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

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PART 7. MEDICAL X-RAY INSTALLATIONS

R 333.5311 Purpose and scope.

Rule 311. (1) This part establishes requirements governing the use of x-radiation in medicine, osteopathy, chiropractic, and podiatry.

(2) This part applies to all registrants who use x-radiation as a health practitioner or on behalf of a health practitioner licensed under article 15 of the act, MCL 333.1101 to 333.25211, for the intentional exposure of humans.

(3) In addition to the requirements of this part, all registrants who use x-radiation as a health practitioner or on behalf of a health practitioner licensed under article 15 of the act are subject to all applicable provisions of these rules.

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

THERAPEUTIC MACHINES OPERATED ABOVE 85 KVP

R 333.5312 X-ray equipment.

Rule 312. (1) The tube housing shall be of the therapeutic type.

(2) Permanent diaphragms or cones used for collimating the useful beam shall afford the same degree of attenuation as is required of the housing.

(3) Adjustable or removable beam-limiting devices shall transmit not more than 5% of the useful beam as determined at the maximum tube potential and with maximum treatment filter.

(4) Filters shall be so mounted as to prevent their movement during the treatment.

(5) The filter slot shall be so constructed that the radiation escaping through it does not produce an exposure rate exceeding 1 R/h at 1 meter, or if the patient is likely to be exposed to radiation escaping from the slot, 30 R/h at 5 centimeters (2 inches) from the external opening.

(6) A removable filter shall be permanently marked with its thickness and material.

(7) A filter indication system shall be used on therapy machines which use changeable filters. It shall indicate, from the control panel, the presence or absence of a filter and it shall be designed to permit easy recognition of the filter in place.

(8) The x-ray tube shall be so mounted that it cannot turn or slide with respect to the housing aperture. A reproducible means of measuring the focal spot to patient distance shall be provided.

(9) Means to immobilize the tube housing during stationary portal treatment shall be provided.

(10) An easily discernible indicator which shows whether or not x-rays are being produced shall be on the control panel.

(11) Beam monitoring devices shall be fixed in the useful beam to indicate an error due to incorrect filter, tube current, or tube potential, unless the device introduces more filtration than is clinically acceptable.

(12) A suitable exposure control device, such as an automatic timer, exposure meter, or dose meter, shall be provided to terminate the exposure after a preset time interval or preset exposure or dose limit. If a timer is used, it shall permit accurate presetting and determination of exposure times as short as 1 second. Means for the operator to terminate the exposure at any time shall be provided.

(13) Mechanical or electrical stops or both shall be provided to insure that the useful beam is oriented only toward primary barriers.

(14) Interlocks shall be provided so that, when a door to the treatment room is opened, the machine turns off automatically or the radiation level within the room is reduced to an average of not more than 2 mR/h and a maximum of 10 mR/h at a distance of 1 meter in any direction from the source. After the shut-off or reduction in exposure rate, it shall be possible to restore the machine to full operation only from the control panel.

(15) The x-ray control circuit shall be so designed that it is not possible to energize the x-ray tube to produce x-rays without resetting the x-ray "ON-OFF" switch at the control panel.

(16) When the relationship between the beam interceptor (when present) and the useful beam is not permanently fixed, mechanical or electrical stops shall be provided to ensure that the beam is oriented only toward primary barriers.

(17) X-ray machines with electron beam extraction capability shall be provided with such additional safety devices as determined necessary and specified in writing by the department to prevent accidental electron beam exposure.

(18) To reduce the electron contamination of high energy treatment beams, shadow trays, or other accessories placed in the primary beam shall be placed at a sufficient distance from the patient that the electron contamination contribution to the skin dose is minimal.

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

Editor's Note: An obvious error in R 333.5312 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 333.5315 Enclosures.

Rule 315. (1) An enclosure shall be a permanent part of the building or equipment. Portable protective barriers 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) All wall, ceiling, and floor areas that can be irradiated by the useful beam plus an additional area extending at least 30 centimeters (1 foot) beyond shall be provided with a primary protective barrier.

(4) For equipment capable of operating above 150 kVp, the control station shall be outside of the therapy room.

(5) The enclosure shall be so constructed that individuals may at all times be able to escape from within.

(6) If the radiation exposure rate within the therapy room is so high that an individual who is accidentally in the treatment room when the machine is turned "ON" may receive as much as 1250 mR exposure during the time required to reach an access door, special cut-off, or panic buttons shall be required. When pressed, these buttons, operable by open hand at appropriate positions about the treatment room, shall cause the irradiation to be terminated.

(7) Effective means shall be provided to prevent access to the treatment room during exposure. For equipment capable of operating above 150 kVp, each access door to the treatment room shall be provided with a fail-safe interlock. The interlock system shall be so designed that the failure of any 1 component cannot jeopardize the safety of the system, such as the use of series connected double switch assemblies at access doors, and dual interlock relays. If an access door is opened when the machine is "ON", the interlock shall cause termination or reduction of exposure as specified in R 333.5312(14).

(8) Red warning signal lights, energized only when the useful beam in "ON", shall be located on the control panel and near each entrance to the therapy room. Under conditions as specified in subrule (6) of this rule a visible signal shall also be located within the therapy room. Depending upon control panel and door locations, a single warning signal light may be sufficient to comply with this subrule.

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

R 333.5317 Conditions of operation.

Rule 317. (1) An installation shall be operated in compliance with all limitations determined necessary and specified in writing by the department.

(2) The output of the x-ray generator shall be calibrated before use for the treatment of patients for each technique or condition of use. The department shall be informed by telephone or in writing of completion of initial calibration before patient treatment is initiated. A written report of this initial calibration shall be submitted within 30 days to the department. Recalibration shall be required after each tube replacement and after any changes or replacement in the generating apparatus which could affect a change in the x-ray output. Check calibrations shall be made on an annual basis and records of all calibration maintained for not less than 7 years.

(3) X-ray therapy equipment capable of operating above 150 kVp shall not be operated routinely until the radiation safety of the installation has been established by a protection survey conducted pursuant to R 333.5063. The department shall be informed by telephone or in writing of completion of the initial survey before patient treatment is initiated. A written report of this initial survey shall be submitted within 30 days to the department. All x-ray therapy equipment shall be operated in conformance with recommendations of the protection survey.

(4) Both the control panel and the patient shall be observable during exposure.

(5) When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices should be used. If the patient must be held by an individual, upon approval by the radiologist in charge followed by written notice to the department, that individual shall be provided protection equivalent to 7 half-value layers and shall be positioned so that no part of his or her body can be struck by the useful beam and is as far as possible from the edge of the useful beam. The exposure of an individual used for this purpose shall be monitored and a permanent record maintained. The individual selected for this purpose shall not otherwise be occupationally exposed to ionizing radiation.

(6) With the exception of subrule (5) of this rule, an individual other than the patient shall not be permitted in the treatment room when the tube is operated at potentials exceeding 85 kVp. At potentials of 85 kVp or below, other individuals may be permitted in the treatment room by the radiologist in charge if they are essential to conduct the treatment, but only if they are protected as specified in subrule (5) of this rule and their radiation exposure is monitored and permanently recorded.

(7) Personnel monitoring shall be performed in controlled areas for each individual occupationally exposed to ionizing radiation from therapeutic 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.

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

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

(10) 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.

(11) Lead, lead rubber, lead foil, and similar materials used for limiting the field shall not transmit more than 5% of the useful beam under the conditions at which the machine is operated for therapy. This subrule does not apply to treatment blocks used to adjust or modify the intended radiation dose to the area of treatment.

(12) A therapeutic 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

THERAPEUTIC MACHINES OPERATED AT OR BELOW 85 KVP

R 333.5321 X-ray equipment.

Rule 321. (1) The x-ray equipment shall comply with the requirements of R 333.5312, excluding subrules (11), (14), and (16).

(2) Maximum potential shall be mechanically or electronically limited to 85 kVp.

(3) A contact therapy machine shall meet the additional requirement that the leakage radiation at 5 centimeters (2 inches) from the surface of the tube housing shall not exceed 0.1 R/h. As used in this subrule, "contact therapy machine" means an x-ray therapy machine designed for source to skin treatment distances of 5 centimeters or less at tube potentials in the range of 20 to 50 kVp.

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

R 333.5322 Enclosures.

Rule 322. An enclosure shall comply with the requirements of R 333.5315(1) and (2).

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

R 333.5323 Conditions of operation.

Rule 323. (1) Operation shall comply with the requirements of R 333.5317.

(2) If the x-ray tube of a contact therapy machine as defined in R 333.5321(3) is hand held during irradiation, the operator shall wear protective gloves and a protective apron. 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 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 shall be taken to prevent accidental exposure to the useful beam.

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

FIXED RADIOGRAPHIC INSTALLATIONS

R 333.5325 X-ray equipment.

Rule 325. (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 325-1.

TABLE 325-1

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) If the filter in the machine is not accessible for examination and the total filtration is not known, subrule (2) of this rule may be assumed to have been met if the half-value layer is not less than any of the following:

(a) 0.6 mm aluminum at 49 kVp.
(b) 1.6 mm aluminum at 70 kVp.
(c) 2.6 mm aluminum at 90 kVp.

(4) Under conditions of subrule (3) of this rule for tube potentials above 90 kVp, subrule (2) of this rule may be assumed to have been met if the half-value layer is not less than that specified in table 325-2.

(5) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in table 325-2.

TABLE 325-2

Design Operating Range (kVp)	Measured Potential (kVp)	Half-value Layer (mm 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…….	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

(6) To determine the half-value layer at an x-ray tube potential which is not listed in table 325-2, linear interpolation or extrapolation may be made. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve these beam quality requirements is in the useful beam during each exposure.

(7) Machines equipped with beryllium window x-ray tubes with removable filters shall contain keyed filter interlock switches in the tube housing and suitable indication on the control panel of the added filter in the useful beam. The total filtration permanently in the useful beam shall not be less than 0.5 millimeter aluminum equivalent and shall be clearly indicated on the tube housing.

(8) Beryllium window x-ray tubes shall not be used routinely for general purpose diagnostic examinations. Such a tube may comprise an x-ray subsystem if needed for special soft tissue technique in accord with subrule (7) of this rule.

(9) 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.

(10) 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.

(11) 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 no 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.

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

(13) 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.

(14) 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.

(15) 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.

(16) Radiographic x-ray machines used for purposes other than mammography or extremity radiography only shall be capable of operation at not less than an average current of 100 milliamperes (mA) during all radiographic techniques used. A machine not capable of sustained operation at not less than an average of 100 mA for the duration of a given technique shall not be used for that technique.

(17) 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 any time by discontinuing pressure upon the exposure switch except that during serial radiography means may be provided to permit completion of a single exposure in progress.

(18) The exposure switch, except for those used in conjunction with spot film devices in fluoroscopy, shall be securely fixed so that the operator is required to be behind a fixed shield which intercepts the useful beam and any radiation which has been scattered only once.

(19) When 2 or more x-ray tube heads are operated from a single exposure switch, there shall be indication at the control panel showing which tube is connected and ready to be energized and means to prevent energizing more than 1 tube head simultaneously. Machines designed for simultaneous multiple tube operation shall have positive means for selecting single tube or multiple tube operation.

(20) The control panel shall provide positive visual identification of the production of x-rays when the x-ray tube is energized. A milliammeter may comply with this subrule.

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

(22) 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 333.5331 Enclosures.

Rule 331. (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. Recommended shielding is posted on the department's website.

(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) Exposure switch location and control shield shall be oriented so that, at arm's length from the exposure switch, the operator is not exposed to the useful beam, leakage radiation, or any radiation scattered only once.

(8) The operator shall be able to see and communicate with the patient 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 an operating room or special procedure installation during radiographic exposures. A primary protective barrier shall be provided for personnel protection under these circumstances unless necessary technique prevents use of such protection. 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 333.5333 Conditions of operation.

Rule 333. (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.

(3) Staff personnel routinely working with or around radiation sources shall not be required by the registrant to hold film or restrain patients during radiography. If such procedure is permitted, personnel exposure shall not exceed the limits in R 333.5057 to R 333.5059 or the procedure shall be prohibited.

(4) When a patient must be held in position for radiography, mechanical supporting or restraining devices shall be available and shall be used unless contraindicated. If the patient must be held by an individual, this individual shall wear protective gloves and a protective apron of 0.5 millimeter minimum lead equivalence and shall be positioned so that no part of his or her body can be 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. An individual, except the patient, shall be protected by 0.5 millimeter minimum lead equivalent aprons unless protected by an approved primary barrier.

(6) 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.

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

(8) 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.

(9) 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.

(10) The gonads of children and individuals who have not passed the reproductive age shall be protected from the useful beam either by the use of shielding (0.5 mm lead equivalent), collimation, or special gonad shields when this does not interfere with the conditions or objectives of the examination.

(11) Intensifying screens shall be employed to reduce patient exposure except in cases where a noticeable decrease in image definition may reduce the clinical value of the examination. Film and screen speed combinations shall be carefully selected to produce the necessary clinical information with the least exposure to the patient consistent with current clinical judgment.

(12) 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 shall be used.

(13) 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 333.5337 X-ray equipment.

Rule 337. (1) All x-ray tube housings of fixed fluoroscopic installations shall be of the diagnostic type.

(2) The beam quality shall comply with the provisions of R 333.5325(5) and R 333.5325(6).

(3) Means shall be provided on all fluoroscopic machines to limit the source-skin distance to not less than 38 centimeters. For image intensified fluoroscopes intended for specific surgical application that would be prohibited at this source-skin distance, provisions may be made for operation at shorter distances but in no case less than 20 centimeters.

(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 which would otherwise reach the fluoroscopist and others near the machine.

(7) The equipment shall be so constructed that, under conditions of normal use, the entire cross section of the useful beam is attenuated by a primary protective barrier, permanently incorporated into the equipment. The exposure shall automatically terminate when the barrier is removed from the useful beam.

(8) 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 any 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 pursuant to subrule (16) 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.

(9) 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.

(10) 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.

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

(12) 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.

(13) X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of 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.

(14) 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.

(15) Entrance exposure rate limits for fluoroscopic equipment 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 a 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.

(16) Compliance with subrule (15) 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.

(17) Means shall be provided to present 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 a preset cumulative on-time. This signal shall continue to sound while x-rays are produced until the timing device is reset.

(18) 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

R 333.5347 Enclosures.

Rule 347. (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, and shall be subject to design approval by the department. Recommended shielding is posted on the department's website.

(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 333.5348 Conditions of operation.

Rule 348. (1) An individual present in a fluoroscopic room, except the patient, 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 comply with 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) Special precautions, consistent with clinical needs, shall be taken to minimize exposure of the gonads of potentially procreative patients and exposure of the embryo or fetus in patients known to be or suspected of being pregnant. Gonadal shielding is advised when it does not interfere with the conditions or objectives of the examination.

(9) In cineradiography, special care shall be taken to limit patient exposure when tube currents and potentials employed are higher than those normally used in fluoroscopy. The exposure rates to which patients are normally subjected shall be determined annually and records of the surveys maintained.

(10) 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 333.5351 X-ray equipment.

Rule 351. (1) Radiographic x-ray equipment shall comply with the requirements of R 333.5325 excluding subrules (11) and (18).

(2) Fluoroscopic x-ray equipment shall comply with the requirements of R 333.5337 excluding subrules (3), (4), (5), (6) and (9).

(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 333.5352 Shielding.

Rule 352. (1) Portable shielding of at least 1.6 millimeter (1/16 inch) lead equivalent shall be used by the operator and other individuals in the room when possible.

(2) Mobile or portable diagnostic x-ray equipment used routinely in 1 location shall be considered a fixed installation and shall comply with the requirements of R 333.5325 and R 333.5331, or R 333.5337 and R 333.5347, or both.

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

R 333.5353 Conditions of operation.

Rule 353. (1) Operation shall comply with the requirements of R 333.5333 and R 333.5348.

(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 R 333.5352(1).

(3) Mobile or portable diagnostic x-ray equipment shall not be used for routine radiography or fluoroscopy in hospitals or private offices of health practitioners licensed under article 15 of the act, MCL 333.1101 to 333.25211. This equipment shall only be used when it is medically inadvisable to move a patient to a fixed radiographic or fixed fluoroscopic installation.

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

MISCELLANEOUS AND SPECIAL INSTALLATIONS

R 333.5355 General provisions.

Rule 355. (1) Types of x-ray sources and uses not specifically covered by this part and not exempted in R 333.5033, shall comply with R 333.5001 to R 333.5101.

(2) For the purpose of registering and approving medical 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