DEPARTMENT OF CONSUMER AND INDUSTRY SERVICES

RADIATION SAFETY SECTION

(By authority conferred on the department of public health by section 13521 of Act No. 368 of the Public Acts of 1978, as amended, and section 48 of Act No. 306 of the Public Acts of 1969, as amended, being SS333.13521 and 24.248 of the Michigan Compiled Laws)

PART 9. DENTAL X-RAY INSTALLATIONS

R 325.5371. 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 parts 1, 4 and 5 and all applicable provisions of the other parts.

(4) The dentist should be aware of the requirements of the Michigan department of labor with regard to the employment of persons under 18 in occupations involving x-ray equipment.

History: 1979 AC.

CONVENTIONAL (SINGLE TUBE) INSTALLATIONS

R 325.5372. Scope.

Rule 372. Rules 373 to 376 apply to installations consisting of a single x-ray source, its individual control unit, and protective enclosure used for the production of intra-oral radiographs.

History: 1979 AC.

R 325.5373 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 2.0 millimeter aluminum for equipment capable of operating at potentials up to 70 kVp and shall not be less than 2.5 millimeter aluminum for equipment capable of operating at potentials greater than 70 kVp. The filter shall be located as near the window of the tube housing as possible.

(3) For diagnostic x-ray machines manufactured after the effective date of these rules the aluminum equivalent of the total filtration in the useful beam shall not be less than that shown in table 1.

TABLE 1

Operating kVp	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

(4) If the filter in the machine is not accessible for examination and the total filtration is not known subrule (3) may be assumed to have been met if the half-value layer is not less than

0.6 mm aluminum at 49 kVp
1.6 mm aluminum at 70 kVp
2.6 mm aluminum at 90 kVp

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

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

TABLE 2

Design operating range (Kilovolts peak)	Measured potential (Kilovolts peak)	Half-value layer (milli-meters 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	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

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

(8) Diaphragms or cones shall be provided for collimating the useful beam to a size no larger than clinically necessary and shall provide the same degree of protection as required of the tube housing. The diameter of the useful beam at the cone tip shall not be greater than 3 inches.

(9) Radiographic equipment manufactured after the effective date of these rules and designed for use with an intra-oral image receptor shall be provided with means to limit the x-ray beam so that:

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

(b) If the minimum SSD 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.

(10) For intra-oral film exposures, means (e.g. cones) shall be provided to limit the source-to-skin distance (SSD) 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.

(11) 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.

(12) 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 any single exposure of the series in progress.

(13) 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.

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

(15) 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.

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

(18) On all diagnostic machines manufactured after the effective date of these rules a signal audible to the operator shall indicate that the exposure has ended.

(19) 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.

(20) X-ray equipment installed after the effective date of these rules shall be installed and used in accord with the appropriate portions of the 1975 national electrical code (NFPA No. 70-1975) reproduced or referenced in rule 359. X-ray equipment installed

before the effective date of these rules shall conform with the appropriate national electrical code in effect at the time of installation.

History: 1979 AC.

R 325.5375. 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: 1979 AC.

R 325.5376. 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 film 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 persons 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) X-ray film with a minimum sensitivity of 12.0 to 24.0 reciprocal roentgens as specified in American standards association speed group D (A.S.A. PH 6.1-1961) shall be used for routine dental radiography.

(10) The x-ray beam and the film shall be aligned very carefully with the area to be radiographed.

(11) Film processing materials and techniques shall be those recommended by the x-ray film manufacturer unless otherwise tested to insure 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.

(12) A variable intensity light source should be used for viewing the finished radiograph.

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

History: 1979 AC.

MULTIPLE TUBE INSTALLATIONS

R 325.5378. Scope.

Rule 378. Rules 379 to 381 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 tube heads operable from a single control panel (multiple tube units).

History: 1979 AC.

R 325.5379. X-ray equipment.

Rule 379. (1) X-ray equipment in multiple tube installations shall comply with the general requirements of rule 373 with regard to each tube housing assembly and each complete x-ray unit.

(2) When 2 or more x-ray tube heads are operated from a single exposure switch (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: 1979 AC.

R 325.5380. 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: 1979 AC.

R 325.5381. Conditions of operation.

Rule 381. Operation shall comply with the general requirements of rule 376.

History: 1979 AC.

PANORAMIC INSTALLATIONS

R 325.5383. Scope.

Rule 383. Rules 384 to 386 apply to panoramic installations and protective enclosures.

History: 1979 AC.

R 325.5384. X-ray equipment.

Rule 384 (1) X-ray equipment in panoramic installations shall comply with the general requirements of rule 373 excluding subrules (8) to (13).

(2) For purposes of this rule, "image receptor" means that portion of the x-ray film instantaneously exposed by the x-ray beam subtended by a beam- limiting diaphragm immediately adjacent to the front of the radiographic film, if the panoramic technique requires such a 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: 1979 AC.

R 325.5385. 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: 1979 AC.

R 325.5386. Conditions of operation.

Rule 386. Operation shall comply with the general requirements of rule 376.

History: 1979 AC.

CEPHALOMETRIC INSTALLATIONS

R 325.5388. Scope.

Rule 388. Rules 389 to 391 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: 1979 AC.

R 325.5389. X-ray equipment.

Rule 389. (1) X-ray equipment in cephalometric installations shall comply with the general requirements of rule 373 excluding subrules (8), (9), (10), (11), and (15).

(2) Beam-limiting devices (diaphragms, cones, 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-film 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 x-ray film 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 radiographic film with radio-opaque material is not a substitute for proper x-ray field limitation.

History: 1979 AC.

R 325.5390. Shielding.

Rule 390. (1) The degree of protection required shall be determined by the workload, use and occupancy factors and the kilovoltage, milliamperage, mechanical movement, and distance factor, and shall be subject to design approval by the department.

(2) 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, occupancy and distance factors. 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 any radiation which 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: 1979 AC.

R 325.5391. Conditions of operation.

Rule 391. Operation shall comply with the general requirements of rule 376 excluding subrule (3).

History: 1979 AC.

MULTIPLE PURPOSE INSTALLATIONS

R 325.5395. 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 and provided for in rules 372 to 391.

(2) X-ray equipment in multiple purpose installations shall comply with the applicable requirements of rules 373, 379, 384 and 389 for each mode of operation permitted by the design of the equipment.

(3) Shielding in multiple purpose installations shall comply with the applicable requirements of rules 375, 380, 385 and 390 for each mode of operation permitted by the design of the equipment.

(4) Operation in multiple purpose installations shall comply with the applicable requirements of rules 376, 381, 386 and 391 for each mode of operation permitted by the design of the equipment.

History: 1979 AC.

R 325.5396. Hand-held portable dental x-ray systems.

Rule 396. (1) X-ray equipment designed to be hand-held shall comply with the general requirements of R 325.5373, excluding subrules (11) and (15).

(2) The x-ray tube housing for tubes designed to be hand-held shall be constructed such that the leakage radiation measured in air at a distance 5 centimeters from any point on the external surface shall 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.

(3) Operation of a hand-held portable x-ray system shall comply with the general requirements of R 325.5376, excluding subrules (3) and (6).

(4) Protective shielding of at least 0.5 millimeter lead equivalence shall be provided for the operator to protect the operator's torso, hands, face, and gonads from backscattered radiation. If the protective shielding is a backscatter shield attached to the unit, the shield shall be positioned as close to the patient as possible and the operator shall take care to remain in a protective position.

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

(6) Hand-held dental x-ray systems shall not be used for routine dental radiography in dental offices. This equipment shall only be used for portable use including use in nursing homes, home health care, or for use on special needs patients.

History: 2007 AACS.

OTHER TYPES OF INSTALLATIONS

R 325.5397. 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 rule 182 shall comply with parts 1, 4 and 5.

History: 1979 AC.