

Georgia Administrative Code
Department 290. RULES OF DEPARTMENT OF HUMAN SERVICES
Chapter 290-5. PUBLIC HEALTH
Subject 290-5-22. X-RAY

Current through Rules and Regulations filed through September 17, 2018

Rule 290-5-22-.04. X-Rays in the Healing Arts

- (1) Scope. This part establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized in accordance with State statutes to engage in the healing arts. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations.
- (2) General Requirements.
 - (a) Training of Operators who Administer X-ray in the Healing Arts.
 1. The registrant shall assure the Department that all radiation machines and associated equipment under his control are operated only by individuals instructed in safe operating procedures.
 2. The registrant shall require persons operating his radiation machine and associated equipment to receive, at a minimum, six hours of instruction. The following subject categories shall be covered:
 - (i) Protection Against Radiation
 - (I) Protective Clothing
 - (II) Patient Holding
 - (III) Time, Distance, Shielding
 - (IV) Radiation Protection Standards
 - (ii) Dark Room Techniques
 - (I) Developing Chemicals
 - (II) Film Protection
 - (III) Cassettes
 - (IV) Screens
 - (iii) Patient Protection
 - (I) Beam Limitation

- (II) Setting Up Techniques
- (III) Biological Effects of Radiation

- (iv) Machine Safety
 - (I) Machine Functions
 - (II) Safety Procedures
 - (III) Recognizing Problems

3. Instruction required by .04(2)(a)2. shall begin within 30 days after employment and shall be completed no later than 90 days after date of employment. The registrant shall maintain a record of all training for each operator. Such record shall be made available for Departmental inspection. This rule shall take effect 180 days after the effective date of these regulations.
 4. Persons who show written proof that they have received the required instruction are considered to meet the requirements of .04(2)(a)2.
- (b) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:
 1. All individuals shall be positioned such that no part of the body will be struck by the useful beam, unless protected by at least 0.5 millimeter meter lead equivalent material; and
 2. Staff and ancillary personnel who must remain in areas because of their required presence during an x-ray procedure, shall be protected from direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent; and
 3. Patients, other than the one being radiographed, who cannot be removed from the x-ray room shall be protected by a barrier of at least .25 mm Pb equivalent or be at least 2 meters from the tube head and the image receptor.
 - (c) Except for dental intraoral radiography, veterinary, or portable x-ray use, the operator's position at the controls shall be in a protected area that will meet the radiation protection requirements of rule **.03(2)(a)1.** of these regulations.
 - (d) Except for therapy exposures, gonad shielding of not less than 0.25 millimeter lead equivalent shall be available and shall be used when the gonads are in the useful beam except when its use will interfere with the diagnostic information on the image receptor.
 - (e) Individuals shall only be exposed to the useful beam for healing arts purposes except as required by law enforcement officials or their designated representatives in the

interest of public safety. This provision specifically prohibits deliberate exposure of persons for non-productive x-ray procedures such as for training, demonstration, or for other non-healing arts purposes.

- (f) When a patient or film must be provided with auxiliary support during a radiation exposure:
 1. Mechanical holding devices shall be used when the technique permits. Holding shall be used only when other means of support cannot be utilized.
 2. No individual shall be used routinely to hold film or patients.
 3. When holding is required, the person holding shall be provided with protective clothing and shall be positioned so that no part of the body is struck by the useful beam.
- (g) Portable equipment shall be used only for examinations where it impractical, for medical purposes, to transfer the patient to the x-ray suite.

(3) Information and Maintenance Records and Associated Information.

- (a) The registrant shall maintain the following information for each radiation machine for inspection by the Department:
 1. Model and serial numbers of x-ray tube housing and generator; and
 2. Records of surveys, calibrations, maintenance, and modifications performed on the radiation machine(s) with the names of persons who performed such services.
- (b) The vendor shall supply the registrant with a record of all maintenance performed, or parts replaced or installed, written in a clear and legible manner.

(4) Light Fields. When used for aligning or centering an x-ray field, a light field shall have a clearly defined perimeter and have illumination intensity equal to the needs for collimation or alignment. For collimators equipped with beam defining lights, this requirement will be deemed to be met if the illumination at the receptor is visible to the x-ray operator under normal room illumination in all quadrants of the light field.

(5) Darkroom and Film Processors.

- (a) Darkrooms used for film processing and/or developing shall be light tight.
- (b) Each darkroom shall be equipped with a safelight which will meet or exceed the requirements of the radiographic film. This will be deemed to have been met if the film manufacturer's recommendations are followed.

- (c) Except for automatic developing systems, each darkroom shall have and use a solution thermometer and timing device. Sight development shall be prohibited.
- (d) The chemical solution used for manual film development shall not be used for periods in excess of two (2) months. Records of solution changes shall be maintained.
- (e) When automatic film processing is used it shall be maintained in accordance with the manufacturer's recommendations and a record of cleaning and developer change shall be maintained.
- (f) Unexposed film shall not be subject to radiation levels in excess of 0.2 mR during the period of storage.
- (g) Unexposed film which is outdated shall not be used for human radiographic procedures.

(6) General Requirements for all Diagnostic Radiation Machines. In addition to other requirements of this part, all diagnostic radiation machines shall meet the following requirements:

- (a) Warning Label. The control panel containing the main power switch shall bear the following warning statement, in a manner legible and accessible to view:
"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed"
- (b) Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.
- (c) Leakage Radiation From The Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly, measured at a distance of 1 meter in any direction from the source, shall not exceed 100 milliroentgens in 1 hour when the x-ray tube is operated at its leakage technique factors.
- (d) Beam Quality.
 - 1. Half-value layer.
 - (i) The half-value layer of the useful beam for a given x-ray tube potential shall be no less than the values shown in Table I. If it is necessary to determine the half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I

Design Operating Range (Kilovolts Peak)	Measured Potential (Kilovolts Peak)	Half-value layer (Millimeters of Aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2

130	3.5
140	3.8
150	4.1

- (ii) The requirements of .04(6)(d)1.(i) will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II.

TABLE II

Filtration Required vs. Operating Voltage

Total Filtration	
Operating Voltage (kVp) (inherent plus added)	
(millimeters aluminum equivalent)	
Below 50	0.5 millimeters
50 to 70	1.5 millimeters
Above 70	2.5 millimeters

- (iii) Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.
- (iv) For capacitor energy storage equipment, compliance with the requirements of .04(6)(d)1.(i) shall be determined with the maximum quantity of charge per exposure.
- (v) The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

2. Filtration Controls. For radiation machines which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by .04(6)(d)1.(i) or (ii) is in the useful beam for the given kVp which has been selected.
- (7) Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.
 - (8) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the radiation machine.
 - (9) Technique Indicators. The technique factors to be used during an exam shall be indicated prior to any exposure. This requirement may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.
 - (10) Exposure Timing.
 - (a) Except in fluoroscopy a device shall be used to terminate and accurately reproduce the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.
 - (b) Except for fluoroscopy, dental intraoral and panographic, veterinary, and procedures requiring the use of portable barriers, the exposure switch shall be so located that it cannot be conveniently operated outside of a shielded area.
 - (c) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second.
 - (d) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.
 - (e) Automatic exposure controls.
 1. When an automatic exposure control is provided, indication shall be made on the control panel when this mode of operation is selected.

2. When an automatic exposure control is provided, a backup timer shall be required. The backup timer shall be capable of terminating the exposure at a preset time should the automatic exposure control fail. The preset time shall be consistent with the technique used.
- (f) The x-ray production shall be controlled by a deadman switch.
 - (g) It shall not be possible to make an exposure when the time is set to a zero or off position if either position is provided.
 - (h) Termination of an exposure shall cause automatic resetting of the timing device to its initial setting or to zero.
- (11) Hand-held fluoroscopic screens are prohibited except for law enforcement or forensic requirements, and then only upon approval by the Department.
- (12) Fluoroscopic Radiation Machines. All fluoroscopic radiation machines shall meet the following requirements:
- (a) Limitation of Useful Beam.
 1. Primary Barrier.
 - (i) Image intensification shall be used with all fluoroscopic machines. 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.
 - (ii) The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier and image intensifier are in position to intercept the entire useful beam.
 2. X-Ray Field.
 - (i) For image-intensified fluoroscopic equipment, neither the length nor the width of the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.
 - (b) Spot film devices which are certified components shall meet the following additional requirements:
 1. 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 that portion of the film which has been selected on the spot film selector; and

2. 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; and
 3. 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 2 percent of the SID.
- (c) Pre-certified fluoroscopic machines are exempt from the requirements of .04(12)(a) and .04(12)(b) provided that:
1. The machine was in service prior to the date of adoption of these regulations and meets all other applicable requirements for fluoroscopic machines. However, these machines shall be brought up to standards referenced in .04(12)(a) and (b) within three years from the date of adoption of these regulations or be taken out of service and electronically disabled.
 2. The shutter mechanism is adjusted so that the x-ray field diameter is limited to the dimensions of the film cassette used during spot filming at a 35 centimeters (14 inches) table-to-image-receptor distance.
 3. When spot films are either unnecessary or not required during a portion of the exam, the leading edge of the shutters shall be restricted to the edge of the image intensifier.
- (d) Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a dead man switch. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.
- (e) Exposure Rate Limits.
1. Entrance Exposure Rate Allowable Limits.
 - (i) When the automatic brightness control is used, the exposure measured at the point where the center of the useful beam enters the patient shall not exceed 10 roentgens per minute, except during recording of fluoroscopic images.
 - (ii) When provided with optional high level control, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated.
 - (I) Special means of activation of high level controls shall be required. The high level control shall only be operable when a continuous secondary level of pressure is provided by the operator.

- (II) When the high level control is activated the entrance exposure rate shall not exceed 10 R/min. except in the recording of fluoroscopic images.
 - (III) A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
- (iii) In addition to the other requirements of .04(12)(e)1.(i) and (ii), certified equipment which does not incorporate an automatic exposure control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of beam enters the patient, except during recording of fluoroscopic images or when provided with an optional high level control.
 - (iv) Non-certified equipment shall not operate at any combination of tube potential and current which will result in an exposure in excess of 10 R/min.
2. Compliance with the requirements .04(12)(e)1. shall be determined as follows:
- (i) Movable grids and compression devices shall be removed from the useful beam during the measurement;
 - (ii) With the source below the table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle;
 - (iii) With the source above the table, the exposure rate shall be measured 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;
 - (iv) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.
- (f) Periodic measurement of Entrance Exposure Rate. The registrant shall cause periodic measurement of entrance exposure rate, including the exposure rate at staff positions around the table and panel, to be made for each fluoroscope by an individual competent to make such measurements. Results of these measurements shall be posted where any fluoroscopist may have ready access to them. An adequate period for such measurements shall be annually or after any maintenance of the unit if such maintenance might affect the exposure rate. Results of the measurements shall include the maximum possible R/minute of the fluoroscope at the maximum kVp and mA used. The posted data shall indicate the technique factors used to determine the data along with the name of the person and/or

company performing the measurements and the date the measurements were performed.

1. Fluoroscopes that incorporate automatic exposure control shall have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the x-ray machine; and
 2. Fluoroscopes that do not incorporate an automatic exposure control shall utilize a milliamperage typical of the clinical use of the radiation machine.
- (g) Barrier Transmitted Radiation Rate Limits. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.
- (h) Indication of Potential and Current. During fluoroscopy and cine-fluorography, the kV and the mA shall be continuously indicated.
- (i) Source-Skin Distance. The source to skin distance shall not be less than:
1. 38 centimeters (15 inches) on stationary fluoroscopes;
 2. 30 centimeters (12 inches) on all mobile fluoroscopes;
 3. 20 centimeters (8 inches) for image intensified fluoroscopes, used for specific surgical application;
 4. 30 centimeters (12 inches) on stationary precertified fluoroscopes.
- (j) Fluoroscopic Timer. Means shall be provided to preset the cumulative "on" time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. Termination of the exposure or a signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on time. Such signal shall continue to sound while x-rays are produced or until the timing device is reset. Audible signals are recommended.
- (k) Radiation Therapy Simulation Machines. Radiation therapy simulation shall be exempt from all the requirements of .04(12)(a), .04(12)(e), .04(12)(f) and of .04(12)(j) provided that:
1. Such machines are designed and used so that no individual other than the patient is in the x-ray room during radiography procedures; and
 2. Such machines which do not meet the requirements of .04(12)(j) are provided with a means of indicating the cumulative exposure time for each individual patient. Procedures shall require in each case that the timer be reset between examinations.

(13) Radiographic Machines Other Than Fluoroscopic, Dental Intraoral, and Veterinary.

- (a) Beam Limitation. The useful beam shall be limited to the area of clinical interest, and shall not be greater than the dimensions of the image receptor.
- (b) General Purpose Stationary and Mobile Radiation Machines.
 - 1. Means for stepless independent adjustment in both the longitudinal and transverse direction of the x-ray field and a light for visually defining the perimeter of the x-ray field shall be provided.
 - 2. Means shall be provided to permit adequate light intensity at the film plane when the light field intersects with the image receptor at a 100 cm SID. This will be deemed to be met if a visual outline of the light field is visible at the receptor.
 - 3. Congruence of the x-ray and light fields shall not have a misalignment in excess of 2% of the SID in any one direction and not more than 3% of the SID when measured as the sum of the absolute misalignment in the longitudinal and transverse direction.
- (c) Additional Requirements for Stationary General Purpose Radiation Machines. In addition to the requirements of .04(13)(b), all stationary radiation machines shall meet the following requirements:
 - 1. Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the film plane with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent; and
 - 2. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted.
- (d) Machines Designed for or Provided With Special Attachments for Mammography.
 - 1. Radiographic machines designed only for mammography and general purpose radiographic machines, when special attachments for mammography are in service, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID, except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID.
 - 2. This requirement can be met with a machine which performs as prescribed in .04(13)(e).
 - 3. Each image receptor support intended for installation on a system designed only for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.
- (e) Special Purpose Radiation Machines. Radiation machines which are limited by design to radiographic examinations of a specific anatomical region shall meet the following requirements:

1. The x-ray field in the plane of the image receptor shall be limited such that the field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor;
2. The center of the x-ray field shall be aligned with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor;
3. Section **.04(13)(e)2.** may be met with a machine that meets the requirements for a general purpose radiation machine as specified in .04(13)(b) or, when alignment means are also provided;
4. For special purpose cephalometric use, an assortment of removable, fixed-aperture, beam-limiting devices sufficient to limit the beam to areas of clinical interest may be used. Each such device shall have clear and permanent markings to indicate the image receptor size and the SID for which it is designed;
5. Special purpose radiographic units will be exempt from the primary barrier requirements of .01(8)(b)1. provided that the tube housing assembly is electronically interlocked to a primary protective barrier, or the tube housing assembly is mechanically fixed such that the entire cross section of the useful beam is always intercepted by a primary barrier sufficient to attenuate the useful beam to the limits specified in .03(2). Secondary barriers shall meet the shielding requirements of .01(8)(b)1.

(f) Radiation Exposure Control Device.

1. Each x-ray control shall meet the following requirements:
 - (i) stationary radiation machines shall have the exposure switch permanently mounted in such a way as to prevent the operator from leaving the protected area of the operator's barrier during the exposure;
 - (ii) except for unique situations such as those found in intensive care units or operating room suites, mobile and portable radiation machines which are used for greater than 1 week in 1 location, (i.e., 1 room or suite) shall meet the requirements of .04(13)(f)1.(i).
 - (iii) The x-ray control device shall provide audible or visual indication observable at or from the operator's protected position whenever x-rays are produced. For certified radiation machines, a signal audible to the operator shall indicate that the exposure has terminated.
2. Portable Equipment.
 - (i) Provisions of .04(13)(f) apply except for exposure switch location.

- (ii) The exposure switch shall be so arranged that the operator can stand at least 1.8 meters (six feet) from the patient, the x-ray tube, and the useful beam unless there is shielding sufficient to assure compliance with .03(2)(a).
- (iii) The source-to-skin distance shall be limited to not less than 30 centimeters (12 inches).
- (iv) Protective aprons of at least 0.25 mm lead equivalent shall be available and their use shall be required of the operator.
- (v) Personnel monitoring is required of all operators.
- (vi) Mobile or portable Radiation machines which are used for greater than one week in one location, i.e., (one room or suite of rooms) shall meet the requirements of .01(8).

(g) Structural Shielding.

1. In addition to the requirements in .01(8), diagnostic radiation machines routinely used in one location shall meet the following requirements for structural shielding:
 - (i) All areas of the walls, floors, and ceiling exposed to the primary beam shall have primary barriers; and
 - (ii) Secondary protective barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers or where primary barrier requirements are less than secondary barrier requirements.
2. For stationary radiation machines and mobile or portable equipment routinely used in one location:
 - (i) Except for those unique situations found in such uses as the intensive care unit, operating suite, etc., the operator's station at the controls shall be behind a protective barrier which will intercept any radiation that has been scattered only once.
 - (ii) The operator's protective barrier shall be equipped with a glass window of lead equivalency equal to that required of the adjacent barrier, or a mirror system so placed that the entire patient can be seen by the operator while the exposure is made.
 - (iii) Facilities constructed or modified after the effective date of these regulations shall have built-in operator's protective barriers which will insure that the limits specified in .03(2)(a) are not exceeded.

(h) Source-to-Skin Distance.

1. All radiographic machines, except as provided for in .04(13) (h)2., shall be provided with means to limit the source-to-skin distance to not less than 30 centimeters (12 inches).
 2. A radiographic machine intended for specific surgical and dental application may be used with a SSD less than 30 centimeters, (12 inches), but in no case less than 20 centimeters (8 inches).
- (i) Radiation From Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(14) Intraoral Dental Radiographic Machines.

- (a) Source-to-Skin Distance. Radiation machines designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, i.e., SSD, to not less than 18 centimeters (7 inches), if operable above 50 kVp, or 10 centimeters (4 inches), if not operable above 50 kVp.
- (b) Field Limitation.
1. Radiographic machines designed for use with an intra-oral image receptor shall be provided with means to limit the x-ray beam such that the diameter of the useful beam at the end of the cylinder shall not be greater than 7.0 centimeters (2.75 inches). For intraoral rectangular collimation the useful beam at the end of the spacer shall not have a diagonal measurement greater than 7.0 centimeters (2.75 inches). Positioning devices should be used to assure beam alignment.
 2. An open ended shielded cylinder, or other open ended shielded spacers that will meet the requirements of .04(14)(a) and (b)1. shall be used.
- (c) Structural Shielding.
1. The provisions of .01(8) shall apply, except that National Council on Radiation Protection and Measurements Report No. 35, "Dental X-Ray Protection," or its current revision or replacement, shall be referenced by the Department.
 2. When dental x-ray units are installed in adjacent rooms or areas, protective barriers sufficient to reduce the exposure to the requirements of .03(2) shall be provided between the rooms and/or areas.
- (d) Operating Procedures.
1. Patient and film holding devices shall be used when the techniques permit.
 2. Neither the tube housing nor the position indicating device shall be hand-held during an exposure.

3. Mechanical support of the tube head shall maintain the exposure position without drift.
 4. Dental fluoroscopy shall not be used without image intensification and shall meet the requirements of .04(12).
 5. Only persons required for the radiographic procedure shall be in the x-ray room during exposure. All persons shall be adequately protected.
 6. The operator shall be able to view the patient during an exposure.
 7. During each exposure, the operator shall stand at least 1.8 meters (6 feet) from the patient and tube head and outside the path of the useful beam or behind a barrier that meets the requirements of .03(2).
- (e) The total filtration in the useful beam shall not be less than the appropriate values stated in .04(6)(d)1.(i) or (ii).

(15) Veterinary Radiographic Installations.

(a) Equipment.

1. The tube housing shall be of the diagnostic type.
2. The primary beam for diagnostic purposes in radiography and fluoroscopy should not be larger than clinically necessary and shall not be greater than the image receptor. Cones, diaphragms, or adjustable collimators capable of restricting the primary beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required in the tube housing.
3. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.
4. The exposure switch shall be of a dead-man type.
5. The total filtration permanently in the useful beam shall not be less than the appropriate value stated in .04(6)(d)1.(i) or (ii).
6. A means shall be provided for aligning the center of the x-ray beam with the center of the image receptor prior to an x-ray examination.
7. An easily discernible indicator which shows whether or not x-rays are being produced shall be on the control panel.
8. The installation shall be so arranged that the operator can stand at least six feet from the animal, the x-ray tube and out of the useful beam.
9. Leaded gloves and aprons shall be available for use, and shall be used by all personnel in the room during an exposure.

10. The effectiveness of protective equipment (i.e., gloves, aprons, etc.), shall not be impaired.

(b) Operating Procedures.

1. Only persons whose presence is necessary shall be in the radiographic area during exposure. Protective clothing of at least 0.25 mm lead equivalent shall be provided and shall be worn by all individuals required to be in controlled areas, except when the individuals are entirely behind protective barriers while the equipment is energized.

2. Patient support:

(i) When an animal patient or film must be held in position for radiography, mechanical supporting or restraining devices, or other means of immobilization, shall be used unless human holding is required by the technique.

(ii) If an animal patient must be held or positioned manually, the individual holding the animal shall wear protective gloves having at least 0.5 mm lead equivalency and a protective apron of at least 0.25 mm lead equivalency;

(iii) Personnel monitoring devices shall be used if radiation measurements indicate potential exposure in excess of 25 percent of the applicable values specified in Section **.03(2)(a)1**. to the head, or trunk of the body.

(c) Fluoroscopy.

1. The provisions of .04(12) shall apply to fluoroscopic equipment.

(d) Structural Shielding. The provisions of .01(8) shall apply except that the National Council on Radiation Protection and Measurements Report No. 36, "Radiation Protection in Veterinary Medicine," or its current revision or replacement, shall be referenced by the Department.

(16) Therapeutic Radiation Machines of Less Than One MeV.

(a) Leakage Requirements. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the value specified, at the distance specified for the classification of that radiation machine.

1. Contact Therapy Machines. Leakage radiation shall not exceed 100 milliroentgens (.0258 mC/Kg) an hour at five (5) centimeters from the surface of the tube housing assembly.

2. 0-150 kVp Machines.

(i) Machines which were manufactured or installed prior to the date of adoption of these regulations shall not permit radiation leakage in excess

of 1 Roentgen (.258 mC/Kg) in one (1) hour at one (1) meter from the source.

(ii) In machines manufactured on, or after the date of adoption of these regulations, leakage radiation shall not exceed 100 mR (.0258 mC/Kg) in one (1) hour at one (1) meter from the source.

3. 151 to 999 kVp Systems. The leakage radiation does not exceed one (1) roentgen (.258 mC/Kg) in one (1) hour at one (1) meter from the source except systems that operate in excess of 500 kVp may have a leakage radiation at 1 meter from the source not to exceed 0.1 percent of the useful beam one meter from the source.

(b) Permanent Beam Limiting Devices. The registrant shall be responsible for assuring that permanent fixed diaphragms or cones used for limiting the useful beam shall provide at least the same protection as required by the tube housing assembly.

(c) Removable and Adjustable Beam Limiting Devices.

1. Removable beam limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful x-ray beam at the maximum kilovoltage and with maximum treatment filter.

2. Adjustable beam limiting devices installed after the effective date of these regulations shall transmit not more than 1 per cent of the useful x-ray beam.

3. Adjustable beam limiting devices installed before the effective date of these regulations shall transmit not more than 5 per cent of the useful x-ray beam.

(d) Filter System.

1. The filter system shall be so designed that the filters cannot be accidentally displaced from the useful beam at any possible tube orientation; and

2. The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 roentgens (7.74 mC/Kg) per hour under any operating conditions; and

3. Each filter shall be conspicuously inscribed as to its material of construction and its thickness. For wedge filters, the wedge factor and wedge angle shall appear on the wedge or wedge tray.

(e) Tube Immobilization. The tube housing assembly shall be capable of being immobilized during stationary treatments.

(f) Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such marking shall be readily accessible for use during calibration procedures.

(g) Timer.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall be graduated in minutes and fractions of minutes.
 2. The timer shall have a preset time selector and an elapsed time indicator.
 3. The timer shall be a cumulative timer which activates with the radiation and retains its reading after irradiation is interrupted or terminated.
 4. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to cycle the present time selector through zero time.
 5. The timer shall permit accurate presetting and determination of exposure times as short as 1 second.
 6. The timer shall not permit an exposure if set at zero.
 7. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.
- (h) Control Panel Functions. The control panel, in addition to the displays required in other provisions of .04(16), shall have:
1. an indication of x-ray production; and
 2. means for indicating kV and x-ray tube current; and
 3. means for terminating an exposure at any time; and
 4. a locking device which will prevent unauthorized use of the radiation machine; and
 5. for radiation machines installed after the date of adoption of these regulations, a positive display of specific filter(s) in the beam.
- (i) Source-to-Skin Distance. There shall be means of determining the SSD distance to within 1 centimeter.
- (j) Low Filtration X-Ray Tubes. Each radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and at the control panel.
- (k) Calibrations and Spot Checks.
1. Calibrations.
 - (i) The calibration of therapeutic radiation machines shall be performed at intervals not to exceed 1 year and after any change or replacement of components which could cause a change in the radiation output.
 - (ii) The registrant shall insure that such calibration is performed by an individual competent to perform such work.

- (iii) Records of calibrations performed shall be maintained by the registrant for at least 5 years after completion of the calibration.
 - (iv) A copy of the most recent radiation machine calibration shall be available at the control panel.
 - (v) The radiation machine shall not be used in the administration of radiation therapy unless the calibrations required by .04(16)(k)1.(i)-(iv) have been met.
2. Spot Calibration Checks. Spot calibration checks on radiation machines capable of operation at greater than 150 kVp shall be performed in accordance with written procedures. A record of such checks shall be maintained for a two (2) year period after completion of the spot-check measurements.

(17) Additional Facility Design Requirements for Therapy Radiation Machines Capable of Operating Above 50 kVp and less than 1 MeV.

- (a) Voice Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.
- (b) Viewing Systems.
 - 1. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.
 - 2. When the primary viewing system is by electronic means, an alternate viewing system, which may also be electronic, shall be available for use in the event of electronic failure.
 - 3. In the event of total failure of patient viewing, therapy shall be discontinued until the system is functioning.
- (c) Structural Shielding. In addition to the provisions of .01(8):
 - 1. For existing equipment operating above 125 kVp the required operator's barrier(s) shall be an integral part of the building;
 - 2. For all therapeutic machines operating below 150 kVp, built or modified after the effective date of these regulations, the operator's barrier(s) shall be an integral part of the building;
 - 3. For equipment operating above 150 kVp, the control panel shall be within a protective booth equipped with an interlocked door, or located outside the treatment room.

(d) Additional Requirements for Radiation Machines Capable of Operation Above 150 kVp and less than 1 MeV.

1. All necessary shielding, except for any beam interceptor, shall be provided by fixed barriers;
2. The control panel shall be outside the treatment room;
3. All doors of the treatment room shall be electrically connected to the control panel such that x-ray production cannot occur unless all doors are closed;
4. When the treatment room door is opened during any exposure, the exposure shall terminate immediately;
5. After termination of the exposure, it shall be possible to restore the radiation machine to full operation only upon closing the door, and subsequently reinitiating the exposure at the control panel.

(e) Operating Procedures.

1. Therapeutic radiation machines shall not be left unattended unless the machine is secured.
2. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used.
3. The tube housing assembly shall not be held by an individual during exposures.
4.
 - (i) For radiation machines operating above 150 kVp, no individual other than the patient shall be in the treatment room during exposures.
 - (ii) For machines operating below 150 kVp, no individual other than the patient shall be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of these regulations.

(18) X-Ray and Electron Therapy Machines with Energies of One MeV and Above.

(a) Scope. This part applies to medical facilities using therapy machines with energies of 1 MeV and above. Additional requirements for these machines are found in Section **290-5-22** -.05 entitled "Radiation Safety Requirements for Particle Accelerators".

(b) Requirements for Equipment.

1. Leakage Radiation to the Patient Area.
 - (i) New equipment shall meet the following requirements:

(I) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including x-rays, electrons, and neutrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to but not exceeding 200 square centimeters.

(II) For each machine, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in (.04)(18)(b)1.(i)(I) for the specified operating conditions. Records of leakage radiation measurements shall be maintained for inspection by the Department.

(ii) Existing equipment shall meet the following requirements:

(I) For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation excluding neutrons at any point in a circular plane of 2 meters radius centered on a perpendicular to the central axis of the beam 1 meter from the virtual source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding 100 square centimeters at the positions specified.

(II) For each machine, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in .04(18)(b)1.(ii)(I) for the specified operating conditions. Records of leakage radiation measurements shall be maintained for inspection by the Department.

2. Leakage Radiation Outside the Patient Area for New Equipment.

(i) The absorbed dose in rads (grays) due to leakage radiation except in the area specified in .04(18)(b)1.(i)(I) when measured at any point 1 meter from the path of the charged particle, before the charged particle strikes

the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in .04(18)(b)1.(i)(I).

(ii) The registrant shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in .04(18)(b)2.(i) for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to but not exceeding 100 square centimeters. Neutron measurements shall be averaged over an area up to but not exceeding 200 square centimeters.

3. The registrant shall assure that adjustable or interchangeable beam limiting devices are provided and that such devices shall transmit no more than 2 percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. Documentation of the transmission factors shall be maintained at the facility for inspection by the Department. The neutron component of the useful beam shall not be included in this requirement.

4. Filters.

(i) Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

(ii) For equipment manufactured after the effective date of these regulations which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters:

I) irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;

(II) an interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

(III) a display shall be provided at the treatment control panel indicating the filter(s) in use;

(IV) an interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

5. Beam Symmetry. In equipment manufactured after the effective date of these regulations, inherently capable of producing useful beams with asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated. It shall be the registrant's responsibility to assure that the above requirements are met and that records of confirming tests are maintained for Departmental inspection.
6. Beam Monitors. All therapy accelerator machines shall be provided with radiation detectors in the radiation head.
 - (i) New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.
 - (ii) Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.
7. Selection and Display of Dose Monitor Units.
 - (i) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.
 - (ii) The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.
 - (iii) After termination of irradiation, it shall be necessary to zero before subsequent treatment can be initiated.
 - (iv) For equipment manufactured after the effective date of these regulations, it shall be necessary after termination of irradiation to manually reset the preselected dose monitor units before irradiation can be initiated.
8. Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.
9. Termination of Irradiation by the Dose Monitoring System or Systems.

- (i) Each of the required monitoring systems shall be capable of independently terminating irradiation.
 - (ii) Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.
 - (iii) If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitoring units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
10. Termination Switches. It shall be possible to terminate irradiation and equipment movements at any time from the operator's position at the treatment control panel.
11. Timer.
- (i) A timer shall be provided which has a display at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.
 - (ii) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
 - (iii) For equipment manufactured after the effective date of these regulations after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.
 - (iv) The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems fail to do so.
12. Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:
- (i) Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.
 - (ii) An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.
 - (iii) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

- (iv) An interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.
 - (v) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.
 - (vi) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
13. Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:
- (i) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.
 - (ii) An interlock system shall be provided to prevent irradiation if any selected operations to be carried out in the treatment room do not agree with those selected operations carried out at the treatment control panel.
 - (iii) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.
 - (iv) For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than 20 percent or 3 MeV, whichever is smaller, from the selected nominal energy.
14. Selection of Stationery Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:
- (i) Irradiation shall not be possible until a selection of stationery beam therapy or moving beam therapy has been made at the treatment control panel.
 - (ii) An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.
 - (iii) An interlock system shall be provided to prevent irradiation if any selected operations to be carried out in the treatment room do not agree with those selected operations carried out at the treatment control panel.
 - (iv) The mode of operation shall be displayed at the treatment control panel.
 - (v) For new equipment, an interlock system shall be provided to terminate irradiation if:

- (I) movement of the gantry occurs during moving stationary beam therapy; or
 - (II) movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function.
- (vi) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.
 - (I) For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.
 - (II) for new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.
- (c) Facility and Shielding Requirements. In addition to Section **.01(8)** of these regulations, the following design requirements shall apply:
 1. The treatment control panel shall be located outside the treatment room; and
 2. Except for entrance doors or beam interceptors, all the required barriers shall be fixed; and
 3. Windows, mirrors, closed-circuit television, or other equivalent viewing devices shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. When the viewing system is by electronic methods, a secondary viewing system, which may also be electronic, shall be available for use in the event of failure of the primary system; and
 4. Provision shall be made for two-way aural communication between the patient and the operator at the treatment control panel; and
 5. The entrance to the treatment room shall be equipped with a steady, red warning light which operates when, and only when, radiation is being produced; and
 6. Interlocks shall be provided such that all entrance doors shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall be possible to restore the machine to operation only by closing the door and reinitiating exposure by manual action at the control panel.

(d) Calibrations and Spot Checks.

1. Calibration.

- (i) A calibration of all new machines and existing machines not previously surveyed shall be performed prior to the initial irradiation of a patient and thereafter at time intervals not to exceed 12 months, and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam. It shall be the responsibility of the registrant to ensure that the individual performing the calibration is competent to perform such calibrations.
- (ii) The calibration of a particle accelerator machine shall be performed in accordance with a calibration protocol such as that published by the American Association of Physicists in Medicine in Volume 10, number 6, issue of Medical Physics, or its current revision or replacement.
- (iii) Any calibration protocol used must contain the following minimum measurement criteria:
 - (I) full calibration measurements shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.
 - (II) spot-check measurements shall be performed using a dosimetry system that has been calibrated in accordance with .04(18)(d)1.(iii)(I) of this rule. Alternatively, a dosimetry system spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with .04(18)(d)1.(iii)(I) of this rule. This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.
- (iv) The full calibration of the therapy beam shall include but not be limited to the following determinations:
 - (I) verification that the equipment is operating in compliance with the design specifications concerning the light localizer, the side light and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at the specified depth.

- (II) the absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, and for each treatment distance used for radiation therapy.
- (III) the uniformity of the radiation field and any dependency upon the direction of the useful beam.
- (IV) verification of depth-dose data and isodose curves applicable to the specific machine.
- (V) verification of transmission factors for all accessories such as wedges shadow trays, etc.
- (VI) records of full calibration measurements and dosimetry system calibrations shall be preserved for 5 years after completion of the full calibration.
- (VII) a copy of the latest full calibration performed as described in .04(18)(d)1.(iv)(I)-(VI) shall be available at the accelerator facility.

2. Spot-Calibration Checks.

- (i) Spot-calibration checks shall be performed on machines subject to .04(18)(b) during calibrations and thereafter at intervals not to exceed one month.
 - (ii) Such spot-calibration checks shall be in accordance with written procedures and shall include absorbed dose measurements in a phantom at intervals not to exceed one week.
 - (iii) Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot-check; and
 - (iv) Records of spot-check measurements performed pursuant to .04(18)(b) shall be maintained by the registrant for a period of 2 years after completion of the spot-check measurements and any necessary corrective actions.
- (e) Qualified Expert. The registrant shall determine if a person is an expert qualified by training and experience to calibrate a therapy machine and establish procedures for (and review the results of) spot-check measurements. The registrant shall determine that the person calibrating their therapy machine:
- 1. is certified by the American Board of Radiology in Therapeutic Radiological Physics, Radiological Physics, Roentgen-Ray and Gamma-Ray Physics, or x-ray and Radium Physics; or

2. has the following minimum training and experience:
 - (i) a Master's or Doctor's degree in physics, biophysics, radiological physics or health physics;
 - (ii) one year of full-time training in therapeutic radiological physics; and
 - (iii) one year of full-time experience in a radiotherapy facility including personal calibration and spot-check of at least one therapy machine.
- (f) Operating Procedures.
1. No individual other than the patient shall be in the treatment room during treatment of a patient.
 2. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.
 3. The machine shall not be used in the administration of radiation therapy unless the requirements of .04(18)(d) have been met.

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