units of milligrays will 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 will be clearly distinguishable from the display of the cumulative air kerma;

(d) The AKR and cumulative air kerma will 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 will be the respective locations specified in paragraph (C)(6)(a), (C)(6)(b) or (C)(6)(d) of this rule; or

(ii) For C-arm fluoroscopes, the reference location will be fifteen centimeters from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location will 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;

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

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

(14) Fluoroscopic equipment manufactured on or after June 10, 2006 will be equipped with means to display a last image hold (LIH) image following 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 will 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 will be selectable prior to the fluoroscopic exposure, and the combination selected will be indicated prior to initiation of the fluoroscopic exposure; and

(c) Means will be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph will 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 will comply with the following:

(1) Any individual who is in the room during the fluoroscopic procedure will be adequately protected by standing behind a whole body protective barrier or will wear a protective lead apron of not less than 0.25 millimeter lead equivalent. If a handler's radiation expert includes documented evidence and specifies in the quality assurance program a distance and time interval in the room from the source at which 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 can forgo the use of a

protective barrier or lead apron for that time at that distance;

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

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

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

(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.

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

(1) Handlers will designate and utilize a radiation expert who will 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;

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

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

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

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

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

(e) Five minute timer evaluations; and

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

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

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

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

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

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

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

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

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

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

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

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

(b) If the source is above the x-ray table, the air kerma rate will 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;

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

(d) For fixed SID lateral fluoroscopes attached to the x-ray table, the maximum air kerma rate will 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 will 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;

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

(f) The maximum air kerma rate will 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 will have sufficient attenuative material placed in the useful

beam to produce the maximum exposure rate of the system.

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

(E) Handlers of c-arm fluoroscopic equipment having a maximum SID less than forty-five centimeters will not be obligated to comply with the obligations 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 will not be obligated to comply with the obligations of paragraph (B)(1) of this rule.

(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, will receive at least two hours of radiation protection training specific to fluoroscopy in addition to the training obligated by rule 3701:1-38-10 of the Administrative Code prior to performing or participating in fluoroscopic procedures. Additionally, each individual will 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.

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

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

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

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

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

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

(6) Radiation protection methods for patient and staff;

(7) Basic properties of radiation; and

(8) 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.

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