

**MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY
AFFAIRS
RADIATION SAFETY SECTION**

**IONIZING RADIATION RULES GOVERNING THE USE
OF RADIATION MACHINES**

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PART 9. DENTAL X-RAY INSTALLATIONS

R 333.5371 Purpose and scope.

Rule 371. (1) This part establishes requirements governing the use of x-radiation in dentistry.

(2) This part applies to all registrants who use x-radiation in dentistry for the intentional exposure of humans.

(3) In addition to the requirements of this part all registrants are subject to all applicable provisions of these rules.

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

CONVENTIONAL (SINGLE TUBE) INSTALLATIONS

R 333.5372 Scope.

Rule 372. R 333.5373 to R 333.5376 apply to installations consisting of a single x-ray source, its individual control unit, and protective enclosure used for the production of intraoral radiographs.

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

R 333.5373 X-ray equipment.

Rule 373. (1) The tube housing shall be of the diagnostic type.

(2) The aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in table 373-1.

TABLE 373-1

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 373-2.

(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 373-2.

TABLE 373-2

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 373-2, 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) Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam to either of the following:

- (a)** If the minimum source-skin distance is 18 centimeters or more, the x-ray field at the minimum source-skin shall be containable in a circle having a diameter of not more than 7

centimeters.

- (b)** If the minimum source-skin distance is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of not more than 6 centimeters.

(8) For intraoral exposures, means shall be provided to limit the source-skin distance to not less than 18 centimeters with apparatus operable above 50 kVp, and not less than 10 centimeters with apparatus not operable above 50 kVp. Open-ended cones are recommended to reduce scattered radiation.

(9) Mechanical support of the tube head and pointer cone shall maintain the exposure position without drift or vibration of sufficient magnitude to cause the need for manually restraining the tube or retaking the x-ray.

(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 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 of the series in progress.

(11) If a recycling timer is employed, it shall not be possible to make a repeat exposure without release of the exposure switch to reset the timer.

(12) The exposure control switch shall have a circuit-closing contact which can be maintained only by continuous pressure on the switch by the operator.

(13) Unless protective shielding is provided for the operator, the length of the exposure control switch cord or remote control location shall be such that the operator shall be able to stand at least 1.8 meters (6 feet) away from the patient and the x-ray tube and out of the useful beam.

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

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

(16) The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the 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 333.5375 Shielding.

Rule 375. Conventional building materials in partitions, floors, and ceilings may provide adequate radiation shielding for dental installations. When a conventional building structure does not provide adequate shielding, the shielding shall be increased by providing greater thickness of building materials or by adding lead, concrete, steel, or other suitable materials to the walls, floor, and ceiling of an existing room. Shielding shall be subject to approval by the department.

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

R 333.5376 Conditions of operation.

Rule 376. (1) Deliberate exposure of an individual to the useful beam for training or demonstration purposes shall not be permitted unless there is a diagnostic need for the exposure and the exposure is prescribed by a dentist or physician.

(2) The operator or the assistant shall not hold the image receptor in place for the patient during the exposure.

(3) During the exposure, the operator shall stand at least 1.8 meters (6 feet) from the patient and the x-ray tube and outside the useful beam or behind a suitable barrier.

(4) Only individuals whose presence is necessary to conduct the radiographic examination shall be permitted in the radiographic room during exposure.

(5) The operator shall direct the x-ray tube such that the useful beam strikes a primary

barrier or unoccupied area after emerging from the patient.

(6) Neither the tube housing nor the cone shall be hand-held during the exposure.

(7) Fluoroscopy shall not be used in dental examinations.

(8) The exposure to the patient shall be kept to the practical minimum consistent with clinical objectives.

(9) The x-ray beam and the image receptor shall be aligned very carefully with the area to be radiographed.

(10) Processing materials and techniques shall be those recommended by the x-ray film manufacturer 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.

(11) 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

MULTIPLE TUBE INSTALLATIONS

R 333.5378 Scope.

Rule 378. R 333.5379 to R 333.5381 apply to installations consisting of more than 1 x-ray source in the same room, or of sources located in separate rooms. These installations may include 2 or more complete x-ray units (single tube units), or a combination of 2 or more x-ray tube heads operable from a single control panel (multiple tube units).

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

R 333.5379 X-ray equipment.

Rule 379. (1) X-ray equipment in multiple tube installations shall meet the requirements of R 333.5373 with regard to each tube housing

assembly and each complete x-ray unit.

(2) On multiple tube units, 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 at the same time.

(3) For multiple tube units there shall be indication at the tube housing assembly when it is connected and ready to be energized.

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

R 333.5380 Shielding.

Rule 380. Conventional building materials in partitions, floors, and ceilings may provide adequate radiation shielding for dental installations. When a conventional building structure does not provide adequate shielding, the shielding shall be increased by providing greater thickness of building materials or by adding lead, concrete, steel, or other suitable materials to the walls, floor, and ceiling of an existing room. In multiple tube installations the possibility of exposure from multiple sources shall be considered. Shielding shall be subject to approval by the department.

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

R 333.5381 Conditions of operation.

Rule 381. Operation shall meet the requirements of R 333.5376.

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

PANORAMIC INSTALLATIONS

R 333.5383 Scope.

Rule 383. R 333.5384 to R 333.5386 apply to panoramic installations and protective enclosures.

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

R 333.5384 X-ray equipment.

Rule 384. (1) X-ray equipment in panoramic installations shall meet the requirements of R 333.5373 excluding subrules (7) to (11).

(2) For purposes of this rule, "image receptor" means that portion of the x-ray film or digital receptor instantaneously exposed by the x-ray beam subtended by a beam-limiting diaphragm immediately adjacent to the front of the radiographic film or digital receptor, if the panoramic technique requires this diaphragm.

(3) The x-ray tube housing shall be provided with a beam-limiting diaphragm which shall limit the field at the plane of the image receptor to dimensions not exceeding the dimensions of the image receptor and shall align the center of the x-ray field with the center of the image receptor to within 2% of the SID.

(4) Mechanical support of the tube head and image receptor shall maintain beam alignment without drift or vibration of sufficient magnitude to cause the need for manually restraining the tube or retaking the x-ray.

(5) 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.

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

R 333.5385 Shielding.

Rule 385. Conventional building materials in partitions, floors, and ceilings may provide adequate radiation shielding for panoramic installations. When a conventional building structure does not provide adequate shielding, the shielding shall be increased by providing greater thickness of building materials or by adding lead, concrete, steel, or other suitable materials to the walls, floor, and ceiling of an existing room. Shielding shall be subject to approval by the department.

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

R 333.5386 Conditions of operation.

Rule 386. Operation shall meet the requirements of R 333.5376.

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

CEPHALOMETRIC INSTALLATIONS

R 333.5388 Scope.

Rule 388. R 333.5389 to R 333.5391 apply to installations consisting of an x-ray source used for the production of radiographs of the skull or related extra-oral radiographs, its individual control unit, and protective enclosure.

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

R 333.5389 X-ray equipment.

Rule 389. (1) X-ray equipment in cephalometric installations shall meet the requirements of R 333.5373 excluding subrules (7), (8), (9), and (13).

(2) 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.

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

(4) 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 exceeding 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.

(5) 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.

(6) 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.

(7) 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 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.

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

R 333.5390 Shielding.

Rule 390. (1) The degree of protection required 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.

(2) In a radiographic room, wall and floor areas exposed to the useful beam plus an area extending at least 30 centimeters (1 foot) beyond shall be provided with a primary protective barrier where necessary 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).

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

(4) Control apparatus for the radiographic equipment shall be shielded by a non-removable primary protective barrier extending to a minimum height of 2.1 meters (7 feet).

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

(6) 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 such that the attenuation effectiveness of the barrier is not impaired.

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

R 333.5391 Conditions of operation.

Rule 391. Operation shall meet the requirements of R 333.5376 excluding subrule (3).

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

MULTIPLE PURPOSE INSTALLATIONS

R 333.5395 General provisions.

Rule 395. (1) This rule applies to installations consisting of an x-ray source or sources used for 2 or more purposes described in R 333.5372 to R 333.5391.

(2) X-ray equipment in multiple purpose installations shall meet the applicable requirements of R 333.5373, R 333.5379, R 333.5384, and R 333.5389 for each mode of operation permitted by the design of the equipment.

(3) Shielding in multiple purpose installations shall meet the applicable requirements of R 333.5375, R 333.5380, R 333.5385, and R 333.5390 for each mode of operation permitted by the design of the equipment.

(4) Operation in multiple purpose installations shall meet the applicable requirements of R 333.5376, R 333.5381, R 333.5386, and R 333.5391 for each mode of operation permitted by the design of the equipment.

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

HAND-HELD PORTABLE DENTAL X-RAY SYSTEMS

R 333.5396 Hand-held portable dental x-ray systems.

Rule 396. (1) As used in this section, "handheld dental X-ray system" or "system" means an X-ray system that is used to take radiographs, is

designed to be handheld during its operation, and is portable.

(2) A handheld dental X-ray system that meets the requirements described in this section may be used for routine dental radiography in a dental office or a situation in which it is impractical to transfer a patient to a radiation machine that is stationary.

(3) X-ray equipment designed to be hand-held must meet the requirements of R 333.5373, excluding subrules (9) and (13).

(4) The x-ray tube housing for tubes designed to be hand-held must be constructed so that the leakage radiation measured in air at a distance 5 centimeters from a point on the external surface does not exceed 0.02 mGy (2 milliroentgens) in 1 hour when operated under conditions of maximum radiation output permitted by the design or operating characteristics of the radiation machine.

(5) Operation of a hand-held portable x-ray system must meet the requirements of R 333.5376, excluding subrules (3) and (6).

(6) A person shall not use a handheld dental X-ray system to perform dental radiography unless the machine is registered with the department under department rules for registration of radiation machines and the system, the personnel operating the system, and the facility in which the system is used meet all of the following requirements:

(a) The system has been approved for human use by the United States Food and Drug Administration and is used in a manner consistent with that approval.

(b) The system has a backscatter shield that meets all of the following requirements:

(i) The shield is composed of a leaded polymer or a lead-equivalent substance that has a substantially equivalent protective capacity.

(ii) The shield has at least 0.5 millimeters of lead or lead-equivalent shielding, as determined by the department.

(iii) The shield is permanently affixed to the system.

(c) The system is calibrated by its manufacturer before its first use and is recalibrated at least every 24 months after the date of the last calibration.

(d) When not in use, the system is stored in a manner that restricts access to the system, such as by storing the system in a locked area of the facility.

(e) Each individual who operates the system is an individual who is authorized to operate a dental radiography machine pursuant to rules promulgated under part 166 of the act, MCL 333.16601 to 333.16659.

(f) An individual operating the system is not required to wear a lead apron or other personal monitoring equipment while operating the system if it is determined that the use of the system is in compliance with part 381 of the Michigan occupational safety and health administration general industry safety and health standards, R 325.60601a to R 325.60618, or equivalent federal occupational safety and health standards; part 33 of the Michigan occupational safety and health administration general industry safety and health standard, R 408.13301 to R 408.13395g, or equivalent federal occupational safety and health standards; R 333.5057; and R 333.5063 to R 333.5065. However, upon request, a registrant shall make a lead apron or other personal monitoring equipment available to an individual who operates the system.

(g) The system is not used if the backscatter shield described in subdivision (b) of this subrule is broken, missing, or malfunctioning.

(7) An operator shall complete the training program supplied by the manufacturer and approved by the department before using the x-ray unit. Records of the training shall be maintained on file for examination by the department.

History: 2016 AACs; 2020 MR 18, Eff Oct 5, 2020

OTHER TYPES OF INSTALLATIONS

R 333.5397 General provisions.

Rule 397. (1) This rule applies to dental x-ray producing equipment and devices not specifically covered elsewhere by this part.

(2) Types of dental x-ray sources and uses not specifically covered by this part and not exempted under R 333.5033 shall meet the requirements of R 333.5001 to R 333.5101.

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