CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(Amendment)

902 KAR 100:125. Fluoroscopic x-ray~~[except for computed tomography x-ray systems]~~.

RELATES TO: KRS 311B, 21 C.F.R. 1020.31, 21 C.F.R. 1020.32~~[211.842-211.852,] [211.990(4)]~~

STATUTORY AUTHORITY: KRS 194A.050, 211.025, 211.842~~[211.090]~~, 211.844

CERTIFICATION STATEMENT:

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet. KRS 211.025 requires the cabinet to administer all laws related to public health and do all other things reasonably necessary to protect and improve the health of the people. KRS 211.842 requires the cabinet to develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, nonionizing, and electronic product radiation. ~~[The Cabinet for Human Resources is authorized by]~~ KRS 211.844 requires the cabinet to provide by administrative regulation for the registration and licensing of the possession or use of sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste.~~[The purpose of]~~ This administrative regulation establishes the~~[is to provide special]~~ requirements for the possession, use, and operation of fluoroscopic x-ray systems in the healing arts.

Section 1. Applicability. This administrative regulation shall apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor~~[fluoroscopic x-ray systems]~~ and to persons~~[, equipment]~~ and materials used in connection with the possession and use or operation of these~~[such]~~ systems.

Section 2. Equipment.

(1) Only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy.

(2) All equipment shall be operated per the manufacturer's specifications and shall comply with the following federal requirements:

(a) 21 C.F.R. 1020.32(a), Primary protective barrier;

(b) 21 C.F.R. 1020.32(b)(1) and (2), Field limitation;

(c) 21 C.F.R. 1020.32(b)(4), Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors;

(d) 21 C.F.R. 1020.32(b)(5), Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently rectangular image receptors;

(e) 21 C.F.R. 1020.32(b)(6), Override capability;

(f) 21 C.F.R. 1020.31(h), Field limitation and alignment for spot-film devices;

(g) 21 C.F.R. 1020.32(c), Activation of tube;

(h) 21 C.F.R. 1020.32(d), Air kerma rates (AKR);

(i) 21 C.F.R. 1020.32(f), Indication of potential and current;

(j) 21 C.F.R. 1020.32(g), Source-skin distance;

(k) 21 C.F.R. 1020.32(h), Fluoroscopic irradiation time, display, and signal;

(l) 21 C.F.R. 1020.32(j)(1), (2), and (3), Display of last-image-hold (LIH); and

(m) 21 C.F.R. 1020.32(k), Displays of values of AKR and cumulative air kerma.

(3) Exceptions.

(a) Compliance with subsection (2)(b) of this section shall be determined with beam axis indicated to be perpendicular to the plan of the image receptor.

(b) Measurement shall be made in perpendicular directions corresponding to the vertical and horizontal directions on the video monitor image.

(c) For collimating systems that are not circular, measurement shall be made along the directions closest to the vertical and horizontal direction on the monitor image.

(d) Absent manufacturers specific tube potential for the indication of potential and current in subsection (2)(i) of this section, kVp shall not vary by plus or minus ten (10) percent.

Section 3. Equipment Performance Evaluations.

(1) Fluoroscopic equipment shall be evaluated by a qualified expert (QE):

(a) Within thirty (30) days of installation; and

(b) Within thirty (30) days of any maintenance or repairs that may affect the exposure rate.

(2) Evaluations shall include:

(a) Measurement of the air entrance exposure rates that covers a sample of patient thickness, including those that are expected to drive the system to maximum output in all modes clinically used. These measurements shall meet the following:

1. For fluoroscopic systems without automatic exposure control (AEC), measurements shall be made using a milliamperage and kVp typical of the clinical use of the system; and

2. For fluoroscopic systems with AEC, measurements shall be made using sufficient attenuating material in the useful beam to produce milliamperage and kVp typical of the clinical use of the system;

(b) A measurement and verification of compliance with maximum AKR for fluoroscopy and high-level control, if applicable, in accordance with section 2(h) of this administrative regulation; and

(c) An evaluation of:

1. The image quality in the modes necessary to achieve the clinical image task;

2. The operation of the five (5) minute timer, warning lights, interlocks, and collision sensors;

3. The availability and accuracy of technique indicators and integrated radiation dose displays;

4. The beam quality and collimation in fluoroscopy mode; and

5. Any changes to the fluoroscopy system or room that may impact radiation safety.

(3) Following the evaluation required by subsection (1) of this section, measurements shall be made annually at intervals not to exceed fourteen (14) months from the date of the prior measurement or under the direction of a QE.

(4) Measurements required by this section shall be performed with a calibrated dosimetry system per manufacturer recommendations or not to exceed two (2) years.

(5) Evaluation records required by this section shall be maintained at the facility for five (5) years for inspection by the cabinet.

Section 4. Control of Scattered Radiation.

(1) All stationary fluoroscopic systems shall have a shielding plan evaluation performed by a qualified expert and approved by the cabinet prior to clinical use. A confirmatory protection survey shall be submitted to the cabinet within thirty (30) days of initial use to confirm shielding meets the requirements of 902 KAR Chapter 100. Records of the shielding plan evaluation, approval from the cabinet, and protection survey shall be kept on file at the facility for the life of the fluoroscopic system.

(2) Mobile fluoroscopic systems used for more than one (1) week in one (1) location shall be considered stationary and shall require a shielding plan evaluation, approval from the

cabinet, and protection survey. Records of the shielding plan evaluation, approval from the cabinet, and protection surveys shall be kept on file at the facility for the life of the system.

(3) All existing stationary and mobile fluoroscopic systems used for more than one (1) week in one (1) location that do not have a shielding plan evaluation and approval from the cabinet on file shall have a confirmatory protection survey performed by a QE by July 1, 2028. Record of this confirmatory survey shall be kept on file at the facility for the life of the system.

(4) Ancillary shielding, including drapes, self-supporting curtains, or viewing shields, shall be available for all stationary fluoroscopic systems and used as supplemental protection for all individuals other than the patient in the room during a fluoroscopy procedure.

(5) The following conditions shall be met when sterile fields or special procedures prohibit the use of normal protective barriers or drapes:

(a) The ancillary shielding required by subsection (4) of this section is maintained to the highest degree possible under clinical conditions;

(b) The fluoroscopic field size is reduced to the minimum required for the procedure being performed (area of clinical interest);

(c) The operating and safety procedures reflect the conditions in subsection (4) of this section; and

(d) Fluoroscopy personnel exhibit awareness of situations requiring the use and non-use of the protective drapes.

Section 5. Operating Procedures and Auxiliary Equipment.

(1) Operators shall be:

(a) Licensed in accordance with KRS Chapter 311B; or

(b) Licensed practitioners operating within their scope of practice.

(2) Operators shall demonstrate competence with standard operating procedures for the fluoroscopic system in use, including available dose-saving features and the relative radiation output rates in various modes of operation.

(3) The registrant shall provide dosimetry to all personnel involved in fluoroscopic procedures.

(4) Protective gloves of at least 0.25 mm lead equivalent shall be readily available to any person whose hands may be in or near the useful beam.

(5) Protective aprons of at least 0.25 mm lead equivalence shall be worn by the fluoroscopist and by persons in the fluoroscopic room except the patient during each examination.

(6) The use of handheld fluoroscopic equipment shall be prohibited.

(7) Fluoroscopic x-ray systems designed for fluoroscopy shall not be used for spot filming or radiography.

(8) Dental fluoroscopic x-ray systems without image intensification shall not be used.

(9) All fluoroscopic images shall be viewed and interpreted by a licensed practitioner of the healing arts.

Section 6. Requirements for Facilities Performing Fluoroscopically Guided Interventional Procedures (FGI).

(1) The facility shall establish a written policy regarding patient dose management in fluoroscopically guided procedures that conforms with the American College of Radiology (ACR)-American Association of Physicists in Medicine (AAPM) Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures, National Council on Radiation Protection and Measurement report 168, or equivalent.

(2) Consistent with the facility policy and procedures established in accordance with subsection (1) of this section, the operator shall use methods available on the fluoroscopy

system to monitor dose during a fluoroscopic procedure.

(3) The written policy shall include a requirement to designate a person in the room to notify the operator that a substantial radiation dose limit (SRDL) or other dose metric value specified in the facility policy is approaching or has been exceeded.

(4) The registrant shall establish and implement written procedures that include:

(a) Identification of individuals who are authorized to use fluoroscopic systems for interventional purposes;

(b) Methods for patient radiation dose management during FGI procedures;

(c) Establishing dose metric notification levels for fluoroscopy procedures at which point the physician or other authorized operator is notified;

(d) SRDL values following nationally recognized standards;

(e) Actions to be taken for cases when a SRDL is exceeded, which may include patient follow-up;

(f) A documented review of the established processes and procedures at an interval not to exceed twelve (12) months; and

(g) Procedures for notifying the cabinet for diagnostic medical events in accordance with 902 KAR 100:147.

(5)

(a) Effective July 1, 2028, all individuals operating fluoroscopic equipment and occupationally exposed in the fluoroscopic room during fluoroscopic procedures, shall receive and document a minimum of four (4) hours of initial safety training.

(b) This training shall be approved by the radiation safety officer, QE, or a staff medical physicist and include:

1. Basic properties or radiation;
2. Biologic effects of x-ray;
3. Radiation protection methods for patients and staff;
4. Units of measurement and dose;
5. Factors that may affect fluoroscopic outputs;
6. High level control options;
7. Dose management including dose reduction techniques; and
8. Principles and operations specific to the fluoroscopic system used.

Section 7. Maintenance of Records for Fluoroscopic Systems.

(1) The following records shall be kept on file for review by the cabinet for five (5) years.

(a) A record of radiation output information shall be maintained by the registrant if a dose reconstruction calculation is necessary in accordance with the registrant's established protocols. The record shall contain:

1. Patient identification;
2. Date and type of examination;
3. Identification of the room or fluoroscopic system used;
4. The operator; and
5. Peak skin dose, cumulative air kerma, or dose area product used.

(b) If the information required by subparagraph 5. of paragraph (a) of this subsection is not displayed on the system, the record shall include:

1. The fluoroscopic mode, such as high level or pulsed mode;
2. Cumulative fluoroscopic exposure time; and
3. Number of recorded exposures.

(c) Safety training records for operators and individuals occupationally exposed shall include the date of the training, the name of the individual trained, and the content of the training.

(d) Repair records and equipment performance evaluations for the fluoroscopic systems.

(2) With the exception of records of shielding plan evaluations, cabinet approvals and protection surveys shall be kept on file at the facility for the life of the room or fluoroscopic system.

Section 8. Incorporation by Reference.

(1) The American College of Radiology (ACR)-American Association of Physicists in Medicine (AAPM) "Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures", National Council on Radiation Protection and Measurement report 168, revised 2023, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Radiation Health Branch, Division of Public Health Protection and Safety, Department for Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. Eastern Time or 7 a.m. to 3:30 p.m. Central Time.

(3) This material is available online at https://gravitas.acr.org/PPTS/GetDocumentView?docId=197. ~~[Fluoroscopic x-ray systems shall meet the following requirements:]~~

~~[(1)] [The tube housing assembly shall be of the diagnostic type;]~~

~~[(2)] [Cones or shutters used to restrict the size of the useful beam shall provide the same degree of attenuation as required of the tube housing; and]~~

~~[(3)] [Fluoroscopic imaging devices used for optical viewing which are not mechanically linked to the x-ray tube shall not be utilized.]~~

~~[Section 3.] [Protective Barrier and Field Size.]~~

~~[(1)] [The fluoroscopic tube shall not be capable of producing x-rays unless the primary protective barrier is in position to intercept the entire useful beam.]~~

~~[(2)] [The entire cross-section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at every SID (e.g., source to image receptor distance).]~~

~~[Section 4.] [Limitation to the Imaging Surface. The x-ray field shall be restricted so that the following requirements are met:]~~

~~[(1)] [On nonimage-intensified fluoroscopic x-ray systems, the x-ray field shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size during both fluoroscopic procedures and spot filming procedures. In addition:]~~

~~[(a)] [Means shall be provided for stepless adjustment of the field size;]~~

~~[(b)] [The minimum field size at the greatest SID shall be equal to or less than five (5) by five (5) centimeters;]~~

~~[(c)] [Equipment manufactured after February 25, 1978, if the angle between the image receptor and the beam axis of the x-ray beam is variable, shall be provided with the means to indicate if the axis of the x-ray beam is perpendicular to the plane of the image receptor; and]~~

~~[(d)] [Compliance with this subsection shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.]~~

~~[(2)] [On image-intensified fluoroscopic systems with manual shutter controls, the x-ray beam shall not exceed the area of the largest image receptor, if measured with the fluoroscopic image assembly positioned thirty-five and five-tenths (35.5) centimeters from the table top or panel surface, and with the manual shutter controls opened to the fullest extent. Collimators located between the image receptor and patients shall not be used to fulfill this requirement. Means shall be provided to reduce the x-ray field size to five (5) by five (5) centimeters or less at the maximum SID; or]~~

~~[(3)] [For image-intensified fluoroscopic equipment, neither the length nor 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 (3) percent of the SID. The sum of the excess length and width shall be no greater than four (4) percent of the SID.]

[(a)] [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.]

[(b)] [Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide] [continuous field sizes from the maximum obtainable to a field size of five (5) by five (5) centimeters or less.]

[(c)] [For equipment manufactured after February 25, 1978, if the angle between the image receptor and beam axis is variable, means shall be provided to indicate if the axis of the x-ray beam is perpendicular to the plane of the image receptor.]

[(4)] [Spot film devices which are certified components shall meet the following additional requirements:]

[(a)] [Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of the portion of the film which has been selected on the spot film selector. This adjustment shall be automatically accomplished except if the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;]

[(b)] [It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five (5) by five (5) centimeters;]

[(c)] [The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two (2) percent of the SID; and]

[(d)] [On spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate if the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.]

[(5)] [If a means exists to override the automatic x-ray field size adjustments required in this section, that means:]

[(a)] [Shall be designed for use only if the system fails:]

[(b)] [Shall incorporate a signal visible at the fluoroscopist's position which shall indicate if the automatic field size adjustment is overridden; and]

[(c)] [Shall be clearly and durably labeled as follows: "FOR X-RAY FIELD LIMITATION SYSTEM FAILURE".]

[Section 5.] [Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of an exposure. If recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposures, but means may be provided to permit completion of a single exposure of the series in process.]

[Section 6.] [Exposure Rate Limits. The entrance exposure rate allowable limits and requirements are as follows:]

[(1)] [The exposure rate at the point where the center of the useful beam enters the patient shall not exceed ten (10) roentgens per minute, except during recording of fluoroscopic images or if provided with optional high level control;]

[(2)] [If provided with optional high level control, the equipment shall not be operable at a combination of tube potential and current which results in an exposure rate in excess of five (5) roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.]

[(a)] [Special means of activation of high level controls shall be required. The high level control shall only be operable if continuous manual activation is provided by the operator.]

[(b)] [A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.]

[(3)] [Certified systems which do not incorporate an automatic exposure control shall not be operable at a combination of tube potential and current which results in an exposure rate in excess of five (5) roentgens per minute at the point where the center of beam enters the patient except during recording of fluoroscopic images or if provided with an optional high level control;]

[(4)] [Compliance with the entrance exposure rate limits shall be determined as follows:]

[(a)] [Movable grids and compression devices shall be removed from the useful beam during the measurement;]

[(b)] [If the source is below the table, exposure rate shall be measured one (1) centimeter above the tabletop or cradle;]

[(c)] [If the source is above the table, the exposure rate shall be measured at thirty (30) centimeters above the tabletop with the end of the beam limiting device or spacers positioned as closely as possible to the point of measurement;]

[(d)] [C-arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits in subsections (1), (2) and (3) of this section thirty (30) centimeters from the input surface of the fluoroscope imaging assembly with the source positioned at an available SID if the end of the spacer assembly or beam-limiting device is not closer than thirty (3) centimeters from the input surface of the fluoroscopic imaging assembly.]

[(5)] [Periodic measurements of the exposure rate shall be made. An adequate period for these measurements shall be annually or after maintenance of the system which might affect the exposure rate;]

[(a)] [Results of these measurements shall be posted where a fluoroscopist has ready access to them while using that fluoroscopic x-ray system and in the records required by these administrative regulations. Results of the measurements shall include the exposure rate in roentgens per minute, as well as the physical factors used to determine the data,] [the name of the person who performed the measurements, and the date the measurements were performed;]

[(b)] [Conditions of periodic measurement of entrance exposure rate are as follows:]

[1.] [The kVp shall be the kVp typical of clinical use of the x-ray system;]

[2.] [The measurement shall be made under the conditions of subsection (4) of this section;]

[3.] [Fluoroscopic x-ray system(s) that incorporate automatic exposure control (e.g., automatic brightness control) shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the fluoroscopic x-ray system; and]

[4.] [Fluoroscopic x-ray system(s) that do not incorporate automatic exposure control shall utilize a milliamperage typical of the clinical use of the fluoroscopic x-ray system. Materials (e.g., an attenuation block) shall be placed in the useful beam to protect the imaging system.]

[Section 7.] [Radiation Rate Limits Transmitted Through the Primary Barrier. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two (2) milliroentgens per hour at ten (10) centimeters from accessible surfaces of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate. The transmitted exposure rate shall be measured so that the following requirements are met:]

[(1)] [The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements] [averaged over an area of 100 square centimeters with no linear dimension greater than twenty (20) centimeters;]

[(2)] [If the x-ray source is below the table top, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned thirty (30) centimeters above the table top;]

[(3)] [If the x-ray source is above the table top and the SID is variable, the measurement shall be made with the end of the beam limiting device or spacer as close to the table top as it can be placed, except that it shall not be closer than thirty (30) centimeters;]

[(4)] [Movable grids and compression devices shall be removed from the useful beam during the measurement; and]

[(5)] [The attenuation block shall be positioned in the useful beam ten (10) centimeters from the point of measurement of the entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.]

[Section 8.] [Indication of Tube Potential and Current. During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated on the control panel or within view of the fluoroscopist.]

[Section 9.] [Source to Skin Distance. The source to skin distance shall not be less than:]

[(1)] [Thirty-eight (38) centimeters on stationary fluoroscopes certified under the federal performance standard;]

[(2)] [Thirty-five and five-tenths (35.5) centimeters on stationary fluoroscopes which are not certified under the federal performance standard;]

[(3)] [Thirty (30) centimeters on mobile fluoroscopic x-ray systems; or]

[(4)] [Twenty (20) centimeters for image-intensified fluoroscopes used for specific surgical applications. The written safety procedures shall provide precautionary measures to be adhered to during the use of this device.]

[Section 10.] [Fluoroscopic Timer. A means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray system. The fluoroscopic x-ray system shall not be able to be activated without this timer also being activated. The end of the predetermined period of irradiation shall be indicated by an audible signal. The audible signal shall continue until the timing device is reset. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting.]

[Section 11.] [Mobile Fluoroscopes. Mobile fluoroscopic systems shall be provided with image intensification. It shall be impossible to operate mobile fluoroscopic systems unless the useful beam is intercepted by the image intensifier.]

[Section 12.] [Control of Scattered Radiation.]

[(1)] [Fluoroscopic table designs combined with procedures utilized shall expose no unprotected part of staff or an ancillary person's body to unattenuated scattered radiation which originates from under the table. The attenuation required shall not be less than 0.25 mm lead equivalent; and]

[(2)] [Equipment configuration design combined with procedures shall expose no portion of staff or an ancillary person's body, except the extremities, to the unattenuated scattered radiation emanating from above the tabletop unless that individual:]

[(a)] [Is at least 120 cm from the center of the useful beam, or]

[(b)] [The radiation has passed through not less than 0.25 mm lead equivalent material (e.g., leaded drapes, Bucky slot cover panel, or self supporting leaded curtains) in addition to lead equivalency provided by protective aprons.]

[(3)] [Exceptions to subsection (2)(a) and (b) of this section may be made in some special procedures if a sterile field does not permit the use of the normal protective barriers. If the use of prefitted sterilized covers for the barriers is practical, the cabinet shall not permit an exception.]

[Section 13.] [Operating Procedures and Auxiliary Equipment. The following operating procedures and auxiliary equipment shall be utilized, if applicable, in the operation of a fluoroscopic x-ray system:]

[(1)] [Fluoroscopy performed by technologists shall be under the direction of a radiologist and be exclusively for localization purposes;]

[(2)] [Spot film images shall be obtained only by a licensed practitioner of the healing arts;]

[(3)] [Protective gloves of at least 0.25 mm lead equivalent shall be readily available to the fluoroscopist during every examination;]

[(4)] [The eyes of the fluoroscopist shall be adequately dark-adapted before using nonimage-intensified fluoroscopic x-ray systems;]

[(5)] [Extraneous light that interferes with the fluoroscopic examination shall be eliminated;]

[(6)] [Hand-held fluoroscopic screens shall not be used;]

[(7)] [Protective aprons of at least 0.25 mm lead equivalence shall be worn by the fluoroscopist and by persons in the fluoroscopic room except the patient during each examination;]

[(8)] [Fluoroscopic x-ray systems designed strictly for fluoroscopy shall not be used for spot filming or radiography; and]

[(9)] [Dental fluoroscopic x-ray systems without image intensification shall not be used.]

[Section 14.] [Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from the requirements of Sections 4, 6, and 10 of this administrative regulation if:]

[(1)] [Systems are designed and used in a manner that no individual other than the patient is in the x-ray room if the system is producing x-rays; and]

[(2)] [Systems which do not meet the requirements of Section 10 of this administrative regulation are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in these cases that the timer be reset between examinations.]

COMPILER'S NOTE: 2025 RS HB 6, enacted by the General Assembly on March 27, 2025, altered the information to be provided at the time an administrative regulation is filed. Aside from formatting changes necessary to upload the regulation into the LRC's publication application, this regulation has been published as submitted by the agency.

JOHN R. LANGEFELD, MD, Commissioner
STEVEN J. STACK, MD, MBA, Secretary

APPROVED BY AGENCY: October 30, 2026
FILED WITH LRC: November 5, 2026 at 1:40 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on January 25, 2027, at 9:00 a.m. Eastern Time, 8 a.m. Central Time, using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by January 15, 2027, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation through January 31, 2027. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; Phone: 502-564-7476; Fax: 502-564-7091; CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Julie Brooks, Krista Quarles; Phone Number: (502) 229-3377, (502) 564-7476; Email: julied.brooks@ky.gov, CHFSregs@ky.gov

Subject Headings:Consumer Protection, Medical Imaging and Radiology, Public Health, Radiation Machines

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This administrative regulation establishes the requirements for the possession, use, and operation of fluoroscopic x-ray systems in the healing arts.

(b) The necessity of this administrative regulation:
This administrative regulation is necessary to help mitigate the potential risks associated with a fluoroscopy procedure.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet. KRS 211.842 requires the cabinet to develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, nonionizing, and electronic product radiation.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
This administrative regulation will ensure medical practitioners who perform fluoroscopy procedures do so in a safe manner that protects the patient and themselves from radiation exposure.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:
The amendment to this administrative regulation adopts the code of federal regulation standards for performance standards for ionizing radiation emitting products, adds requirements for equipment performance evaluations, adds procedures to control scatter radiation, updates operating procedures including requirements for facilities performing fluoroscopically guided interventional procedures, adds safety training requirements for all personnel who are occupationally exposed during fluoroscopic procedures, updates the record keeping requirements, and incorporates by reference the technical standard for management of the use of radiation in fluoroscopic procedures.

(b) The necessity of the amendment to this administrative regulation:
The amendment to this administrative regulation is necessary to ensure all fluoroscopy procedures are performed in a safe manner that protects the patient and medical personnel from accidental exposure. The adoption of the code of federal regulation standards for performance standards for ionizing radiation is necessary to ensure the state standards are in full compliance with federal standards.

(c) How the amendment conforms to the content of the authorizing statutes:

KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet. KRS 211.842 requires the cabinet to develop and conduct programs for evaluation and control of hazards associated with the use of sources of ionizing, nonionizing, and electronic product radiation. The amendment to this administrative regulation ensures all fluoroscopic x-ray systems are operated in a manner that protects the user and the patient.

(d) How the amendment will assist in the effective administration of the statutes:
The amendment to this administrative regulation will ensure the use of fluoroscopy x-ray systems meets the most current federal standards and is utilized in a safe manner that protects both the patient and the individuals using the system.

(3) Does this administrative regulation or amendment implement legislation from the previous five years?No.

(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
There are currently 1,100 medical, hospital, and therapeutic facilities utilizing computed tomography (CT scan), fluoroscopy, and therapeutic external beam radiation therapy.

(5) Provide an analysis of how the entities identified in question (4) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (4) will have to take to comply with this administrative regulation or amendment:
All facilities will need to be aware of the revised standards and update internal practices, policies, and procedures to comply with the amendment to this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4):
There should be minimal to no cost to the facilities to comply with the amendment to this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4):
By complying with the amendment to this administrative regulation, facilities will be able to ensure the safety of patients and staff who are exposed to this source of ionizing radiation.

(6) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:
This is an ongoing program; there are no initial costs.

(b) On a continuing basis:
There are no increased costs on an ongoing basis.

(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation or this amendment:
The Radiation Health Branch is supported through a mix of state General Fund dollars and revenue received from registration and inspection fees.

(8) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

An increase in fees or funding is not necessary to implement the amendment to this administrative regulation.

(9) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

There are no fees established in this administrative regulation.

(10) TIERING: Is tiering applied?

Tiering is not applied as the requirements of this administrative regulation are applied equally to all regulated entities.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 194A.050, 211.025, 211.842, and 211.844.

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:

The Cabinet for Health and Family Services, Department for Public Health, Division of Public Health Protection and Safety, is the promulgating agency.

(a) Estimate the following for the first year:

Expenditures:There will be no impact on program expenditures. The Radiation Health Branch currently issues licenses for the use of fluoroscopic x-ray systems, and staff regularly conduct inspections of these systems. These functions will not be impacted by the amendment to this administrative regulation.

Revenues:This administrative regulation does not generate revenue.

Cost Savings:This administrative regulation will not result in cost savings.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

There will be no change in expenditures, revenues, or cost savings in subsequent years.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts):

There are no identified local entities.

(a) Estimate the following for the first year:

Expenditures:Not applicable.

Revenues:Not applicable.

Cost Savings:Not applicable.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

Not applicable.

(4) Identify additional regulated entities not listed in questions (2) or (3):

The additional regulated entities include medical, hospital, and therapeutic facilities utilizing computed tomography (CT scan), fluoroscopy, and therapeutic external beam radiation therapy.

(a) Estimate the following for the first year:

Expenditures:This administrative regulation should not result in increased expenditure for the additional regulated entities in the first year. If funds are expended for compliance with this administrative regulation, the range can be between $40,000 and $400,000 to purchase new fluoroscopy systems. This range is dependent on the type of fluoroscopy system purchased. Refurbished systems can range between $15,000 and $40,000. This would be a one-time expense and be considered part of the cost of doing business.

Revenues:This administrative regulation does not generate revenue for the additional regulated entities.

Cost Savings:This administrative regulation does not result in overall cost savings for the additional regulated entities.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?
There will be no change in expenditures, revenues, and cost savings in subsequent years.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:
The amendment to this administrative regulation will have no fiscal impact on the department. The impact to the additional regulated entities will be dependent on the need to update or replace any existing fluoroscopy systems. Most facilities utilizing fluoroscopy systems are in compliance with the requirements of this administrative regulation. Newly purchased fluoroscopy systems can range in price from $40,000 to $400,000 depending on the type of system purchased. Refurbished systems are available at a lower cost.

(b) Methodology and resources used to determine the fiscal impact:
The cost of fluoroscopy systems was obtained through an internet search.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). ($500,000 or more, in aggregate)
This administrative regulation does not have an overall negative or adverse major economic impact. If a facility needs to purchase a new fluoroscopy system, the cost would not exceed $500,000.

(b) The methodology and resources used to reach this conclusion:
The internet search showed a variety of fluoroscopy systems, ranging from mini-C arm systems as the lowest cost ($40,000 to $80,000) up to advanced 3D flat-panel systems ($180,000 to $400,000). The cost to the facility will be dependent on the number and type of systems purchased

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.
21 C.F.R. 1020.31, Radiographic equipment, and 21 C.F.R. 1020.32, Fluoroscopic equipment.

(2) State compliance standards.
KRS 194A.050(1).

(3) Minimum or uniform standards contained in the federal mandate.
The provisions of 21 C.F.R. 1020.31 are applicable to all equipment for radiography manufactured on or after November 29, 1984. The provisions of 21 C.F.R. 1020.32 are applicable to all equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, manufactured on or after November 29, 1984. These standards ensure all equipment used throughout the commonwealth are safe and protect the patient and staff from accidental radiation exposure.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?
No, this administrative regulation does not impose stricter requirements, or additional or different responsibilities or requirements.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.
Not applicable.