

**MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
RADIATION SAFETY SECTION
IONIZING RADIATION RULES GOVERNING THE USE OF RADIATION
MACHINES**

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PART 10. VETERINARY X-RAY INSTALLATIONS

R 333.5401 Purpose and scope.

Rule 401. (1) This part establishes requirements governing the use of x-radiation in veterinary medicine.

(2) This part applies to all registrants who use x-radiation in veterinary medicine or research for the intentional exposure of animals.

(3) In addition to the requirements of this part, all registrants are subject to R 333.5001 to R 333.5101 and all applicable provisions of the other parts.

History: 2016 MR 10, Eff. May 25, 2016

THERAPEUTIC MACHINES USED FOR VETERINARY X-RAY TREATMENT

R 333.5402 X-ray equipment.

Rule 402. The x-ray equipment shall meet the requirements of R 333.5312 and R 333.5321.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5403 Enclosures.

Rule 403. The enclosure shall meet the requirements of R 333.5315 and R 333.5322.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5404 Conditions of operation.

Rule 404. (1) Operation shall meet the requirements of R 333.5317 excluding subrules (2), (5), (6), and (11).

(2) The output of the x-ray generator should be calibrated initially before use for the treatment of animals. It should also be recalibrated after each tube replacement and after all changes or replacement in the generating apparatus which could affect a change in the x-ray output. Check calibrations should be made on an annual basis and records of all calibration maintained for not less than 5 years.

(3) Patients shall not be hand-held in position for radiation therapy. Mechanical supporting or restraining devices shall be used if restraint is required.

(4) An individual shall not be permitted in the treatment room when the tube is operated at any potential.

(5) The x-ray tube of a contact therapy machine as defined in R 333.5321(3) shall not be hand-held during irradiation. When practical, a cap of at least 0.5 millimeter lead equivalence should cover the aperture window of the tube housing of the apparatus when the apparatus is not

being used. Because the exposure rate at the surface of the window of contact therapy and beryllium window machines may be more than 10,000 roentgens per minute, extreme precautions are necessary to prevent accidental exposure to the useful beam.

(6) Lead, lead rubber, lead foil, and similar materials used for limiting the field, should not transmit more than 5% of the useful beam under the conditions at which the machine is operated for therapy.

FIXED RADIOGRAPHIC INSTALLATIONS

R 333.5405 X-ray equipment.

Rule 405. (1) All x-ray tube housings in fixed radiographic installations shall be of the diagnostic type.

(2) The aluminum equivalent of the total filtration in the useful beam shall not be less than the values shown in table 405.

TABLE 405

Operating Potential	Minimum Total Filter (Inherent plus added)
Below 50 kVp	0.5 mm aluminum
50-70 kVp	1.5 mm aluminum
Above 70 kVp	2.5 mm aluminum

(3) Beam-limiting devices, such as diaphragms, cones, or adjustable collimators, capable of restricting the useful beam to the area radiographically recorded shall be provided to define the beam and shall provide the same degree of attenuation as that required of the tube housing.

(4) Beam-limiting devices shall be calibrated in terms of the size of the projected useful beam at specified source-image receptor distances (SID). This calibration shall be clearly and permanently recorded on the beam-limiting device. Calibration of adjustable beam-limiting devices shall permit reproducible settings.

(5) X-ray systems designed for only 1 image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions not greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2% of the SID.

(6) General purpose radiographic x-ray systems should be equipped with adjustable beam-limiting devices containing light localizers that define the entire field.

(7) The size of the x-ray beam projected by fixed aperture beam-limiting devices, except those used for stereoradiography, shall not exceed the dimensions of the image receptor by more than 2% of the SID when the axis

of the x-ray beam is perpendicular to the plane of the image receptor.

(8) The calibrated field size indicator on adjustable beam-limiting devices shall be accurate to within 2% of the SID. The light field shall be aligned with the x-ray field with the same degree of accuracy. The field size projected by automatic adjustable beam-limiting devices shall provide the same precision.

(9) For radiographic procedures resulting in multiple views on a single image receptor the beam-limiting device shall limit the x-ray field size to the recorded radiographic image size within 2% of the SID. Covering a portion of the image receptor with radio-opaque material is not a substitute for proper x-ray field limitation.

(10) A device shall be provided which terminates the exposure at a preset time interval or exposure limit. The operator shall be able to terminate the exposure at all times by discontinuing pressure upon the exposure switch except that during serial radiography means may be provided to permit completion of a single exposure of the series in progress.

(11) A primary radiographic exposure switch shall be provided which shall be securely fixed so that the operator shall be behind a fixed shield which intercepts the useful beam and radiation which has been scattered only once.

(12) An auxiliary foot switch may be provided to activate the radiographic tube in addition to, but not in substitution of, the requirement of subrule (11) of this rule. This auxiliary switch need not be fastened behind a fixed shield.

(13) The control panel shall provide positive visual identification of the production of x-rays when the x-ray tube is energized. A millimeter may meet the requirement of this subrule.

(14) A signal audible to the operator shall indicate that the exposure has ended.

(15) The technique factors to be used during an exposure shall be indicated before the exposure begins. When automatic exposure controls are used, only those technique factors which are set before the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5407 Enclosures.

Rule 407. (1) An enclosure shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations.

(2) The degree of protection required for an enclosure shall be determined by the workload, use and occupancy factors, and the tube potential, tube current, mechanical movement, and distance. The design shall be subject to approval by the department.

(3) In a radiographic room, wall and floor areas exposed to the useful beam plus an additional area extending at least 30 centimeters (1 foot) beyond shall be provided with a primary protective barrier as determined by workload, use and occupancy factors, and distance. All vertical primary protective barriers specified in this rule shall extend continuously from the floor to a minimum height of 2.1 meters (7 feet).

(4) Secondary protective barriers shall be provided in the radiographic room ceiling and in those walls not requiring primary barriers.

(5) Control apparatus for the radiographic equipment shall be shielded by a primary protective barrier which cannot be removed from a protective position between the operator and the radiation source during machine operation.

(6) Movable barriers with electrical interlocks shall not be approved in place of compliance with subrule (5) of this rule.

(7) The primary exposure switch location and control shield shall be oriented so that, at arm's length from the exposure switch, the operator shall not be exposed to the useful beam, leakage radiation, or radiation which has been scattered only once.

(8) The operator shall be able to see and communicate with personnel within the room from a shielded position at the control panel. When an observation window is provided, it shall have a lead equivalence at least equal to that required of the control barrier and shall be installed so that the attenuation effectiveness of the barrier is not impaired.

(9) At times it may be necessary for personnel to remain within operating room or special procedure installations during radiographic exposures. A primary protective barrier shall be provided for personnel protection under these circumstances unless necessary technique prevents its use. This barrier may be movable if necessary. Movable barriers shall not be permitted in place of the provisions of subrules (3) and (5) of this rule.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5409 Conditions of operation.

Rule 409. (1) An operator shall properly utilize the beam-limiting devices provided to restrict the useful beam to the smallest area consistent with clinical requirements. Particular care shall be taken to align accurately the x-ray beam with the patient and film.

(2) The operator shall ensure the presence of adequate filtration before a radiographic procedure pursuant to R 333.5405(2).

(3) When a patient or film is held in position for radiography, mechanical supporting or restraining devices shall be available and shall be used unless contraindicated. Proper use of these devices shall permit the operator to stand behind the primary control shield during most radiographic procedures.

(4) If the patient or film is held by 1 or more individuals, each individual shall wear protective gloves and body aprons of 0.5 millimeter minimum lead equivalence. Each individual shall be so positioned that no part of his or her body is struck by the useful beam and that his or her body is as far as possible from the edge of the useful beam.

(5) Only individuals whose presence is necessary shall be permitted in the radiographic room during an exposure. These individuals shall be protected as specified in subrule (4) of this rule unless protected by an approved primary barrier.

(6) If an auxiliary foot switch is provided as specified in R 333.5405(12), it shall be used only by a licensed veterinarian and only at times when sufficient personnel are not available to permit use of the primary exposure switch specified in R 333.5405(11).

(7) To protect the feet of the veterinarian or his or her assistant from the primary beam while restraining patients, the underside of the radiographic table shall be protected by at least 1.6 millimeter (1/16 inch) lead or equivalent protection approved by the department.

(8) Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to ionizing radiation from diagnostic x-ray equipment. Individual monitoring devices, such as film badge dosimeters or thermoluminescent dosimeters, shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

(9) Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs.

(10) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of all other body parts shall comply with R 333.5065.

(11) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he or she is exposed as a patient for a medical or dental reason.

(12) Medical x-ray screen type films and intensifying screens shall be employed to reduce patient exposure except in cases where a noticeable decrease in image

definition resulting from increased sensitivity may reduce the clinical value of the examination.

(13) Film processing materials and techniques shall be those recommended by the x-ray film and processing materials manufacturers unless otherwise tested to ensure maximum information content of the developed film. Sight developing is not permitted except under extreme emergency conditions. Correct temperature control and development time are necessary to minimize radiation dose to the patient.

(14) A radiographic x-ray system shall not be left unattended without locking the apparatus, room, or building in some manner which prevents use of the apparatus by unauthorized persons.

History: 2016 MR 10, Eff. May 25, 2016

FIXED FLUOROSCOPIC INSTALLATIONS

R 333.5411 X-ray equipment.

Rule 411. (1) All x-ray tube housings in fixed fluoroscopic installations shall be of the diagnostic type.

(2) The aluminum equivalent of the total filtration permanently in the useful beam shall not be less than 2.5 millimeters aluminum.

(3) The source-patient distance on fluoroscopic machines should not be less than 45 centimeters (18 inches) and shall not be less than 30 centimeters (12 inches).

(4) Provision shall be made to intercept the scattered x-rays from the undersurface of the table top and other structures under the fluoroscopic table if the tube is mounted under the table. A cone or shield shall provide the same degree of attenuation as is required of the tube housing.

(5) A shielding device of at least 0.25 millimeter lead equivalence for covering the bucky slot during fluoroscopy shall be provided.

(6) A shielding device of at least 0.25 millimeter lead equivalence, such as overlapping protective drapes or hinged or sliding panels, shall be used to intercept scattered radiation that would otherwise reach the fluoroscopist and others near the machine.

(7) A fluoroscopic machine shall comply with both of the following:

- (a) The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID. The fluoroscopic tube shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The exposure rate due to transmission through the

barrier with the attenuation block in the useful beam combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens per hour at 10 centimeters from an accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

- (b) The entrance exposure rate shall be measured as described in subrule (15) of this rule. The exposure rate due to transmission through the primary 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 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, if it is not closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 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.

(8) The lead equivalence of the barrier of conventional fluoroscopes shall be not less than 1.5 millimeters at 100 kVp, 1.8 millimeters at 125 kVp, and 2.0 millimeters at potentials greater than 125 kVp.

(9) A beam-limiting device shall be provided to restrict the size of the useful beam to less than the area of the barrier. The x-ray tube and beam-limiting system shall be linked with the fluorescent screen assembly so that the useful beam at the fluorescent screen is confined within the barrier irrespective of the panel-screen distance. For image intensifiers, the useful beam shall be centered on the input phosphor. It should not exceed the diameter of the input phosphor during fluoroscopy or cine-recording. For spot film radiography with image intensifier equipment, the shutters should automatically open to the required field size before the exposure.

(10) Beam-limiting devices, such as collimators, adjustable diaphragms, or shutters, shall provide the same degree of attenuation as is required of the tube housing.

(11) A fluoroscopic machine shall comply with either of the following:

- (a) The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided to

permit further limitation of the field. The minimum field size at the greatest SID shall be equal to or less than 5 by 5 centimeters.

- (b) For image-intensified fluoroscopic equipment, the total misalignment of the edges of the x-ray field with the respective edges of the visible area of the image receptor along any dimension of the visually defined field in the plane of the image receptor shall not exceed 3% of the SID. The sum, without regard to sign, of the misalignment along any 2 orthogonal dimensions intersecting at the center of the visible area of the image receptor shall not exceed 4% of the SID. 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. Means shall be provided to permit further limitation of the field. The minimum field size, at the greatest SID, shall be equal to or less than 5 by 5 centimeters.

(12) X-ray production in the fluoroscopic mode shall be controlled by a device that requires continuous pressure by the operator for the entire time of an exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposures at any time, but means may be provided to permit completion of any single exposure of the series in progress.

(13) When the fluoroscope is operated at 80 kVp, the exposure rate at the position where the beam enters the patient shall not exceed 3.2 R/mA-min and should not exceed 2.1 R/mA-min.

(14) Entrance exposure rate limits for fluoroscopic machines shall be as follows:

- (a) Machines with automatic exposure rate control shall not be operable at a combination of tube potential and current which results in an exposure rate in excess of 10 roentgens per minute at the point where the center of the useful beam enters the patient, except during recording of fluoroscopic images or when an optional high level control is provided. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.
- (b) Machines without automatic exposure rate control shall not be operable at a combination of tube potential and current which results in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient, except during recording of fluoroscopic images or when an optional high level control is activated. Special means of activation of high level controls, such

as additional pressure applied continuously by the operator, shall be provided to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(15) Compliance with subrule (14) of this rule shall be determined as follows:

- (a) If the source is below the table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle.
- (b) If the source is 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.
- (c) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(16) 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. A signal audible to the fluoroscopist shall indicate the completion of the preset cumulative on-time. This signal shall continue to sound while x-rays are produced until the timing device is reset.

(17) Devices which indicate the x-ray tube potential and current shall be provided. On image intensified fluoroscopic equipment, these devices should be located in such a manner that the operator may monitor the tube potential and current during fluoroscopy.

History: 2016 MR 10, Eff. May 25, 2016

Editor's Note: An obvious error in R 333.5411 was corrected at the request of the promulgating agency, pursuant to Section 56 of 1969 PA 306, as amended by 2000 PA 262, MCL 24.256. The rule containing the error was published in Michigan Register, 2016 MR 10. The memorandum requesting the correction was published in Michigan Register, 2016 MR 16.

R 333.5417 Enclosures.

Rule 417. (1) An enclosure shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations.

(2) The degree of protection required for an enclosure shall be determined by the workload, the use and occupancy factors, and the tube potential, tube current, mechanical movement, and distance. The design shall be subject to approval by the department.

(3) For conventional fluoroscopy extraneous light that interferes with the fluoroscopic examination shall be eliminated. Dark adaptation normally is not necessary when using image intensifiers.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5418 Conditions of operation.

Rule 418. (1) An individual present in a fluoroscopic room shall wear a protective apron of at least 0.5 millimeter lead equivalence.

(2) Only individuals whose presence is needed to conduct the examination, to conduct radiation protection surveys, or to undergo specific training shall be permitted in the fluoroscopy room during x-ray exposures.

(3) Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to ionizing radiation from diagnostic x-ray equipment. Individual monitoring devices, such as film badge dosimeters or thermoluminescent dosimeters, shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

(4) Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs.

(5) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of all other body parts shall meet the requirements of R 333.5065.

(6) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he or she is exposed as a patient for a medical or dental reason.

(7) The fluoroscopist's eyes should be sufficiently dark-adapted for the visual task required before commencing conventional fluoroscopy. Under no circumstances shall he or she attempt to compensate for inadequate adaptation by increasing exposure factors employed or by prolonging the fluoroscopic examination.

(8) A fluoroscopic x-ray system shall not be left unattended without locking the apparatus, room, or building in some manner which prevents use of the apparatus by unauthorized persons.

History: 2016 MR 10, Eff. May 25, 2016

MOBILE OR PORTABLE DIAGNOSTIC X-RAY EQUIPMENT

R 333.5421 X-ray equipment.

Rule 421. (1) Radiographic x-ray equipment shall meet the requirements of R 333.5405 excluding subrules (5) and (11).

(2) Fluoroscopic x-ray equipment shall meet the requirements of R 333.5411 excluding subrules (3), (4), (5), and (7).

(3) The radiographic exposure control switch shall be located on the machine where adequate personnel protection is provided to attenuate the direct and scatter radiation, or the length of switch cord shall be such that the operator shall be able to stand at least 1.8 meters (6 feet) from the patient, the x-ray tube, and out of the useful beam. A coil type extension switch cord capable of providing more than 1.8 meters (6 feet) of distance protection is recommended.

(4) Hand-held fluoroscopic screens and others not attached to a diagnostic source assembly with stable mounting shall not be used.

(5) Image intensification shall always be provided on mobile fluoroscopic equipment. Mobile fluoroscopic equipment shall be impossible to operate unless the useful beam is intercepted by the image intensifier. Means shall be provided to limit the source-skin distance to not less than 30 centimeters (12 inches). For fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this subrule, provisions may be made for operation at shorter source-skin distances but in no case less than 20 centimeters.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5422 Shielding.

Rule 422. (1) Portable shielding of at least 1.6 millimeter (1/16 inch) lead equivalent shall be used by the operator and other individuals nearby when possible.

(2) Mobile or portable diagnostic x-ray equipment used routinely in 1 location shall be considered a fixed installation and shall meet the requirements of R 333.5405 and R 333.5407, or R 333.5411 and R 333.5417, or both.

History: 2016 MR 10, Eff. May 25, 2016

R 333.5423 Conditions of operation.

Rule 423. (1) Operation shall meet the requirements of R 333.5409 and R 333.5418.

(2) Individuals operating mobile or portable diagnostic x-ray equipment shall wear a protective apron of minimum 0.5 millimeter lead equivalence unless portable shielding is provided as specified in of R 333.5422(1).

History: 2016 MR 10, Eff. May 25, 2016

MISCELLANEOUS AND SPECIAL INSTALLATIONS

R 333.5425 General provisions.

Rule 425. (1) Types of x-ray sources and uses not specifically covered by this part and not exempted in R 333.5033, shall meet the requirements in R 333.5001 to R 333.5101.

(2) For the purpose of registering and approving veterinary x-ray producing equipment and devices not specifically covered by this part the protective design, the workload, the use factor, and the occupancy factor shall be considered.

History: 2016 MR 10, Eff. May 25, 2016