DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

DIRECTOR'S OFFICE

IONIZING RADIATION RULES GOVERNING THE USE OF RADIATION MACHINES

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(By authority conferred on the director of the department of licensing and regulatory affairs by section 13521, 1978 PA 368, MCL 333.13521 and Executive Reorganization Order Nos. 1996-1, 1996-2, 2003-1, and 2011-4 being MCL 330.3101, 445.2001, 445.2011, and 445.2030)

R 333.5001, R 333.5002, R 333.5003, R 333.5004, R 333.5005, R 333.5006, R 333.5007, R 333.5008, R 333.5009, R 333.5010, R 333.5011, R 333.5012, R 333.5013, R 333.5015, R 333.5017, R 333.5018, R 333.5019, R 333.5020, R 333.5021, R 333.5023, R 333.5024, R 333.5026, R 333.5031, R 333.5032, R 333.5033, R 333.5034, R 333.5036, R 333.5037, R 333.5038, R 333.5039, R 333.5040, R 333.5041, R 333.5042, R 333.5043, R 333.5045, R 333.5046, R 333.5047, R 333.5051, R 333.5052, R 333.5053, R 333.5055, R 333.5057, R 333.5058, R 333.5059, R 333.5060, R 333.5061, R 333.5063, R 333.5064, R 333.5065, R 333.5067, R 333.5068, R 333.5069, R 333.5071, R 333.5072, R 333.5073, R 333.5074, R 333.5075, R 333.5077, R 333.5079, R 333.5080, R 333.5081, R 333.5082, R 333.5083, R 333.5084, R 333.5086, R 333.5087, R 333.5088, R 333.5089, R 333.5091, R 333.5092, R 333.5093, R 333.5094, R 333.5096, R 333.5097, R 333.5098, R 333.5100, R 333.5101, R 333.5281, R 333.5282, R 333.5293, R 333.5294, R 333.5296, R 333.5297, R 333.5298, R 333.5299, R 333.5302, R 333.5305, R 333.5306, R 333.5307, R 333.5308, R 333.5309, R 333.5311, R 333.5312, R 333.5315, R 333.5317, R 333.5321, R 333.5322, R 333.5323, R 333.5325, R 333.5331, R 333.5333, R 333.5337, R 333.5347, R 333.5348, R 333.5351, R 333.5352, R 333.5353, R 333.5355, R 333.5361, R 333.5362, R 333.5365, R 333.5366, R 333.5368, R 333.5371, R 333.5372, R 333.5373, R 333.5375, R 333.5376, R 333.5378, R 333.5379, R 333.5380, R 333.5381, R 333.5383, R 333.5384, R 333.5385, R 333.5386, R 333.5388, R 333.5389, R 333.5390, R 333.5391, R 333.5395, R 333.5396, R 333.5397, R 333.5401, R 333.5402, R 333.5403, R 333.5404, R 333.5405, R 333.5407, R 333.5409, R 333.5411, R 333.5417, R 333.5418, R 333.5421, R 333.5422, R 333.5423, R 333.5425, R 333.5431, R 333.5432, R 333.5435, R 333.5437, R 333.5438, R 333.5439, R 333.5440, R 333.5441, R 333.5442, R 333.5445, R 333.5446, R 333.5447, R 333.5448, R 333.5449, R 333.5450, R 333.5452, R 333.5481, R 333.5482, R 333.5484, R 333.5485, R 333.5486, R 333.5487, R 333.5491, R 333.5492, R 333.5493, R 333.5494, R 333.5495, R 333.5505, R 333.5506, R 333.5507, R 333.5508, R 333.5511, R 333.5601, R 333.5602, R 333.5603, R 333.5604, R 333.5605, R 333.5606, R 333.5607, R 333.5608, R 333.5609, R 333.5610, R 333.5611, R 333.5612, R 333.5613, R 333.5626, R 333.5627, R 333.5628, R 333.5629, R 333.5630, R 333.5634, R 333.5635, R 333.5637, R 333.5655, R 333.5656, R 333.5657, R 333.5658, R 333.5667, R 333.5668, R 333.5669, R 333.5674, R 333.5675, R 333.5676, R 333.5677, R 333.5678, R 333.5679, R 333.5681, R 333.5682, R 333.5683, R 333.5684, R 333.5685, R 333.5686, R 333.5687, R 333.5688, R 333.5689, R 333.5690, R 333.5691,

R 333.5692, R 333.5693, R 333.5694, R 333.5695, R 333.5696, R 333.5697, R 333.5701, R 333.5703, R 333.5705, R 333.5707, R 333.5709, R 333.5711, R 333.5713, R 333.5715, R 333.5717, R 333.5719, and R 333.5721 are added to the Michigan Administrative Code as follows:

PART 1. GENERAL PROVISIONS FOR THE USE OF RADIATION MACHINES

R 333.5001 Scope.

Rule 1. (1) Except as otherwise specified, these rules apply to a person who acquires, receives, owns, possesses, uses, stores, or transfers a radiation machine.

(2) Terms used in these rules shall have the same meaning as defined in the act.

R 333.5002 Definitions; A.

Rule 2. (1) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

(2) "Accelerator" means a machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt (MeV).

(3) "Act" means 1978 PA 368, MCL 333.1101 to 333.25211. The terms defined in the act have the same meanings when used in these rules.

(4) "Annual" means a period of 12 consecutive months.

(5) "As low as reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of registered radiation machines in the public interest.

R 333.5003 Definitions; C.

Rule 3. (1) "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than 1 calendar quarter and no day in any 1 year is omitted from inclusion within a calendar quarter. The method observed by the registrant for determining calendar quarters shall only be changed at the beginning of a year.

(2) "Calibration" means the determination of either of the following:

(a) The response or reading of an instrument relative to a series of known radiation values over the range of the instrument.

(b) The strength of a source of radiation relative to a standard.

(3) "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(4) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the registrant for any reason.

R 333.5004 Definitions; D.

Rule 4. (1) "Deep dose equivalent" (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

(2) "Department" means the department of licensing and regulatory affairs.

(3) "Dose" or "radiation dose" means absorbed dose, dose equivalent, or effective dose equivalent as appropriate.

(4) "Dose equivalent (H_T)" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

(5) "Dose limits" or "limits" means the permissible upper bounds of radiation doses established under these rules.

R 333.5005 Definitions; E.

Rule 5. (1) "Effective dose equivalent (H_E)" means the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factor (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma W_T H_T$).

(2) "Embryo or fetus" means the developing human organism from conception until the time of birth.

(3) "Entrance or access point" means a location through which an individual could gain access to radiation areas. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(4) "Exposure" means being exposed to ionizing radiation.

(5) "External dose" means that portion of the dose equivalent received from a source of radiation outside the body.

(6) "Extremity" means hand, elbow, and arm below the elbow, foot, knee, and leg below the knee.

(7) "Extremity radiography" means radiography of the hand or arm excluding the shaft of the humerus or the foot or leg excluding the shaft of the femur.

R 333.5006 Definitions; H.

Rule 6. (1) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from a source of radiation or 30 centimeters from any surface that the radiation penetrates.

(2) "Human use" means the internal or external administration of radiation to human beings.

R 333.5007 Definitions; I.

Rule 7. (1) "Individual" means a human being.

(2) "Individual monitoring" means the assessment of dose equivalent by the use of individual monitoring devices or by the use of survey data.

(3) "Individual monitoring device" means a device designed to be worn by a single individual for the assessment of dose equivalent. Film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and optically stimulated luminescence (OSL) dosimeters are examples of individual monitoring devices.

(4) "Inspection" means an official examination or observation including, but not limited to,

tests, surveys, and monitoring to determine compliance with the act, these rules, registration conditions or orders of the department.

(5) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

R 333.5008 Definitions; L to O.

Rule 8. (1) "Lens dose equivalent (LDE)" means the external exposure to the lens of the eye as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

(2) "Member of the public" means an individual except when that individual is receiving an occupational dose.

(3) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties for the registrant involve exposure to sources of radiation, whether in the possession of the registrant or other person.

R 333.5009 Definitions; P and Q.

Rule 9. (1) "Physician" means an individual licensed under section 17011 or 17511 of article 15 of the public health code, 1978 PA 306, MCL 333.17011 and 333.17511 to practice medicine or osteopathic medicine.

(2) "Protective apron" means an apron made of radiation-attenuating materials used to reduce exposure to radiation.

(3) "Public dose" means the dose received by a member of the public from exposure to a radiation machine under the control of the registrant. Public dose does not include occupational dose, or doses received from a medical administration the individual has received, or from voluntary participation in medical research programs.

(4) "Quality factor" (Q) means the modifying factor, listed in tables 20-1 and 20-2, that is used to derive dose equivalent from absorbed dose.

R 333.5010 Definitions; R.

Rule 10. (1) "Radiation" means ionizing radiation. Radiation, as used in these rules, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

(2) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (5 mrem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

(3) "Radiation machine" means a machine that emits ionizing radiation when energized.

(4) "Radiation protection supervisor" means the individual specified by the registrant who has the knowledge, authority, and responsibility for radiation protection.

(5) "Registrant" means a person who is registered with the department and is legally obligated to register with the department pursuant to these rules and the act.

(6) "Registration" for the purpose of these rules means registration of a radiation machine in writing with the department.

(7) "Research and development" means 1 of the following:

(a) Theoretical analysis, exploration, or experimentation.

(b) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the

experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation to human beings.

(8) "Restricted area" means an area, access to which is limited by the registrant, for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(9) "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58×10^{-4} coulombs per kilogram of air.

R 333.5011 Definitions; S.

Rule 11. (1) "Shallow dose equivalent" (H_s), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter ($7\ mg/cm^2$) averaged over an area of 1 square centimeter.

(2) “SI” means the abbreviation for the international system of units.

(3) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

(4) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the use of radiation machines. When appropriate, this evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation.

R 333.5012 Definitions; T to V.

Rule 12. (1) “Traceable to a national standard” means an instrument is calibrated at either the national institute of standards and technology (NIST) or at a calibration laboratory that participates in a proficiency program with the NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within 3% of the national standard in the appropriate energy range.

(2) "Unrestricted area" or “uncontrolled area” means an area, access to which is neither limited nor controlled by the registrant for purposes of protection of individuals from exposure to radiation, or an area used for residential quarters.

(3) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from a radiation machine could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rads) in 1 hour at 1 meter from a radiation machine or 1 meter from any surface that the radiation penetrates.

R 333.5013 Definitions; W to Y.

Rule 13. (1) "Week" means 7 consecutive days starting on Sunday.

(2) "Weighting factor" w_T for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are as follows:

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30
Whole Body	1.00

(3) "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

(4) "Worker" means an individual engaged in activities under a registration issued by the department and controlled by a registrant, but does not include the registrant.

(5) "Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The registrant may change the starting date of the year used to determine compliance by the registrant if the change is made at the beginning of the year. If a registrant changes in a year, the registrant shall assure that no day is omitted or duplicated in consecutive years.

EXEMPTIONS

R 333.5015 Exemptions.

Rule 15. The department may, in response to a request or on its own initiative, grant an exemption or exception from the requirements of these rules as it determines is authorized by law and shall not result in an undue hazard to public health and safety, property, or the environment.

GENERAL REQUIREMENTS

R 333.5017 Records.

Rule 17. A registrant shall comply with all record requirements of these rules including, but not limited to, the use, storage, transfer, and disposal of each radiation machine.

R 333.5018 Inspections.

Rule 18. (1) Under the authority of MCL 333.13517(1), the department may enter at all reasonable times upon private or public property to conduct compliance investigations.

(2) Under the authority of MCL 333.13517(2), the department may obtain a warrant if necessary for search of property or seizure of sources of radiation or evidence of a violation of the act or any rule or license.

(3) A registrant shall make available to the department for inspection, all records maintained pursuant to these rules.

R 333.5019 Tests.

Rule 19. (1) A registrant shall make or cause to be made, tests that the department considers appropriate or necessary including, but not limited to, tests of the following:

(a) The radiation machine.

(b) Facilities where a radiation machine is used.

(c) Radiation detection and monitoring instruments.

(d) Other equipment and devices used in connection with the use of a radiation machine.

(2) The registrant shall allow the department to perform tests that it considers appropriate to determine compliance with these rules.

R 333.5020 Units of dose.

Rule 20. (1) As used in these rules, the units of dose are the following:

(a) Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rads).

(b) Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram. (0.01 Gy)

(c) Sievert (Sv) is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor. (1 Sv = 100 rem)

(d) Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rads multiplied by the quality factor. (1 rem = 0.01 Sv)

(2) As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in table 20-1:

TABLE 20-1
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

Type of Radiation	Quality Factor *	Absorbed Dose Equal to a Unit Dose Equivalent
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

*Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

(3) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in subrule (2) of this rule, 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of 25 million neutrons per square

centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the registrant may use the fluence rate per unit dose equivalent or the appropriate quality factor from table 20-2 to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE 20-2
MEAN QUALITY FACTORS AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor*	Fluence per Unit Dose Equivalent** (Neutrons cm^{-2} Sv^{-1})	Fluence per Unit Dose Equivalent** (Neutrons cm^{-2} rem^{-1})
(thermal)	2.5×10^{-8}	2.0	9.8×10^{10}	9.8×10^{8}
	1.0×10^{-7}	2.0	9.8×10^{10}	9.8×10^{8}
	1.0×10^{-6}	2.0	8.1×10^{10}	8.1×10^{8}
	1.0×10^{-5}	2.0	8.1×10^{10}	8.1×10^{8}
	1.0×10^{-4}	2.0	8.4×10^{10}	8.4×10^{8}
	1.0×10^{-3}	2.0	9.8×10^{10}	9.8×10^{8}
	1.0×10^{-2}	2.5	1.0×10^{11}	1.0×10^{9}
	1.0×10^{-1}	7.5	1.7×10^{10}	1.7×10^{8}
	5.0×10^{-1}	11.0	3.9×10^{9}	3.9×10^{7}
	1.0	11.0	2.7×10^{9}	2.7×10^{7}
	2.5	9.0	2.9×10^{9}	2.9×10^{7}
	5.0	8.0	2.3×10^{9}	2.3×10^{7}
	7.0	7.0	2.4×10^{9}	2.4×10^{7}
	1.0×10^{1}	6.5	2.4×10^{9}	2.4×10^{7}
	1.4×10^{1}	7.5	1.7×10^{9}	1.7×10^{7}
	2.0×10^{1}	8.0	1.6×10^{9}	1.6×10^{7}
	4.0×10^{1}	7.0	1.4×10^{9}	1.4×10^{7}
	6.0×10^{1}	5.5	1.6×10^{9}	1.6×10^{7}
	1.0×10^{2}	4.0	2.0×10^{9}	2.0×10^{7}
	2.0×10^{2}	3.5	1.9×10^{9}	1.9×10^{7}
	3.0×10^{2}	3.5	1.6×10^{9}	1.6×10^{7}
	4.0×10^{2}	3.5	1.4×10^{9}	1.4×10^{7}

*Value of quality factor at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

**Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

R 333.5021 Additional requirements.

Rule 21. The department may impose additional requirements on a registrant in accordance with the act, 1978 PA 368, MCL 333.1011 to 333.25211, by rule, order, or

registration conditions that it considers appropriate or necessary to minimize danger to public health and safety, property, and the environment.

ENFORCEMENT REQUIREMENTS

R 333.5023 Violations.

Rule 23. (1) Under authority of MCL 333.13536, the department may obtain an injunction or other court order prohibiting a violation of the act, a rule, an order, or a registration condition issued under the act.

(2) Under the authority of MCL 333.2262, the department, in addition to taking other enforcement action, may impose a civil penalty, not to exceed $1,000 for each violation, on a person who violates the act, a rule, an order, or a registration condition issued under the act. Each day that a violation continues shall constitute a separate violation.

(3) A person who violates the act, a rule, an order, or a registration condition issued under the act may be guilty of a misdemeanor and, on conviction, may be fined, imprisoned, or both, as provided by law.

R 333.5024 Emergency orders and impounding.

Rule 24. (1) The department may issue an emergency order pursuant to MCL 333.13516. A person responsible for the radiation machine shall bear expenses incidental to the order.

(2) A radiation machine shall be subject to impoundment pursuant to MCL 333.13517. Impoundment by the department shall not relieve the owner of the responsibility for the radiation machine. A person who has a radiation machine impounded shall bear expenses incidental to the impoundment.

HEARING PROCEDURE

R 333.5026 Hearing procedure.

Rule 26. (1) Before the issuance of an order, the department shall afford an opportunity for a hearing that shall be conducted pursuant to the administrative procedures act of 1969 PA 306, MCL 24.201 to MCL 24.328.

(2) In a contested case, the department shall conduct a hearing as provided in the administrative procedures act of 1969 PA 306, MCL 24.201 to MCL 24.328.

PART 2. REGISTRATION OF RADIATION MACHINES

R 333.5031 Purpose and scope.

Rule 31. (1) This part provides for the registration of radiation machines, including particle accelerators, whether used primarily for x-ray production or other purposes.

(2) In addition to the requirements of this part, all registrants are subject to the applicable provisions of other parts of these rules.

R 333.5032 Definition.

Rule 32. As used in this part, “facility” means the location, building, vehicle, or complex under 1 administrative control, where 1 or more radiation machines are installed or located.

R 333.5033 Exemptions.

Rule 33. (1) Unless specifically covered elsewhere in these rules, electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this part if the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 5 microsieverts (0.5 mrem) per hour at 5 centimeters from any accessible surface of the equipment. The production, testing, or factory servicing of the equipment shall not be exempt.

(2) Radiation machines that are electrically disconnected pending sale, transfer of ownership, or destructive disposal or that are made inoperable are exempt from the requirements of this part. An inoperable radiation machine is one that cannot be energized when connected to a power supply without repair or modification.

(3) Domestic television receivers and video display monitors are exempt from the requirements of this part.

(4) Electron microscopes are exempt from this part if the instrument is not capable of exceeding an operating potential of 50 kilovolts.

R 333.5034 Responsibility for compliance with rules.

Rule 34. The owner or registrant, the person effectively in control of radiation machines not exempt under R 333.5033, and the individual who, pursuant to R 333.5037, is designated as the radiation protection supervisor shall be responsible for full compliance with all provisions of these rules.

R 333.5036 Shielding plan review.

Rule 36. (1) An applicant, before registration, shall submit the floor plans, shielding specifications, and equipment arrangement of all new installations, or modifications of existing installations, using a radiation machine, to the department for review and approval. Application for a radiation shielding plan review shall be completed on an application form supplied by the department according to the instructions contained in that form. Radiation shielding plans are not required to be submitted for any of the following:

(a) Dental intraoral or panoramic machines used in dental clinical facilities.

(b) Cabinet x-ray systems, analytical systems, process or control gauges, or cold-cathode gas discharge tubes.

(c) Bone densitometers.

(d) Mobile or portable radiographic machines unless routinely used in 1 location.

(e) C-arm fluoroscopic systems having a maximum source-image receptor distance of less than 45 centimeters that are used for extremity use only.

(2) The department may require the applicant to use the services of a health physicist or medical physicist to determine the shielding requirements before the department's plan review and approval.

(3) The department's approval of a plan shall not preclude the requirement of additional modifications if a subsequent analysis shows an individual could receive a dose exceeding the limits in R 333.5057 to R 333.5060.

(4) Shielding design goals of 0.1 millisievert (10 mrem) per week for controlled areas and 0.02 millisievert (2 mrem) per week and 0.02 millisievert (2 mrem) in any 1 hour for uncontrolled areas shall be applied to new facilities and to new construction in existing facilities.

(a) For the purpose of this subrule, “controlled area” means a limited access area where the occupational exposure of personnel to radiation is under the supervision of an individual in charge of radiation protection. In a controlled area, the access, occupancy, and working conditions are controlled for the purpose of radiation protection.

(b) For the purpose of this subrule, “uncontrolled area” means all areas of the facility and the surrounding environs that are not controlled for the purpose of radiation protection.

(5) For machines installed after the effective date of this part, the registrant shall maintain for inspection by the department a scale drawing of the room where a stationary radiation machine system is located. The drawing or accompanying attachments shall indicate the use of areas adjacent to the room and include an estimate of the occupancy in each area. In addition, the drawing or attachment shall include at least 1 of the following:

(a) The type and thickness of materials, or lead equivalency, of each protective barrier.

(b) The results of a survey for radiation levels at the operator's position and at pertinent points outside the room under specified test conditions.

(6) The department may withhold initial registration of a radiation machine pending receipt of either of the following:

(a) Plans and specifications for room design and shielding and approval of those plans and specifications.

(b) Documentation from the applicant that a certificate of need (CON) has been issued if the use of that machine is a covered clinical service as defined in the act.

R 333.5037 Registration of radiation machines.

Rule 37. (1) A person with 1 or more radiation machines shall do both of the following:

(a) Apply for registration of each radiation machine with the department before operating the machine. Application for registration shall be completed on forms provided by the department and shall contain all the information required by the form and associated instructions. The appropriate registration fee specified in R 333.5043 shall be submitted with the application.

(b) Designate, on the application form, a radiation protection supervisor to be responsible for radiation protection and ensure that the individual meets all of the following:

(i) Has completed a radiation safety officer training course, completed educational courses related to ionizing radiation safety, or has experience in the use and familiarity with the type of equipment used.

(ii) Is knowledgeable about the hazards and precautions in the handling of the radiation machines for which this individual is responsible.

(iii) Has read and understands the applicable requirements of these rules.

(iv) Authorizes operation of radiation machines only by individuals who have received instructions in their safe use. These instructions shall include, but are not limited to, the proper use of individual monitoring devices, the registrant’s operating and safety procedures, and all other applicable rules governing the use of the radiation machine that the individual will be operating.

(v) Has the authority to make or cause to be made radiation surveys and other procedures as may be necessary to demonstrate compliance with these rules.

(vi) Has the authority to make or cause to be made changes as may be necessary to comply with these rules.

(2) A person that registers 1 or more radiation machines will be issued a department facility

registration number.

R 333.5038 Machine registration tags.

Rule 38. (1) The department shall issue a registration tag for each radiation machine when it is properly registered with the department. The tag shall include a registration number uniquely assigned to that specific machine.

(2) The registrant shall apply the registration tag in a visible location on the control panel of the specified radiation machine. If applying the registration tag to the control panel is not practical, the registrant shall place the tag in another visible location on a component of the machine not likely to be replaced.

(3) The registrant shall not authorize removal of the registration tag from the radiation machine unless instructed by the department. If the tag is removed or defaced, the registrant shall notify the department and request a replacement tag. The request shall specify the tag number and machine description from the certificate of registration.

R 333.5039 Certificates of registration.

Rule 39. (1) The department shall issue a certificate of registration if it determines that an application meets the requirements of this part.

(2) The department may incorporate in the certificate of registration additional requirements in the form of registration conditions regarding the registrant's receipt, possession, and use of a radiation machine as it considers appropriate or necessary. The registrant shall comply with all registration conditions.

(3) The certificate of registration shall list all radiation machines registered at a facility.

R 333.5040 Expiration of registration.

Rule 40. Except as provided by R 333.5041(2), a registration shall expire at the end of the specified day in the month and year stated in the certificate of registration.

R 333.5041 Renewal of registration.

Rule 41. (1) The registrant shall annually file an application to renew the registration pursuant to R 333.5037 and shall submit the appropriate registration fee as specified in R 333.5043 with the application.

(2) If a registrant has filed an application to renew the registration in proper form not less than 30 days before the expiration of the existing registration, the existing registration shall not expire until the application status is determined by the department.

R 333.5042 Notice of change.

Rule 42. (1) The registrant shall notify the department in writing before making a change that would render the information contained in the application for registration, the certificate of registration, or both, no longer accurate. When a radiation machine is sold, transferred, or disposed, the notification shall specify the proposed recipient of the machine, or the location and method of disposal.

(2) A complete change in ownership, possession, or location of all machines listed on a certificate of registration terminates the certificate of record and shall require a new application for registration except as provided in subrule (4) of this rule.

(3) If there is a partial change, the department may terminate the certificate of registration

of record and issue a new certificate pursuant to R 333.5039.

(4) Notwithstanding subrule (2) of this rule, replacement of all machines listed on a certificate of registration shall be considered a partial change if the name and address of the registrant and the name and address of the facility are not changed.

R 333.5043 Fees.

Rule 43. (1) Pursuant to section 13522 of the act, MCL 333.13522, fees for registration of radiation machines, fees for follow-up inspections due to noncompliance, fees for mammography machine inspections, and fees assessed in connection with mammography authorization shall be adjusted annually by an amount determined by the state treasurer to reflect the cumulative annual percentage change in the Detroit consumer price index, not to exceed 5%. As used in this part, "Detroit consumer price index" means the most comprehensive index of consumer prices available for the Detroit area from the bureau of labor statistics of the United States Department of Labor.

(2) A total or partial refund of a registration fee shall not be made due to a notice of change resulting in the deletion of tubes or machines, or in the termination of the radiation machine registration certificate before the expiration date of the registration.

(3) Specific registration fees depend on the number of x-ray tubes included in the application for registration or renewal of registration. Current radiation machine registration fees are posted on the website of the department.

R 333.5045 Approval not implied.

Rule 45. A person, in an advertisement, shall not refer to the fact that a facility is registered with the department pursuant to this part. A person shall not state or imply that the department has approved an activity under a registration.

R 333.5046 Vendor obligation; notification of transfer; duty to report.

Rule 46. (1) A person who sells, leases, transfers, lends, disposes, assembles, or installs a radiation machine in this state shall notify the department in writing, within 15 days after the end of the calendar quarter, all of the following:

(a) The name and address of the person who has received the machine.

(b) The manufacturer, model, type, and number of x-ray tubes of each radiation machine transferred.

(c) The date of transfer of each radiation machine.

(d) The department facility registration number and machine registration tag number, if the facility is registered or if the machine was previously registered with the department.

(e) If a diagnostic x-ray system contains certified components, a copy of the assembler's report, prepared in compliance with the federal performance standards for ionizing radiation products, 21 C.F.R. 1020.30(d) (June 2006), shall be submitted in place of subdivisions (a) to (c) of this subrule.

(2) A person shall not make, sell, lease, transfer, lend, assemble, or install a radiation machine or the supplies used with a machine, unless the supplies and equipment, when properly placed in operation and used, meet the requirements of these rules.

R 333.5047 Out-of-state radiation machines.

Rule 47. (1) If a person brings a radiation machine into the state for any use, that person

shall register the machine with the department, comply with all applicable rules of the department, and supply the department with other information as the department may request.

(2) If a person plans to bring a radiation machine into the state for temporary use, that person shall provide written notice to the department not less than 3 working days before the machine is to be used in the state. The notice shall include all of the following:

(a) The facility registration number.

(b) The machine registration number.

(c) The nature, duration, and scope of use.

(d) The exact location or locations where the radiation machine will be used.

(e) Documentation that radiation shielding plan review information was submitted pursuant to R 333.5036.

(3) If, for a specific situation, the 3 working-day period would impose an undue hardship on the person, the department may grant permission to proceed sooner.

PART 3. STANDARDS FOR PROTECTION AGAINST RADIATION FOR USERS OF RADIATION MACHINES

GENERAL PROVISIONS

R 333.5051 Purpose.

Rule 51. (1) This part establishes standards for protection against ionizing radiation resulting from activities conducted under registrations of radiation machines issued by the department.

(2) The requirements of this part are designed to control the receipt, possession, use, and transfer of radiation machines by a registrant so that the total dose to an individual, including doses resulting from all radiation machines, does not exceed the standards for protection against radiation prescribed in this part. Nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety.

R 333.5052 Scope.

Rule 52. This part applies to radiation machine registrants of the department. The limits in this part do not apply to doses due to background radiation, exposure of patients to radiation for medical diagnosis or therapy, exposure from individuals administered radioactive material, or exposure from voluntary participation in medical research programs.

R 333.5053 Definitions.

Rule 53. As used in these rules, the following definitions apply:

(1) "Declared pregnant woman" means a woman who has voluntarily informed the registrant, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

(2) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring equipment to determine the radiation dose delivered to the monitoring equipment.

R 333.5055. Intentional exposure of humans.

Rule 55. (1) Nothing in these rules shall be construed as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis, medical therapy, or medical research conducted by a health practitioner licensed under article 15 of the act, MCL 333.1101 to 333.25211.

(2) Intentional exposure of individuals to radiation for diagnostic or therapeutic purposes shall be limited to supervision or prescriptions by a person licensed under article 15 of the act to provide such.

(3) Nothing in these rules shall be construed as authorization to conduct medical diagnosis, medical therapy, or medical research that is not fully consistent with the standards of practice for a health practitioner licensed under article 15 of the act.

OCCUPATIONAL DOSE LIMITS

R 333.5057 Occupational dose limits for adults.

Rule 57. (1) A registrant shall control the occupational dose to individual adults, to the following dose limits:

(a) An annual limit, which is the more limiting of the following:

(i) The effective dose equivalent of 0.05 sievert (5 rem).

(ii) The deep dose equivalent to an individual organ or tissue other than the lens of the eye of 0.5 sievert (50 rem).

(b) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are the following:

(i) A lens dose equivalent of 0.15 sieverts (15 rem).

(ii) A shallow dose equivalent of 0.5 sievert (50 rem) to the skin of the whole body or to the skin of an extremity.

(2) For exposure determined by measurement with an external individual monitoring device, the deep-dose equivalent shall be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the department.

(3) The assigned deep dose equivalent shall be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent shall be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

(a) If the individual monitoring device was not in the region of highest potential exposure or the results of individual monitoring are unavailable, the deep dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements to demonstrate compliance with the occupational dose limits.

(b) When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in R 333.5065, the effective dose equivalent shall be determined by any of the following:

(i) When only 1 individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation.

(ii) When only 1 individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25% of the limit specified in subrule (1)

of this rule, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation.

(iii) When 2 individual monitoring devices are worn, 1 under the protective apron at the waist and the other outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

(4) The registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by another person during the current year. Requirements for determining prior occupational exposure are provided in R 333.5080.

R 333.5058 Occupational dose limits for minors.

Rule 58. The annual occupational dose limits for a minor are 10% of the annual occupational dose limits specified for an adult worker in R 333.5057.

R 333.5059 Dose equivalent to embryo or fetus.

Rule 59. (1) The registrant shall ensure that the dose equivalent to the embryo or fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 5 millisieverts (500 mrem). Records for doses to the embryo or fetus shall be kept according to R 333.5081(4).

(2) The registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman to satisfy the limit in subrule (1) of this rule.

(3) The dose equivalent to the embryo or fetus is the deep dose equivalent to the declared pregnant woman.

(4) If the dose equivalent to the embryo or fetus has exceeded 4.5 millisieverts (450 mrem), when the woman declares the pregnancy to the registrant, the registrant shall be considered in compliance with subrule (1) of this rule if the additional dose equivalent to the embryo or fetus does not exceed 0.5 millisievert (50 mrem) during the remainder of the pregnancy.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

R 333.5060 Dose limits for individual members of the public.

Rule 60. (1) A registrant shall conduct operations in compliance with both of the following:

(a) The dose equivalent to a member of the public from the registered operation does not exceed 1 millisievert (100 mrem) in a year, excluding dose contributions from both of the following:

(i) Medical administrations the individual has received.

(ii) Voluntary participation in medical research programs.

(b) The dose in an unrestricted area from radiation machines does not exceed 0.02 millisievert (2 mrem) in any 1 hour.

(2) If a registrant allows members of the public to have access to controlled areas, the dose

limits for members of the public shall apply to those individuals.

(3) The department may impose additional restrictions on radiation levels in unrestricted areas to restrict the collective dose.

R 333.5061 Compliance with dose limits for individual members of the public.

Rule 61. A registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in R 333.5060.

SURVEYS AND MONITORING

R 333.5063 General.

Rule 63. (1) A registrant shall make, or cause to be made, surveys that may be necessary to demonstrate compliance with the rules in this part and are reasonable under the circumstances to evaluate both of the following:

(a) The magnitude and extent of radiation levels.

(b) All potential radiological hazards.

(2) A registrant shall ensure that instruments and equipment used for quantitative radiation measurements are calibrated annually for the radiation measured, except as otherwise specified in another part of these rules or in a registration condition.

(3) This subrule applies to personnel dosimeters, including dosimeters used to measure the dose to an extremity, that require processing to determine the radiation dose and that a registrant uses to comply with R 333.5057, with other applicable provisions of these rules, or with conditions specified in a registration. This subrule does not apply to direct and indirect reading pocket dosimeters and electronic personnel dosimeters. Personnel dosimeters shall be processed and evaluated by a dosimetry processor that meets both of the following:

(a) Holds a current personnel dosimetry accreditation from the national voluntary laboratory accreditation program of the national institute of standards and technology.

(b) Is approved in this accreditation process for the type of radiation or radiations included in the national voluntary laboratory accreditation program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

R 333.5064 Conditions requiring individual monitoring of occupational dose.

Rule 64. A registrant shall monitor occupational exposure to radiation from radiation machines under the control of the registrant and shall supply and require the use of individual monitoring devices by all of the following:

(a) An adult likely to receive in 1 year a dose greater than 10 % of the limits specified in R 333.5057(1).

(b) A minor likely to receive in 1 year a deep dose equivalent greater than 1 millisievert (100 mrem), a lens dose equivalent greater than 1.5 millisieverts (150 mrem), or a shallow dose equivalent to the skin or to the extremities greater than 5 millisieverts (500 mrem).

(c) A declared pregnant woman likely to receive during the entire pregnancy a deep dose equivalent greater than 1 millisievert (100 mrem).

(d) An individual who enters a high or very high radiation area.

(e) An individual for whom personnel monitoring is required under other parts of these rules pertaining to specific uses of radiation machines.

R 333.5065 Location of individual monitoring devices.

Rule 65. If R 333.5064 or other parts of these rules require occupational dose monitoring for an individual, the registrant shall ensure that the individual wears an individual monitoring device or devices according to 1 of the following:

(a) An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck as described in R 333.3057(3)(b)(i).

(b) An individual monitoring device used to monitor the dose to an embryo or fetus of a declared pregnant woman, pursuant to R 333.5059(1), shall be worn at the waist under any protective apron being worn by the woman.

(c) An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with R 333.5057(1)(b)(i), shall be worn at the neck, outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye.

(d) An individual monitoring device used for monitoring the dose to the skin of the extremities, to demonstrate compliance with R 333.5057(1)(b)(ii), shall be worn on the extremity likely to receive the highest exposure. The individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

CONTROL OF EXPOSURE IN RESTRICTED AREAS

R 333.5067 Control of access to high radiation areas.

Rule 67. (1) A registrant shall ensure that each entrance or access point to a high radiation area has 1 or more of the following control features:

(a) A device that, upon entry into the area, causes the radiation level to be reduced below the level where an individual could receive a deep dose equivalent of 1 millisievert (100 mrem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

(b) A device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry.

(c) Locked entryways, except when access to the area is required, with positive control over each individual entry.

(2) In place of the controls required for a high radiation area by subrule (1) of this rule, a registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(3) A registrant or applicant for a registration may apply to the department for approval of alternative methods for controlling access to high radiation areas.

(4) A registrant shall establish the controls required by subrules (1) and (3) of this rule in a way that does not prevent individuals from leaving a high radiation area.

(5) The registrant is not required to control entrance or access to rooms or other areas containing radiation machines capable of producing a high radiation area as described in subrule (1) of this rule if the registrant meets all the specific requirements for access and control specified in other applicable parts of these rules.

R 333.5068 Control of access to very high radiation areas.

Rule 68. (1) In addition to the requirements in R 333.5067, a registrant shall institute additional measures to ensure that an individual cannot gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 grays (500 rads) or more in 1 hour at 1 meter from a radiation machine or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation.

(2) A registrant is not required to control entrance or access to rooms or other areas containing radiation machines capable of producing a very high radiation area as described in subrule (1) of this rule if the registrant meets all the specific requirements for access and control specified in other applicable parts of these rules.

R 333.5069 Security and control of sources of radiation.

Rule 69. A registrant shall use devices or administrative procedures, or both, to prevent unauthorized use or removal of radiation machines.

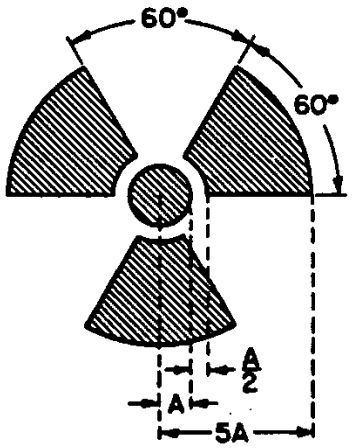
PRECAUTIONARY PROCEDURES

R 333.5071 Caution signs.

Rule 71. (1) Except as otherwise authorized by the department, symbols prescribed by R 333.5072 shall use the conventional 3-bladed design as follows:

RADIATION SYMBOL

1. Cross-hatched area is to be magenta or purple.
2. Background is to be yellow.



(2) In addition to the contents of signs and labels required in this part, a registrant may provide, on or near the required signs and labels, additional information to make individuals aware of potential radiation exposures and to minimize those exposures.

R 333.5072 Posting requirements.

Rule 72. (1) The registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, RADIATION AREA”.

(2) The registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words “CAUTION, HIGH RADIATION AREA” or “DANGER, HIGH RADIATION AREA”.

(3) The registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words “GRAVE DANGER, VERY HIGH RADIATION AREA”.

(4) The registrant shall post access openings to manufacturing or process equipment such as tanks and vessels on or in which radiation machines are mounted, if an individual can gain access to the radiation beam and receive a dose to any part of his or her body greater than the applicable limits for individuals in R 333.5057 to R 333.5061. The posting shall include a conspicuous sign or signs bearing the radiation symbol and warning of the hazard.

R 333.5073 Exceptions to posting requirements.

Rule 73. A registrant is not required to post caution signs pursuant to R 333.5072 in areas or rooms in any of the following situations:

(a) The radiation machines are in the room for periods of less than 8 hours and constantly attended by an individual who takes the precautions necessary to prevent the exposure of individuals to radiation above the limits specified in this part. The area or room shall be under the registrant’s control.

(b) The room is used for teletherapy and access is controlled pursuant to the applicable radiation therapy rules. Attending personnel shall take the necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation above the limits specified in this part.

(c) The area or room contains radiation machines used for diagnosis by, or on behalf of, health practitioners licensed under article 15 of the act, MCL 333.1011 to 333.25211.

R 333.5074 Labeling radiation machines.

Rule 74. A registrant shall ensure that each radiation machine is labeled in a conspicuous manner that cautions individuals that radiation is produced when the machine is energized.

R 333.5075 Use of safety equipment.

Rule 75. (1) The requirements for safety interlocks, protective enclosures, protective clothing, precautionary labels, or other safety equipment presume the proper use of this equipment. Unauthorized override of safety interlocks or other intentional misuse or non-use of required safety equipment shall be considered willful violation of these rules.

(2) Authorized override of safety interlocks shall be requested by the radiation protection supervisor in writing from the department. The request shall include justification, precautionary procedures during override, and statement of immediate supervision by the radiation protection supervisor or his or her authorized representative. Prior approval by the department is required. The approval may be granted by written condition on the registration certificate or by telephone followed by written confirmation from the department.

RECORDS

R 333.5077 General provisions for records.

Rule 77. (1) A registrant shall use either the international system of units (SI) gray, sievert, and coulomb per kilogram, or the special units rad, rem, and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this part.

(2) The registrant shall make a clear distinction among the quantities entered on the records required by these rules. The dose to an individual shall be specified in quantities such as the effective dose equivalent, shallow dose equivalent, lens dose equivalent, or deep dose equivalent.

R 333.5079 Records of surveys and calibrations.

Rule 79. (1) A registrant shall retain records of the results of surveys and calibrations required by R 333.5063 for 3 years after the record is made.

(2) A registrant shall maintain records of the results of surveys used to determine exposures, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents. A registrant shall retain these records until the department terminates the registration requiring the record.

R 333.5080 Determination and records of prior occupational dose.

Rule 80. (1) For each individual likely to receive an annual occupational dose requiring monitoring under R 333.5064, the registrant shall determine the occupational radiation dose received during the current year. To comply, a registrant may do any of the following:

(a) Accept, as a record of an individual's occupational dose, a written and signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that documents the nature and the amount of occupational dose the individual may have received during the current year.

(b) Accept, as the record of cumulative radiation dose, an up-to-date department Form MIOSHA-RSS-101, or equivalent, signed by the individual and countersigned by either an appropriate official of the most recent employer for work involving radiation exposure, or by the individual's current employer if the individual is not employed by the registrant.

(c) Obtain reports of the individual's dose equivalents from the most recent employer for work involving radiation exposure, or the individual's current employer if the individual is not employed by the registrant, by telephone, telegram, facsimile, other electronic media, or letter. The registrant shall request a written verification of the dose data if the authenticity of the reports cannot be established.

(3) The registrant shall record the exposure history of each individual, as required by subrule (1) of this rule, on department Form MIOSHA-RSS-101, or other clear and legible record, that includes all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation. For each period for which the registrant obtains reports, the registrant shall use the dose shown in the report in preparing department Form MIOSHA-RSS-101 or equivalent. For a period in which the registrant does not obtain a report, the registrant shall place a notation on department Form MIOSHA-RSS-101, or equivalent, indicating the periods for which data are not available.

(4) If the registrant cannot obtain a complete record of an individual's occupational dose for the current year, the registrant shall assume, in establishing administrative controls pursuant to R 333.5057(4) for the current year, that the allowable dose limit for the individual is reduced by 12.5 millisieverts (1,250 mrem) for each calendar quarter for which records are unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure.

(5) The registrant shall retain the records on department Form MIOSHA-RSS-101, or equivalent, until the department terminates each pertinent registration requiring this record. The registrant shall retain records used in preparing department Form MIOSHA-RSS-101, or equivalent, for 3 years after the record is made.

R 333.5081 Records of individual monitoring results.

Rule 81. (1) A registrant shall maintain records of doses received by all individuals for whom monitoring is required pursuant to R 333.5064. When applicable, these records shall include the deep-dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities.

(2) The registrant shall make entries of the records specified in subrule (1) of this rule at least annually.

(3) The registrant shall maintain the records specified in subrule (1) of this rule on department Form MIOSHA-RSS-102, pursuant to the instructions for department Form MIOSHA-RSS-102, or in clear and legible records containing all the information required by department Form MIOSHA-RSS-102.

(4) The registrant shall maintain the records of dose to an embryo or fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.

(5) The registrant shall retain the required form or record until the department terminates each pertinent registration requiring the record.

R 333.5082 Records of dose to individual members of the public.

Rule 82. (1) A registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public as required by R 333.5060.

(2) A registrant shall retain the records required by subrule (1) of this rule until the department terminates each pertinent registration requiring the record.

R 333.5083 Records of testing entry control devices for very high radiation areas.

Rule 83. (1) A registrant shall maintain records of tests performed on entry control devices for very high radiation areas. These records shall include the date, time, and results of each test.

(2) The registrant shall retain the records required by subrule (1) of this rule for 3 years after the record is made.

R 333.5084 Form of records.

Rule 84. (1) A record required by these rules shall be legible, readily identifiable, and retrievable throughout the specified retention period. The record shall be 1 of the following:

(a) The original.

(b) A reproduced copy.

(c) An electronic copy stored in an electronic recordkeeping system.

(d) A microform if it is authenticated by authorized personnel and is capable of producing a clear copy throughout the required retention period.

(2) Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures.

(3) The registrant shall maintain adequate safeguards against tampering with and loss of records.

NOTIFICATIONS AND REPORTS

R 333.5086 Notifications and reports of theft or loss of registered radiation machines.

Rule 86. (1) A registrant shall notify the department by telephone of a stolen, lost, or missing radiation machine within 10 days after its absence becomes known.

(2) A registrant required to notify the department under subrule (1) of this rule shall, within 30 days after making the telephone notification, make a written report to the department containing all of the following information:

(a) A description of the radiation machine involved, including the manufacturer and model, and the registration tag number of the radiation machine.

(b) A description of the circumstances under which the loss or theft occurred.

(c) A statement of disposition, or probable disposition, of the radiation machine involved.

(d) Exposures of individuals to radiation, the circumstances under which the exposures occurred, and the possible total effective dose equivalent to individuals in unrestricted areas.

(e) Actions that have been taken, or will be taken, to recover the radiation machine.

(f) Actions taken or planned to prevent a recurrence of the loss or theft of the radiation machine.

(3) After filing the written report, the registrant shall make an additional written report to the department containing any additional substantive information regarding the loss or theft within 30 days after the registrant learns of the new information.

(4) The registrant shall prepare a report filed with the department pursuant to this rule so that the names of individuals who may have received exposure to radiation are contained in a separate and detachable part of the report.

R 333.5087 Notification of incidents.

Rule 87. (1) In addition to any other requirements for notification, a registrant shall immediately notify the department of an event involving a radiation machine possessed by the registrant that may have caused or threatens to cause an individual to receive any of the following:

(a) An effective dose equivalent of 0.25 sievert (25 rem) or more.

(b) A lens dose equivalent of 0.75 sievert (75 rem) or more.

(c) A shallow dose equivalent to the skin or extremities of 2.5 grays (250 rads) or more.

(2) Within 24 hours of discovery of the event, a registrant shall notify the department of an event involving a registered radiation machine possessed by the registrant that may have caused, or threatens to cause, an individual to receive, in a period of 24 hours, any of the following:

(a) An effective dose equivalent exceeding 0.05 sievert (5 rem).

(b) A lens dose equivalent exceeding 0.15 sievert (15 rem).

(c) A shallow dose equivalent to the skin or extremities exceeding 0.5 sievert (50 rem).

(3) Registrants shall make the notifications required by subrules (1) and (2) of this rule by telephone to the department and shall confirm the notification within 24 hours by e-mail, facsimile, or overnight mail to the department.

(4) The registrant shall prepare the written confirmation filed with the department pursuant to this rule so that the names of individuals who have received an exposure to radiation are contained in a separate and detachable part of the written confirmation.

R 333.5088 Reports of exposures and radiation levels exceeding limits.

Rule 88. (1) In addition to the notification required by R 333.5087, a registrant shall submit a written report to the department within 30 days after learning of any of the following occurrences:

(a) An event requiring notification under R 333.5087.

(b) A dose exceeding any of the following:

(i) The occupational dose limits for adults in R 333.5057.

(ii) The occupational dose limits for a minor in R 333.5058.

(iii) The limit for an embryo or fetus of a declared pregnant woman in R 333.5059.

(iv) The limits for a member of the public in R 333.5060.

(v) Any applicable limit in the registration.

(c) Levels of radiation in either of the following conditions:

(i) A restricted area exceeding an applicable limit in the registration.

(ii) An unrestricted area exceeding 10 times an applicable limit in this part or in the registration, whether or not this involves a dose to an individual in excess of the limits in R 333.5060.

(2) A written report required by subrule (1) of this rule shall include, as appropriate, all of the following:

(a) The registrant's name, address, and facility registration number.

(b) A description of the event, including the possible cause and the manufacturer and model number, if applicable, of any equipment that failed or malfunctioned.

(c) The location of the event.

(d) The date and time of the event.

(e) The results of any evaluations or assessments, including an estimate of each individual's dose and the levels of radiation involved.

(f) Actions taken or planned to prevent a recurrence, including the schedule for achieving conformance with applicable limits and applicable registration conditions.

(3) After filing a report required by this rule, the registrant shall make an additional written report to the department containing any additional substantive information regarding the event within 30 days after the registrant learns of the new information.

(4) A report filed with the department under this rule shall include the name, a unique identification number or social security number as appropriate, and the date of birth of each overexposed individual. The report shall be prepared so that the information is contained in a separate and detachable part of the report and shall be clearly labeled "Protected Information: Not for Public Disclosure."

R 333.5089 Reports to individuals of exceeding dose limits.

Rule 89. When R 333.5088 requires a registrant to report to the department, the registrant

shall also provide to any affected individual a report on his or her exposure data included in the report submitted to the department. This report shall be transmitted no later than the transmittal to the department.

PART 4. NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS FOR USERS OF RADIATION MACHINES

R 333.5091 Purpose and scope.

Rule 91. This part establishes requirements for notices, instructions and reports by registrants to individuals engaged in activities associated with radiation machines and options available to these individuals in connection with department inspections of registrants to determine compliance with the act and rules regarding radiological working conditions. The rules in this part apply to all persons who receive, possess, use, own, or transfer radiation machines registered with the department under R 333.5031 to R 333.5047.

R 333.5092 Posting of notices to workers.

Rule 92. (1) A registrant shall post current copies of the following documents or a notice that describes each document and states where it may be examined:

(a) The rules in this part and R 333.5051 to R 333.5089.

(b) The certificate of registration and all conditions or documents incorporated into the registration by reference.

(c) The operating procedures applicable to activities under the registration.

(2) A registrant shall post a notice of violation involving radiological working conditions, a proposed imposition of a civil penalty or order issued under R 333.5023 or R 333.5024, and required responses from the registrant.

(3) A registrant shall post department Form MIOSHA-RSS-100 “Notice to Employees” as required by these rules.

(4) A registrant shall conspicuously post documents, notices, and forms as required by this rule in a sufficient number of places to allow individuals engaged in work under the registration to observe them on the way to or from work locations to which the document applies, and shall replace a document if it is defaced or altered.

(5) A registrant shall post documents pursuant to subrule (2) of this rule within 5 working days after receipt of the documents from the department. The registrant's response shall be posted within 5 working days after dispatch from the registrant. These documents shall be posted for a minimum of 5 working days or until the violation has been corrected, whichever is later.

R 333.5093 Instructions to workers.

Rule 93. (1) A registrant shall ensure that each individual, who during employment is likely to receive in a year an occupational dose greater than 1 millisievert (100 mrem), shall be the following:

(a) Instructed in the risks associated with exposure to radiation to the individual and potential offspring and in precautions or procedures to minimize exposure.

(b) Instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of these rules for the protection of personnel from exposures to radiation.

(c) Instructed in his or her responsibility to report promptly to the registrant a condition that may constitute, lead to, or cause a violation of the act, these rules, a registration condition, or unnecessary exposure to radiation.

(d) Instructed in the appropriate response to warnings made due to an unusual occurrence or malfunction that may involve exposure to radiation.

(e) Advised as to the radiation exposure reports that workers shall be provided pursuant to R 333.5094.

(2) A registrant shall keep records of the instructions described in this rule.

(3) The extent of these instructions shall be commensurate with the potential radiological hazards in the workplace.

R 333.5094 Notifications and reports to individuals.

Rule 94. (1) A registrant shall report radiation exposure data for an individual as specified in this rule. The information reported shall include data and results obtained pursuant to these rules, orders, or registration conditions, as shown in records kept by the registrant pursuant to R 333.5081. A notification and report shall be in writing and include all of the following:

(a) The name of the registrant, the name of the individual, and the individual's unique identification number or social security number.

(b) The individual's exposure information.

(c) The following statement:

"This report is provided to you pursuant to Part 4 of the Michigan Department of Licensing and Regulatory Affairs rules entitled 'Ionizing Radiation Rules Governing the Use of Radiation Machines'. You should keep this report for future reference."

(2) A registrant shall make dose information available to workers as shown in records kept by the registrant pursuant to R 333.5081. A registrant shall provide an annual report to each individual monitored pursuant to R 333.5064 of the dose received in that monitoring year for either of the following reasons:

(a) The individual's occupational dose exceeds 1 millisievert (100 mrem) effective dose equivalent or 1 millisievert (100 mrem) to an individual organ or tissue.

(b) The individual requests his or her annual dose report.

(3) At the request of a worker formerly engaged in work controlled by the registrant, the registrant shall provide a written report of the worker's exposure to radiation machines. The report shall include the dose record for each year the worker was required to be monitored pursuant to R 333.5064. The report shall be provided within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the registrant, whichever is later. The report shall cover the period of time the worker's activities involved exposure to radiation machines. The report shall include the dates and locations of work associated with radiation machines in which the worker participated during this period.

(4) When a registrant is required pursuant to R 333.5087 or R 333.5088 to report to the department an exposure of an individual to radiation, the registrant shall also provide the individual a written report of the exposure data included in the report. This report shall be transmitted at a time not later than the transmittal to the department.

(5) At the request of a worker who is terminating employment with the registrant in work involving exposure to radiation during the current year, or at the request of a worker who, while employed by another person, is terminating a work assignment involving radiation

exposure in the registrant's facility during the current year, each registrant shall provide at termination to the worker, or to the worker's designee, a written report of the radiation dose received by that worker from operations of the registrant during the current year. If the most recent individual monitoring results are not available, a written estimate of the dose shall be provided. Estimated doses shall be clearly indicated as estimated doses.

R 333.5096 Presence of representatives of registrants and workers during inspection.

Rule 96. (1) A registrant or an applicant for a registration shall allow the department at all reasonable times, the opportunity to inspect machines, activities, facilities, premises, and records under these rules.

(2) During an inspection, the registrant shall allow department inspectors to consult privately with workers as specified in R 333.5097. The registrant may accompany department inspectors at times other than the private consultation with workers.

(3) If the workers have authorized an individual to represent them during department inspections, the registrant shall notify the inspectors of the authorization and shall permit the workers' representative to accompany the inspectors during the inspection of physical working conditions.

(4) A worker's representative shall be routinely engaged in work under control of the registrant and shall have received instructions as specified in R 333.5093.

(5) If there is no resulting interference with the conduct of the inspection, different representatives of registrants and workers may accompany the inspectors during different phases of an inspection. However, only 1 workers' representative at a time may accompany the inspectors.

(6) With the approval of the registrant and the workers' representative, an individual who is not routinely engaged in work under control of the registrant, for example, a consultant to the registrant or to the workers' representative, may accompany department inspectors during the inspection of physical working conditions.

(7) Department inspectors may refuse to permit accompaniment by an individual who deliberately interferes with a fair and orderly inspection.

(8) Unless previously authorized by the registrant, a worker's representative shall not have access to an area containing proprietary information.

R 333.5097 Consultation with workers during inspections.

Rule 97. (1) Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of these rules to the extent that the inspectors consider necessary for the conduct of an effective and thorough inspection.

(2) During an inspection, a worker may report privately to the inspectors, either orally or in writing, a past or present condition that the worker believes may have contributed to or caused a violation of the act, these rules, a registration condition, or unnecessary exposure of an individual to radiation from machines under the registrant's control. If this notice is in writing, the worker shall comply with the requirements of R 333.5098(1).

(3) The provisions of subrule (2) of this rule shall not be interpreted as authorization to disregard instructions pursuant to R 333.5093.

R 333.5098 Requests by workers for inspections.

Rule 98. (1) A worker or a representative of workers who believes that a violation of the act, these rules, or registration conditions exists or has occurred regarding radiological working conditions may request an inspection of the facility by the department. The request shall be in writing, describe the circumstances of the perceived violation or condition, and be signed by the worker or the representative of the workers. The department shall provide a copy of the request to the registrant before or during the inspection. At the request of the worker, the department shall protect the worker's name and the name of individuals referred to in the request, except for good cause shown.

(2) If, upon receipt of a request for an inspection, the department determines that the complaint meets the requirements of subrule (1) of this rule, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practical to determine if the alleged violation exists or has occurred. An inspection authorized by this rule need not be limited to matters referred to in the complaint.

R 333.5100 Inspections not warranted; informal review.

Rule 100. (1) If the department determines, with respect to a complaint filed pursuant to R 333.5098, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the department shall notify the complainant in writing of the determination. To request a review of the determination the claimant shall submit a written statement of position to the department director. The department director, or his or her designated representative, shall send the registrant a copy of the statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The registrant may submit an opposing written statement of position to the department director. The department director, or his or her designated representative, shall send the complainant a copy of the statement by certified mail.

(2) At the request of the complainant, the department may hold an informal conference in which the complainant and the registrant may orally present their views. An informal conference may also be held at the request of the registrant, but disclosure of the identity of the complainant shall be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the department director, or designated representative shall affirm, modify, or reverse the determination of the department and provide the complainant and the registrant a written notification of the decision. The notification shall include a discussion of the basis for the decision.

(3) If, upon receipt of a request for an inspection, the department determines that an inspection is not warranted because the complaint does not meet the requirements of R 333.5098(1), the department shall notify the complainant in writing of the determination. The determination shall be without prejudice to the filing of a new complaint meeting the requirements of R 333.5098(1).

R 333.5101 Employee protection.

Rule 101. Employment discrimination by a registrant, or contractor or subcontractor of a registrant against an employee for engaging in protected activities under this part is prohibited.

PART 6. INDUSTRIAL RADIOGRAPHIC OPERATIONS AND INSTALLATIONS

R 333.5281 Purpose and scope.

Rule 281. (1) This part establishes radiation safety requirements for persons utilizing radiation machines for industrial radiography and a classification system for industrial radiographic installations and use.

(2) This part applies to all registrants who use radiation machines for industrial radiography. Nothing in this part applies to the use of radiation machines by a health practitioner licensed under article 15 of the act, MCL 333.1101 to 333.25211.

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

R 333.5282 Definitions.

Rule 282. As used in this part:

(a) "Industrial radiography" means the examination of the macroscopic structure of materials by nondestructive methods utilizing radiation machines.

(b) "Installation" means a location, having boundaries specified by the registrant, where for a period of more than 30 days 1 or more radiation machines are used. A part of a building, an entire building, a plant, or plant site may be designated as an installation.

(c) "Radiographer" means an individual who performs or who, in attendance at the site where radiation machines are being used, personally supervises class D radiographic operations and who is responsible to the registrant for assuring compliance with the requirements of these rules and all registration conditions.

(d) "Radiographer's assistant" means an individual who, under the personal supervision of a radiographer, uses radiation machines or survey instruments in class D radiographic operations.

CLASSIFICATION

R 333.5293 Class enumeration.

Rule 293. (1) For registration and approval purposes, industrial radiographic installations shall be classified as class AA, class A, class B, or class C.

(2) For the purpose of registering and approving industrial radiography and radiation machines intended for limited use at temporary job site locations, this use shall be classified as a class D operation.

R 333.5294 Class AA installations.

Rule 294. (1) In class AA installations the radiation machine and objects exposed thereto shall be contained within a permanent enclosure.

(2) The enclosure shall be constructed such that the radiation dose rate at a distance of 5 centimeters from any point on the external surface shall not exceed 0.02 millisievert per hour (2 mrem/h). The dose rate shall be measured with the source of radiation placed at the position of closest source-wall distance that is radiographically usable and under conditions of maximum radiation output permitted by the design or operating characteristics of the radiation machine.

(3) Mechanical or electrical limiters shall limit movement or alignment of the radiation machine within the enclosure if necessary to comply with subrule (2) of this rule.

(4) A personnel barrier posted pursuant to R 333.5067 to R 333.5072 restricting access to

the roof of the enclosure shall meet the requirement of subrule (2) of this rule.

(5) Reliable interlocks shall be provided which will prevent anyone from opening the enclosure while the radiation machine is on or which will terminate machine operation should anyone open the enclosure.

(6) Enclosures of sufficient size to permit human occupancy shall be provided with visible signals or audible signals, or both, within the enclosure, which are activated a minimum of 5 seconds before radiation machine activation. Individuals shall at all times be able to escape from within the enclosure.

(7) Individuals shall not be permitted to remain within the enclosure while the radiation machine is in operation.

(8) Protective enclosures and equipment shall be kept in good repair.

(9) Industrial fluoroscopy shall meet the requirements of class AA installations.

(10) Notwithstanding the provisions of subrule (2) of this rule, the enclosure for industrial fluoroscopy shall be constructed such that the radiation dose rate at a distance of 5 centimeters from any accessible point on the external surface shall not exceed 0.005 millisievert per hour (0.5 mrem/h) under conditions of maximum radiation output permitted by the design or operating characteristics of the installation.

(11) Industrial cabinet radiography conducted in enclosures of insufficient size to permit human occupancy shall meet the requirements of class AA installations.

(12) Notwithstanding the provisions of subrule (2) of this rule, the enclosure for industrial cabinet radiography of insufficient size to permit human occupancy shall be constructed such that the radiation dose rate at a distance of 5 centimeters from any accessible point on the external surface shall not exceed 0.005 millisievert per hour (0.5 mrem/h) under conditions of maximum radiation output permitted by the design or operating characteristics of the installation.

(13) For class AA enclosures of sufficient size to permit human occupancy, a personnel radiation dosimeter shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

(14) Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs for inspection by the department.

(15) Class AA approval permits unlimited use at maximum capacity.

R 333.5296 Class A installations.

Rule 296. (1) Class A installations shall comply with all requirements of R 333.5294 except for a permissible dose rate of 0.07 millisievert per hour (7 mrem/h) at any accessible external point.

(2) A personnel radiation dosimeter shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

(3) Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs for inspection by the department.

(4) Class A approval permits unlimited use at maximum capacity.

R 333.5297 Class B installations.

Rule 297. (1) Class B installations shall comply with all requirements of R 333.5296.

(2) Radiation machine current and potential controls shall be mechanically or electrically

limited so as not to exceed the normal operating conditions as specified by the registrant at the time of application for registration.

(3) Class B approval permits unlimited use under normal operating conditions as specified by subrule (2) of this rule.

R 333.5298 Class C installations.

Rule 298. (1) Class C installations shall comply with all requirements of R 333.5296 except for a permissible dose rate of 0.5 millisievert (50 mrem) per hour at any accessible external point.

(2) The maximum weekly exposure time of radiation machines within the enclosure shall be established by the department under the conditions specified by the registrant at the time of application.

(3) Warning signs shall be posted in those areas outside the enclosure in which the radiation dose rate at any accessible external point exceeds 0.02 millisievert per hour (2 mrem/h). The dose rate shall be measured with the radiation machine tube placed at position of nearest source-wall distance that is radiographically usable under conditions of maximum radiation output permitted by the design or limited operating characteristics of the radiation machine.

R 333.5299 Class D operations.

Rule 299. (1) Industrial radiography conducted under conditions not meeting the provisions and requirements of R 333.5294 to R 333.5298 shall be classified as class D operations and shall not be operated longer than 30 days unless written authorization is granted by the department.

(2) Written authorization may be granted by the department for class D operations longer than 30 days but not longer than 6 months when an undue and unnecessary hardship may result from the 30-day limitation. Written request by the registrant for this authorization is required and shall describe the hardship involved as well as provide written assurance of compliance with the requirements of these rules for class D operations.

(3) Notwithstanding subrules (1) and (2) of this rule, a registrant routinely engaged in providing industrial radiography services with mobile or portable radiation machines at temporary job site locations may conduct such class D operations without time limitation subject to all of the following conditions:

(a) The registrant shall give written notice to the department at least 2 working days before starting radiographic work at a job site. The notice shall include the radiographer's name; the machine registration number; the nature, duration, and scope of use; and the exact location of each job site. If the 2 work-day period would impose an undue hardship on the registrant, upon application to the department, he or she may arrange for other notification to comply with the intent of this requirement.

(b) These class D operations shall be limited to locations and circumstances which cannot meet the provisions and requirements of permanent installation classification without undue and unnecessary hardship.

(c) A copy of written operating and emergency procedures shall be filed with and approved by the department.

(d) Upon reasonable notice from the department, the registrant shall submit to the department or otherwise make available copies of specific records pertaining to radiographic

operations and personnel conducting these operations within this state.

(4) A fence, rope, or other suitable barrier shall be erected along the 0.05 millisievert per hour (5 mrem/h)contour line during class D radiographic operations to exclude unauthorized individuals from the radiation area.

(5) Notwithstanding the requirements of R 333.5073, the radiation area and high radiation area shall be posted with caution signs as specified in R 333.5067 to R 333.5072.

(6) A registrant shall not permit an individual to act as a radiographer or as a radiographer's assistant unless, at all times during radiographic operation, the individual wears a long-term monitoring device such as a film badge or TLD and a short-term monitoring device such as a pocket dosimeter or pocket chamber. Pocket dosimeters and pocket chambers shall be capable of measuring doses from 0 to at least 2 millisieverts (200 mrem). A long-term monitoring device shall be assigned to and worn by only 1 individual.

(7) Pocket dosimeters and pocket chambers shall be read and doses recorded daily. A film badge or similar device shall be immediately processed if a pocket chamber or pocket dosimeter is discharged beyond its range. All personnel exposure reports and records of pocket dosimeter and pocket chamber readings shall be maintained for inspection by the department.

(8) Written operating and emergency procedures shall be available at each class D radiographic operation.

REQUIREMENTS FOR CLASS D RADIOGRAPHIC OPERATIONS

R 333.5302 Operating and emergency procedures.

Rule 302. A registrant's written operating and emergency procedures for class D radiographic operations shall include instructions in at least the following:

(a) The use of radiation machines to be employed such that an individual is not likely to be exposed to radiation doses in excess of the limits established in R 333.5057 to R 333.5061.

(b) Methods and occasions for conducting radiation surveys.

(c) Methods for controlling access to radiographic areas.

(d) Personnel monitoring and the use of individual monitoring devices.

(e) Transportation to field locations, including packing of radiation machines in the vehicles, posting of vehicles, and control of radiation machines during transportation.

(f) Minimizing exposure of persons in the event of an accident.

(g) Procedure for notifying proper persons in the event of an accident.

(h) Maintenance of records.

(i) Inspection and maintenance of radiation machines.

R 333.5305 Security.

Rule 305. (1) During each class D radiographic operation, the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, except where the high radiation area is equipped with interlocks as described in R 333.5294 (5), or where the high radiation area is locked to protect against unauthorized or accidental entry.

(2) A radiographer or radiographer's assistant shall not perform or permit class D radiographic operation unless all individuals present in or entering the resulting radiation area are wearing individual monitoring devices.

R 333.5306 Radiation surveys and survey records.

Rule 306. (1) A class D radiographic operation shall not be conducted unless calibrated and operable radiation survey instrumentation, as described in R 333.5307, is available and used at each site where radiographic exposures are made.

(2) For class D radiographic operations, a physical radiation survey shall be conducted to determine that the radiation machine is off before each entry into the radiographic exposure area.

R 333.5307. Radiation survey instruments.

Rule 307. (1) A registrant shall maintain calibrated and operable radiation survey instruments to make physical radiation surveys as required by R 333.5306 and R 333.5063. A radiation survey instrument shall be calibrated at least annually and after each instrument servicing. A record of the calibration shall be maintained for examination by the department.

(2) Instrumentation required by this rule shall have a range such that 0.02 millisievert per hour (2 mrem/h) through 0.01 sievert per hour (1 rem/h) can be measured and shall be capable of measuring radiation of the energies and at the dose rates to be encountered.

(3) During repair or calibration of survey instruments required by this rule, spare operable and calibrated instruments shall be provided or class D radiographic operations shall be terminated pursuant to R 333.5306(1).

R 333.5308 Utilization logs.

Rule 308. A registrant shall maintain for inspection by the department current logs, which contain all of the following information for each radiation machine:

(a) The machine registration number.

(b) The identity of the radiographer to whom the machine is assigned.

(c) The locations where used and dates of use.

(d) The signature or initials of the individual certifying each entry.

R 333.5309 Limitations for radiographers and radiographer assistants.

Rule 309. (1) A registrant shall not permit an individual to act as a radiographer until all of the following have been met:

(a) The individual was instructed in the subjects outlined in table 309 and has demonstrated understanding of these subjects.

TABLE 309
Instruction of radiographers

I Fundamentals of Radiation Safety

A. Characteristics of x-radiation
B. Units of radiation dose
C. Hazards of excessive radiation exposure
D. Levels of radiation from radiation machines
E. Methods of controlling radiation dose
1. Working time
2. Working distances

3. Shielding

II Radiation Detection Instrumentation to be Used

A. Use of radiation survey instruments
1. Operation
2. Calibration
3. Limitations
B. Survey techniques
C. Use of individual monitoring devices

III. Radiographic Equipment to be Used

A. Operation and control of x-ray equipment

IV. The Requirements of Pertinent State Regulations

V. The Registrant's Written Operating and Emergency Procedures

VI. Registration Conditions

(b) The individual received copies of and instruction in the rules contained in this part and the applicable sections of R 333.5051 to R 333.5089, registration conditions, and the registrant's operating and emergency procedures, and has demonstrated an understanding of these subjects.

(c) The individual demonstrated competence to use the radiation machine and survey instruments which will be employed in his or her assignment.

(2) A registrant shall not permit an individual to act as a radiographer's assistant until both of the following have been met:

(a) The individual received copies of and instruction in the registrant's operating and emergency procedures, and has demonstrated an understanding of these procedures.

(b) The individual demonstrated competence to use, under the personal supervision of the radiographer, the radiation machines and radiation survey instruments which will be employed in his or her assignment.

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.

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 and are manufactured after the effective date of these rules. 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.

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.

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.

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.

R 333.5322 Enclosures.

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

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

PART 8. MEDICAL EXTREMITY X-RAY INSTALLATIONS

R 333.5361 Purpose and scope.

Rule 361. (1) This part establishes requirements governing the use of x-radiation in a healing arts discipline for human extremity radiography only.

(2) This part applies to all registrants who use x-radiation for the intentional exposure of human extremities only.

(3) In addition to the requirements of this part, all registrants performing human extremity radiography are subject to all applicable provisions of these rules. Uses of x-radiation for intentional human exposure other than or in addition to extremity radiography are subject to R 333.5311 to R 333.5359.

FIXED RADIOGRAPHIC INSTALLATIONS

R 333.5362 X-ray equipment.

Rule 362. (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 that shown in table 362.

TABLE 362

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 in R 333.5325(5).

(5) 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.

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

(7) 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.

(8) 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.

(9) 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 collimators shall provide the same precision.

(10) 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.

(11) A device shall be provided to terminate 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.

(12) 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. When protective shielding is provided, the operator shall always be entirely behind the shield during the exposure.

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

(14) 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.

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

R 333.5365 Enclosures.

Rule 365. (1) 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.

(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.

(3) Secondary protective barriers shall be provided in the radiographic room ceiling and in those walls not requiring primary barriers. Common building materials often fulfill this requirement.

(4) A fixed barrier of 1.6 millimeters (1/16 inch) lead equivalence, such as a shielded wall partition or immobilized portable shield, is recommended for operator protection. When this protection is provided, the operator shall be able to see and communicate with the patient from a shielded position.

R 333.5366 Conditions of operation.

Rule 366. (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 each 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 the 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 is held in position for radiography, mechanical supporting or restraining devices shall be available and shall be used unless contraindicated. If the patient is 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) During each 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.

(6) 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.

(7) 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.

(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 all 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) 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. Special gonadal aprons (0.25 mm lead equivalent) are recommended, but not required, for patient protection from secondary radiation.

(12) 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.

(13) Film processing materials and techniques shall be those recommended by the x-ray film and processing materials manufacturers 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 shall be used.

(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.

MOBILE OR PORTABLE RADIOGRAPHIC EQUIPMENT

R 333.5368 General provisions.

Rule 368. (1) Radiographic x-ray equipment shall meet the requirements of R 333.5362.

(2) Mobile or portable radiographic x-ray equipment used routinely in 1 location shall be considered a fixed installation and enclosures shall meet the requirements of R 333.5365.

(3) Operation shall comply with the requirements of R 333.5366.

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.

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.

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 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.

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.

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.

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).

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.

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.

R 333.5381 Conditions of operation.
Rule 381. Operation shall meet the requirements of R 333.5376.

PANORAMIC INSTALLATIONS

R 333.5383 Scope.
Rule 383. R 333.5384 to R 333.5386 apply to panoramic installations and protective enclosures.

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.

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.

R 333.5386 Conditions of operation.
Rule 386. Operation shall meet the requirements of R 333.5376.

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.

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.

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.

R 333.5391 Conditions of operation.

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

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.

HAND-HELD PORTABLE DENTAL X-RAY SYSTEMS

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

Rule 396. (1) X-ray equipment designed to be hand-held shall meet the requirements of R 333.5373, excluding subrules (9) and (13).

(2) The x-ray tube housing for tubes designed to be hand-held shall 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.

(3) Operation of a hand-held portable x-ray system shall meet the requirements of R 333.5376, 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) 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.

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

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.

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.

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.

R 333.5403 Enclosures.

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

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 milliammeter 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.

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.

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.

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 (14) 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 (13) 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.

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.

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.

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.

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.

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).

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.

PART 11. PARTICLE ACCELERATOR INSTALLATIONS

R 333.5431 Purpose and scope.

Rule 431. (1) This part establishes procedures for the registration of particle accelerators, a classification system for particle accelerator installations and use, and radiation safety requirements for persons utilizing all types of particle accelerators except those specifically exempted from this part.

(2) This part applies to all registrants who use particle accelerators for a purpose other than those exempted under R 333.5432.

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

R 333.5432 Definition.

Rule 432. "Particle accelerator" or "accelerator", as used in this part, means a radiation machine designed for or capable of accelerating electrically charged particles, such as electrons, protons or deuterons, with an electrical potential in excess of 1 MeV. Radiation machines designed and used exclusively for the production of electron beams or x-radiation for any of the following purposes except those capable of producing radioactive material in excess of exempt quantities listed in schedule B of R 325.5147 are excluded from this definition:

(a) The diagnosis or treatment of patients.

(b) Industrial radiography.

(c) Examination of the microscopic structure of materials.

(d) Manufacturing process control.

(e) Research and development.

(f) Demonstration of scientific principles for educational purposes.

LICENSE OR REGISTRATION

R 333.5435 General provisions.

Rule 435. A person having a particle accelerator subject to this part shall comply with the registration requirements of R 333.5031 to R 333.5049.

CLASSIFICATION

R 333.5437 Class enumeration.

Rule 437. (1) For registration and approval purposes, particle accelerator installations shall be classified as class AA, class A, class B, or class C.

(2) For the purpose of registering and approving mobile or portable particle accelerators intended for limited use at temporary job site locations, this use shall be classified as class D operation.

R 333.5438 Class AA installations.

Rule 438. (1) In class AA installations the accelerator and objects exposed thereto shall be contained within a permanent enclosure.

(2) The enclosure shall be constructed so that the dose equivalent rate as measured in air at a distance of 5 centimeters from an accessible point on the external surface shall not exceed 2 millirems per hour under conditions of maximum radiation output permitted by the design or operating characteristics of the accelerator.

(3) Mechanical or electrical limiters shall limit movement or alignment of the accelerated beam within the enclosure if necessary to comply with subrule (2) of this rule.

(4) A personnel barrier posted pursuant to R 333.5067 to R 333.5072 restricting access to the roof of the enclosure shall meet the requirement of subrule (2) of this rule.

(5) Reliable interlocks shall be provided which prevent an individual from opening the enclosure while the accelerator is in operation or which terminate machine operation if an individual opens the enclosure. These interlocks shall meet the requirements of R 333.5448.

(6) Enclosures of sufficient size to permit human occupancy shall be provided with visible or audible signals or both within the enclosure which are activated a minimum of 5 seconds before accelerator operation. Individuals shall at all times be able to escape from within the enclosure.

(7) An individual shall not be permitted to remain within the enclosure while the accelerator is in operation except as a human patient undergoing radiation treatment.

(8) Protective enclosures and equipment shall be kept in good repair.

(9) Electron beam welders shall meet class AA requirements.

(10) Class AA approval permits unlimited use at maximum capacity.

R 333.5439 Class A installations.

Rule 439. (1) Class A installations shall comply with all requirements of R 333.5438 except for a permissible dose equivalent rate of 7 millirems per hour at an accessible external point.

(2) An individual monitoring device, such as a film badge dosimeter or thermoluminescent dosimeter, shall be permanently assigned to each occupationally exposed individual. This monitoring shall be continuous during employment as a radiation worker.

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

(4) Class A approval permits unlimited use at maximum capacity.

R 333.5440 Class B installations.

Rule 440. (1) Class B installations shall comply with all requirements of R 333.5439.

(2) Accelerator beam current and potential controls shall be mechanically or electrically

limited so as not to exceed the normal operating conditions as specified in the application for specific license or registration.

(3) Class B approval permits unlimited use under normal operating conditions as specified by subrule (2) of this rule.

R 333.5441 Class C installations.

Rule 441. (1) Class C installations shall comply with all requirements of R 333.5439 except for a permissible dose equivalent rate of 50 millirems per hour at an accessible external point.

(2) The maximum weekly accelerator beam on time shall be established by the department under the conditions specified in the application for specific license or registration.

(3) Warning signs shall be posted in those areas outside the enclosure in which the radiation exposure dose equivalent rate in air at an accessible external point exceeds 2 millirems per hour under conditions of maximum radiation output permitted by the design or limited operating characteristics of the accelerator.

(4) A daily usage log shall be maintained to record machine operation. The record shall be available at the accelerator site for examination by the department.

R 333.5442 Class D operations.

Rule 442. (1) Particle accelerator operations conducted under conditions not meeting the provisions and requirements of R 333.5438 to R 333.5441 shall be classified as class D operations and shall not be operated longer than 30 days unless written authorization is granted by the department.

(2) Written authorization in the form of a registration condition may be granted by the department for class D operations longer than 30 days but not longer than 6 months at 1 location when an undue and unnecessary hardship may result from the 30-day limitation. Written request by the applicant for this authorization is required and shall describe the hardship involved as well as provide written assurance of compliance with the requirements of these rules for class D operation. This assurance shall be in the form of satisfactory written procedures which shall be approved by the department before the issuance of a certificate of registration.

SAFETY REQUIREMENTS FOR THE USE OF PARTICLE ACCELERATORS

R 333.5445 General provisions.

Rule 445. (1) R 333.5445 to R 333.5452 establish radiation safety requirements for the use of particle accelerators. These requirements are in addition to, and not in substitution for, other applicable provisions of these rules.

(2) A registrant shall be responsible for assuring that all requirements of this part are met.

R 333.5446 Limitations.

Rule 446. (1) A registrant shall not permit an individual to act as an accelerator operator until the individual has met all of the following:

(a) Been instructed and demonstrated an understanding of radiation safety.

(b) Received copies of, instruction in, and demonstrated an understanding of R 333.5431 to R 333.5452 and the applicable requirements of all of the following:

(i) R 333.5051 to R 333.5089.

(ii) Pertinent registration conditions.

(iii) The registrant's operating and emergency procedures.

(c) Demonstrated competence to use the particle accelerator, related equipment, and survey instruments employed in his or her assignment.

(2) The radiation safety committee or the radiation protection supervisor shall have the authority to terminate the operations at an accelerator facility or of a class D operation if this action is necessary to protect and minimize danger to public health and safety or property.

R 333.5447 Shielding.

Rule 447. (1) The design and shielding specifications for an accelerator shall be submitted to and approved by the department before issuance of a certificate of registration. After construction, the radiation safety of the installation shall be established by a protection survey conducted pursuant to R 333.5063. A written report of the initial survey shall be submitted to the department and approved in writing before continued operation of the accelerator.

(2) An accelerator installation shall be provided with primary or secondary barriers as are necessary to ensure compliance with R 333.5057 to R 333.5061.

R 333.5448 Accelerator controls and interlock systems.

Rule 448. (1) Instrumentation, readouts, and controls on the accelerator control console shall be clearly identified and easily discernible.

(2) All entrances or openings into a target room or other high radiation area shall be provided with interlocks.

(3) When an interlock system has been tripped, operation of the accelerator shall only be resumed by first manually resetting controls at the position where the interlock has been tripped, and lastly at the main control console.

(4) A safety interlock shall be on a circuit which will allow it to operate independently of all other safety interlocks.

(5) A safety interlock shall be fail safe. A defect or component failure in the interlock system shall prevent operation of the accelerator.

(6) A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. This cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

R 333.5449 Warning devices.

Rule 449. (1) Locations designated as high radiation areas, and entrances to these locations, shall be equipped with easily observable warning lights that operate when, and only when, radiation is being produced.

(2) Except in installations designed for human exposure, a high radiation area shall have an audible warning device which shall be activated for 15 seconds before the possible creation of a high radiation area. This warning device shall be clearly discernible in all high radiation areas and all radiation areas.

(3) Barriers and pathways leading to high radiation areas shall be identified pursuant to R 333.5067 to R 333.5074.

R 333.5450 Equipment control and operations.

Rule 450. (1) A particle accelerator shall not be left unattended without locking the control panel in a manner which prevents its use by unauthorized individuals.

(2) A mobile or portable particle accelerator shall not be left unattended without locking the room or building in which it is housed in a manner which prevents its removal by unauthorized persons.

(3) Access to keys used to comply with the requirements of subrules (1) and (2) of this rule shall be limited to specific individuals authorized by the radiation protection supervisor.

(4) Only a switch on the accelerator control console shall be routinely used to turn the accelerator beam on and off. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency or during periodic testing of the interlock system.

(5) All safety and warning devices, including interlocks, shall be checked for proper operability at least quarterly. Results of these tests shall be maintained for inspection by the department at the accelerator installation.

(6) Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall be kept current and on file at each

accelerator installation.

(7) If it is necessary to intentionally bypass a safety interlock or interlocks, the action shall be in conformance with all of the following:

(a) Authorized by the radiation protection supervisor pursuant to R 333.5075.

(b) Recorded in a permanent log and a notice posted at the accelerator control console.

(c) Terminated as soon as possible.

(8) A copy of the operating and the emergency procedures shall be maintained at the accelerator control panel.

R 333.5452 Radiation surveys.

Rule 452. (1) A registrant shall maintain at each accelerator installation or class D operation appropriate calibrated and operable portable radiation monitoring instruments to make physical radiation surveys as required by this part and R 333.5051 to R 333.5089.

(2) These instruments shall be capable by design, calibration, and operation of measuring the intensity of the various types and energies of radiation produced by the accelerator. These instruments shall be tested for proper operation at the beginning of each day they are to be used and calibrated at least quarterly.

(3) During repair or calibration of a radiation monitoring instrument, a spare calibrated and operable instrument shall be provided or accelerator operations which require the instrument shall be terminated until required instrumentation is available.

(4) A radiation protection survey shall be performed and documented pursuant to R 333.5063 when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

(5) Radiation levels in all accessible high radiation areas shall be continuously monitored except in installations designed for human exposure. The monitoring devices shall be independent and capable of providing a remote and local readout with visual or audible alarms, or both, at the control panel and at the monitoring stations.

(6) All area monitors shall be calibrated at established periodic intervals approved by the department.

(7) All area surveys shall be made as specified in the written procedures established by a

health physics consultant or the radiation protection supervisor of the accelerator facility and approved by the department.

(8) Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility.

PART 13. MISCELLANEOUS SOURCES

R 333.5481 Purpose and scope.

Rule 481. (1) This part establishes radiation safety requirements for miscellaneous radiation sources and for persons utilizing sources not exempted under R 333.5015 and not specifically covered elsewhere by these rules.

(2) This part applies to all persons who use sources of radiation not specifically covered by the other parts.

(3) In addition to the requirements of this part all persons and activities covered by this part are subject to the applicable provisions of R 333.5001 to R 333.5101.

ANALYTICAL X-RAY SOURCES

R 333.5482 X-ray equipment.

Rule 482. (1) Tube housing leakage from analytical x-ray sources shall not exceed 0.5 milliroentgen per hour at a 5 centimeter distance from the surface of the tube housing with the beam ports blocked and the tube operating at its leakage technique factors. Also, radiation originating from the high voltage power supplies shall not exceed this limit.

(2) For instruments in which the primary x-ray beam is completely enclosed, the radiation shall be less than 2 milliroentgens per hour at a distance of 25 centimeters from the cabinet surface.

(3) For enclosed equipment, interlocks shall be provided on all access panels which terminate exposure and prevent operation while the panel is removed.

(4) Open beam analytical x-ray equipment shall meet all of the following:

(a) X-ray diffraction cameras shall have the appropriate ports arranged so that the camera collimating system is in place before the x-ray tube can be energized or the shutter can be opened.

(b) An adapter between the x-ray tube and the collimator of the diffractometer camera or other accessory shall provide protection equivalent to that required by subrule (1) of this rule.

(c) Safety interlocks shall not be used as routine cut-off switches during normal operation. They shall be operated as safety devices only, and tested periodically. When the interlock system terminates the x-ray beam, it shall be necessary to reset the "on" switch at the control panel to resume operation.

(d) Tube head ports which are not in use shall be secured in a closed position and interlocked to the x-ray generator or warning system.

(e) The shutter indicator shall be conspicuously displayed to disclose the "open" or "closed" position of the shutter.

(f) The instrument shall display a conspicuous warning label such as "CAUTION RADIATION - THIS EQUIPMENT PRODUCES X-RADIATION WHEN ENERGIZED."

(g) A red warning light shall indicate "X-RAY ON" when the equipment is producing x-rays. Other signal lights or alarms shall operate only to indicate a malfunction which may

produce a radiation, electrical, or other hazard.

R 333.5484 Administrative procedures.

Rule 484. A radiation protection supervisor shall be appointed to be responsible for radiation safety. This individual's primary job duty shall not be operating the x-ray equipment. The radiation protection supervisor or designated representative shall do all of the following:

(a) Ensure that operational and maintenance procedures are followed.

(b) Provide instruction in safety practices for all individuals working with the x-ray equipment, and those working in the immediate area or periodically review the safety instruction provided for these individuals.

(c) Maintain a personnel monitoring system, as required by R 333.5487.

(d) Review, approve, and supervise modifications or replacement of parts for the x-ray apparatus.

(e) Conduct surveys and tests as necessary to certify compliance with these rules, including specific registration conditions, and maintain records thereof for examination by the department.

R 333.5485 Operators.

Rule 485. (1) An individual shall not act as the operator of analytical x-ray equipment until he or she has received training in radiation safety and has been approved by the radiation protection supervisor or designated representative. The operator shall also demonstrate competence in the use of the machine and radiation survey instruments.

(2) The operator shall be responsible for complying with all procedures associated with the x-ray equipment.

R 333.5486 Operating procedures.

Rule 486. A set of operating procedures, written in understandable and concise language, shall be posted on or adjacent to the machine,.

R 333.5487 Personnel monitoring.

Rule 487. An operator of analytical x-ray equipment having an open-beam configuration shall be provided with finger or wrist radiation monitoring devices. An analytical x-ray system having an open-beam configuration is one in which an individual could accidentally place some part of his or her body in the primary beam path during normal operation. An individual coming in contact with equipment capable of exposing a major portion of the body shall be required to wear whole-body monitoring equipment at all times. Personnel coming in contact with this equipment shall be warned of the nature and type of physiological effects that may be expected when overexposed to radiation.

COLD-CATHODE GAS DISCHARGE TUBES

R 333.5491 Rules applicable.

Rule 491. Cold-cathode gas discharge tubes designed to demonstrate the effects of a flow of electrons or the production of x-radiation are subject to the requirements of R 333.5492 to R 333.5495.

R 333.5492 Exposure rate limit.

Rule 492. (1) Radiation exposure rates produced by cold-cathode gas discharge tubes shall not exceed 10 mR/hr at a distance of 30 centimeters from a point on the external surface of the tube, as measured pursuant to R 333.5493.

(2) The divergence of the exit beam from tubes designed primarily to demonstrate the effects of x-radiation, with the beam blocking device in the open position, shall not exceed π (Pi) steradians.

R 333.5493 Measurements.

Rule 493. (1) Compliance with the exposure rate limit specified in R 333.5492 (1) shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension exceeding 20 centimeters.

(2) Measurements of exposure rates from tubes in enclosures from which the tubes cannot be removed without destroying the function of the tube may be made at a distance of 30 centimeters from a point on the external surface of the enclosure under either of the following conditions:

(a) In the case of enclosures containing tubes designed primarily to demonstrate the production of x-radiation, measurements shall be made with a beam blocking device in the beam blocking position.

(b) In the case of enclosures containing tubes designed primarily to demonstrate the effects of a flow of electrons, measurements shall be made with all movable or removable parts of the enclosure in the position which would maximize external exposure levels.

R 333.5494 Test conditions.

Rule 494. (1) Measurements shall be made under the conditions of use specified in instructions provided by the manufacturer.

(2) Measurements shall be made with the tube operated under forward and reverse polarity.

R 333.5495 Instructions; labels and warnings.

Rule 495. (1) For each tube to which R 333.5492 to R 333.5495 are applicable, the registrant shall ensure the availability of appropriate safety instructions and instructions for the use of the tube. These instructions shall include the specification of a power source for use with the tube.

(2) An enclosure or tube shall have tags or labels inscribed on or permanently affixed , which identify the intended polarity of the terminals and shall include either of the following:

(a) In the case of tubes designed primarily to demonstrate the heat effect, fluorescence effect, or magnetic effect, a warning that application of power in excess of that specified may result in the production of x-rays in excess of allowable limits.

(b) In the case of tubes designed primarily to demonstrate the production of x-radiation, a warning that this device produces x-rays when energized.

(3) The tag or label required by subrule (2) of this rule shall be located on the tube or enclosure so as to be readily visible and legible when the product is fully assembled for use.

ELECTRON MICROSCOPES

R 333.5505 Equipment.

Rule 505. (1) During all phases of operation of an electron microscope at the maximum rated continuous tube current for the maximum rated peak tube potential the radiation exposure rate as measured in air at a distance of 5 centimeters from an accessible point on the external surface of the microscope shall not exceed 0.5 milliroentgen per hour.

(2) Interlocks shall be provided on all potential radiation hazard access panels which terminate exposure and prevent operation while the panel is removed.

(3) The instrument shall display a conspicuous warning label such as "CAUTION RADIATION - THIS EQUIPMENT PRODUCES X-RADIATION WHEN ENERGIZED."

(4) Electron microscopes that are not capable of exceeding an operating potential of 50 kilovolts are exempt from the requirements of R 333.5505 to R 333.5508.

R 333.5506 Administrative procedures.

Rule 506. A radiation protection supervisor shall be appointed to be responsible for radiation safety. This individual shall not normally operate the electron microscope. The radiation protection supervisor or a designated representative shall do all of the following:

(a) Ensure that operational and maintenance procedures are followed.

(b) Provide instruction in safety practices for all persons working with the electron microscope, and those working in the immediate area.

(c) Maintain a personnel monitoring system, if provided.

(d) Review, approve, and supervise modifications or replacement of parts for the electron microscope.

(e) Conduct surveys and tests as necessary to certify compliance with these rules, including specific registration conditions.

(f) Maintain records of surveys and tests for examination by the department.

R 333.5507 Operators.

Rule 507. (1) An individual shall not act as operator of an electron microscope unless he or she has demonstrated to the satisfaction of the radiation protection supervisor or designated representative both of the following:

(a) Competence in the safe use of the instrument.

(b) Awareness of the potential radiation hazard which could result from improper adjustment or misuse of the instrument.

(2) The operator shall be responsible for complying with all procedures associated with the instrument.

R 333.5508 Operating procedures.

Rule 508. A set of operating procedures, written in understandable and concise language shall be posted on or adjacent to the electron microscope.

OTHER MISCELLANEOUS SOURCES

R 333.5511 Registration conditions.

Rule 511. Types of radiation sources and uses not specifically covered by these rules shall be subject to specific requirements designated by the department in the form of registration conditions for the protection of public health, safety, and property until these rules are

amended to specifically cover these sources and uses.

PART 14. MAMMOGRAPHY

GENERAL PROVISIONS

R 333.5601 Purpose and scope.

Rule 601. (1) This part establishes requirements governing the use of x-radiation for mammography and applies to all persons who use x-radiation for mammography for the intentional exposure of humans. A person shall not use a radiation machine to perform mammography unless the radiation machine is registered with the department pursuant to R 333.5031 to R 333.5049 and is authorized pursuant to the act to perform mammography.

(2) In addition to the requirements of this part, all persons are subject to all applicable provisions of these rules.

(3) A facility shall not misrepresent to its employees, to the public, or to the department its status with respect to accreditation of the mammography equipment by the American college of radiology, department authorization to perform mammography, or compliance with department rules.

R 333.5602 Adoption by reference.

Rule 602. Some of these rules refer to all or parts of the following nationally recognized standards, which are adopted by reference and identified by date:

(a) Standards of the United States department of health & human services, title 21 - food and drugs, part 900 - mammography. These standards are available for no cost from either of the following sources:

(i) The website of the Michigan department of licensing and regulatory affairs, radiation safety section at http://www.michigan.gov/rss.

(ii) The website of the United States department of health & human services, mammography quality standards act and program at http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm.

(b) The regulations in 21 C.F.R. 1020.30, "Diagnostic x-ray systems and their major components" (April 2007), and 21 C.F.R. 1020.31, "Radiographic equipment" (June 2005). These regulations are available for no cost from either of the following sources:

(i) The website of the Michigan department of licensing and regulatory affairs, radiation safety section at http://www.michigan.gov/rss.

(ii) The website of the United States department of health & human services, U.S. food and drug administration at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.

(c) Criteria of the American college of radiology, "Mammography Accreditation Program Requirements" (January 2014), and "Stereotactic Breast Biopsy Accreditation Program Requirements" (July 2013). These criteria are available for no cost from either of the following sources:

(i) The website of the Michigan department of licensing and regulatory affairs, radiation safety section at http://www.michigan.gov/rss.

(ii) The website of the American college of radiology at http://www.acr.org.

R 333.5603 Definitions.

Rule 603. (1) As used in this part the definitions in 21 C.F.R. 900.2, "Definitions" (2002),

are adopted by reference with the exception of the definition of “mammography.”

(2) As used in this part the following definitions apply:

(a) “Interpreting physician” means a physician who interprets mammograms and who meets the requirements of R 333.5627 to R 333.5629.

(b) "Mammography" means radiography of the breast for the purpose of enabling a physician to determine the presence, size, location, and extent of cancerous or potentially cancerous tissue in the breast. Mammography includes interventional mammography.

(c) “Stereotactic breast biopsy” means the imaging of a breast performed in at least 2 planes to localize a target lesion during invasive interventions for biopsy procedures.

(d) “Stereotactic breast biopsy physician” means a physician who conducts stereotactic breast biopsy.

R 333.5604 Department inspections.

Rule 604. (1) The department shall inspect a mammography machine and system not later than 60 days after initial mammography authorization is issued. After that initial inspection, the department shall annually inspect the mammography machine and system. The department may inspect more frequently than annually.

(2) After a satisfactory inspection by the department, the department shall issue a certificate of radiation machine inspection which identifies the facility and the machine inspected and which provides a record of the date that the machine was inspected. The facility shall conspicuously post the certificate on or near the inspected machine and in a location that is observable by patients.

(3) The department may issue a notice of violations certificate if violations found during an inspection are not corrected within the specified time limit or if the department has not received written verification of corrections within the specified time limit. The notice of violations certificate shall be conspicuously posted on or near the inspected machine and in a location observable by patients.

(4) A facility shall remove the certificate of radiation machine inspection if directed by the department due to subsequent failure to comply with these rules as determined by follow-up inspections by the department.

(5) In conducting inspections, the department shall have access to all equipment, materials, records, personnel, and information that the department considers necessary to determine compliance with these rules. The department may copy, or require the facility to submit to the department, any of the materials, records, or information considered necessary to determine compliance with these rules.

(6) The department shall designate department employees to conduct regulatory inspections.

(7) The department may conduct tests and evaluations as the department considers appropriate to determine compliance with all of the provisions of these rules.

MAMMOGRAPHY AUTHORIZATION

R 333.5605 Standards for authorization.

Rule 605. The department shall issue a 3-year mammography authorization if the mammography facility is in compliance with all of the following standards:

(a) The radiation machine meets any of the following requirements:

(i) The machine and the facility in which the machine is used meet the criteria for the American college of radiology mammography accreditation program dated January 2014, and the facility submits an evaluation report issued by the American college of radiology as evidence that the criteria are met. The criteria are adopted by reference in these rules for the purpose of applying this paragraph only.

(ii) A machine used for stereotactic breast biopsy and the facility in which the machine is used meet the criteria of the American college of radiology stereotactic breast biopsy accreditation program dated July 2013, and the facility submits an evaluation report issued by the American college of radiology as evidence that the criteria are met. The criteria are adopted by reference in these rules for the purpose of applying this paragraph only. A mammography machine that uses a specially designed add-on device for breast biopsy shall be authorized for both mammography and stereotactic breast biopsy.

(iii) The machine is used in a facility that has successfully completed the department's evaluation of the items described in R 333.5610.

(b) The radiation machine, the film or other image receptor used with the machine, and the facility where the machine is used meet the requirements of this part and applicable provisions of these rules.

(c) The radiation machine is specifically designed to perform mammography.

(d) The radiation machine is used exclusively to perform mammography.

(e) The radiation machine is used in a facility that, before the machine is used on patients and at least annually thereafter, has a qualified medical physicist provide on-site consultation to the facility as described in these rules.

(f) The radiation machine is used according to R 333.5667 or R 333.5690 for stereotactic breast biopsy.

(g) The radiation machine is operated only by an individual who can demonstrate to the department that he or she meets the standards described in this part.

R 333.5606 Temporary mammography authorization.

Rule 606. (1) The department may issue a nonrenewable temporary mammography authorization. A temporary authorization may only be issued if additional time is needed to allow the submission of evidence that is satisfactory to the department to demonstrate compliance with the provisions of R 333.5605.

(2) The department may withdraw a temporary authorization before its expiration if the radiation machine does not meet 1 or more of the criteria specified in R 333.5605.

R 333.5607 Application.

Rule 607. (1) An applicant who seeks mammography authorization shall apply to the department using an application form that is supplied by the department. If mammography is performed at more than 1 address, a separate application shall be used for each address. An applicant shall accurately provide all information that is requested on the form. The information submitted as part of the application shall be sufficient, as determined by the department, to address all of the standards for authorization. Applications that do not provide sufficient information shall be returned to the applicant for completion and resubmission. Applications shall include all of the following information:

(a) Information about the facility, including all of the following:

(i) Mammography facility name, address, and telephone number.

(ii) Type of practice.
(iii) The facility registration number, if currently registered.
(iv) A contact person's name and telephone number.
(b) Personnel information, including the education, training, experience, and certification of the lead interpreting physician, any qualified medical physicist who provides on-site consultation, and any radiologic technologist who performs mammography.
(c) Mammography machine technical information, including all of the following:
(i) Machine registration number, if currently registered.
(ii) Manufacturer.
(iii) Model.
(iv) Target material.
(v) Filter material.
(d) Imaging system information, including all of the following:
(i) The type of imaging system being used.
(ii) Review workstation monitor information, if the machine uses digital imaging.
(iii) Laser printer information, as applicable, for machines using digital imaging.
(iv) Film and screen information, if the machine uses screen-film imaging.
(v) Film processor information, if the machine uses screen-film imaging.
(e) The date of the most recent medical physicist survey.
(2) The department shall respond to an application within 30 days after the date of receipt of the application.

R 333.5608 Application fee schedule; waiver.
Rule 608. (1) An application form for mammography authorization shall be accompanied by a nonrefundable payment, in full, by the applicant, for department evaluation of compliance with the provisions of R 333.5605(a). The fee schedule is on the website of the department.
(2) If an applicant for mammography authorization submits an evaluation report which is issued by the American college of radiology and which demonstrates compliance with the provisions of R 333.5605(a), then the fee for department evaluation of compliance with the provisions of R 333.5605(a) shall be waived.

R 333.5609 Application expiration.
Rule 609. An application for mammography authorization submitted to the department shall expire 6 months from the date of the department's receipt of the completed application unless the time limit is extended by the department.

R 333.5610 Supplemental machine information; effect of failure to submit information.
Rule 610. (1) Upon notice from the department that an application for mammography authorization is complete and complies with these rules and at the specific request of the department, the applicant shall, within 45 days of the department's request, provide all of the following information for each radiation machine for which mammography authorization is being sought:
(a) Confirmation that a department-approved mammography phantom is on-site when mammography is performed and is used in the facility's ongoing quality control program.
(b) Processor or laser film printer quality control data and corrective actions, if any, taken

as a result of that data for a 30-day period beginning after the date the application was sent to the department.

(c) An x-ray image of a department-approved mammography phantom which is taken during the 30-day period for which processor quality control data is required under subdivision (b) of this subrule. The phantom image shall be taken using routine machine settings being used by the facility for that mammography machine for a 4.2-centimeter compressed breast of average density. The phantom image shall be accompanied by documentation of the date that the image was taken and the machine settings that were used.

(d) Determinations of the half-value layer, radiation exposure at skin entrance, and mean glandular dose. These determinations shall be made with the use of a department-approved dosimetry device exposed on the phantom during the same exposure that is used to produce an x-ray image to be submitted under subdivision (c) of this subrule, or that are made by other methods as specified or approved by the department.

(e) A set of clinical images produced on or after the date that the application was sent to the department. Mammography images shall be without pathology for each of 2 representative patients, 1 with dense breasts and 1 with fatty breasts. Stereotactic breast biopsy images shall be from 1 calcification biopsy case that demonstrates accurate needle location and includes the case's corresponding mammograms. The submitted images shall meet all of the following:

(i) The cases are examples of the facility's best work.

(ii) The images are from actual patients.

(iii) Both screen-film and digital images are labeled with the identification information required in R 333.5657 for mammography images or R 333.5683 for stereotactic breast biopsy images.

(iv) The lead interpreting physician reviews and approves the clinical images.

(f) A copy of the medical physicist's most recent equipment survey report.

(2) The department may waive the requirements of subrule (1) of this rule if the mammography machine is accredited, or is in the process of becoming accredited, by the American college of radiology. To have the requirements of subrule (1) of this rule waived, an applicant shall provide, to the department, within 45 days of the department's request, copies of the applicant's current accreditation application, current accreditation-related correspondence to and from the American college of radiology, or current accreditation certificate that is issued by the American college of radiology.

(3) Failure of an applicant to submit the information required by the provisions of either subrule (1) or (2) of this rule within 45 days of the department's request may be considered a basis for withdrawal or denial of the mammography authorization, unless the time limit is extended by the department for cause.

R 333.5611 Contracts for technical evaluation.

Rule 611. (1) In evaluating clinical image quality and acceptability for mammography authorization, upon receipt of the information required in R 333.5610(1)(e), the department may enter into any necessary contracts with mammography experts, submit the images to those experts for technical evaluation, and rely upon their expert evaluation in arriving at a department conclusion regarding image quality and acceptability in terms of granting or not granting mammography authorization.

(2) Technical parameters that are used in evaluating clinical image quality and acceptability

pursuant to subrule (1) of this rule shall include judgments of all of the following:

(a) Positioning.

(b) Compression.

(c) Radiation exposure and dose level.

(d) Sharpness.

(e) Contrast.

(f) Noise.

(g) Exam identification.

(h) Artifacts.

R 333.5612 Notice of change in application information; authorization not transferable.

Rule 612. (1) A facility that is authorized to perform mammography shall notify the department, in writing, of any change in the information contained in the application or supporting material upon which authorization was granted or any change that affects the accuracy of information which is provided or obtained during the application and evaluation process for authorization. Changes that shall be reported include changes in any of the following:

(a) Facility ownership.

(b) Facility location.

(c) Mammography machine.

(d) Image modality.

(e) American college of radiology accreditation status.

(2) Upon receipt of a notice of change, the department shall advise the facility if reapplication for mammography authorization, resubmittal of phantom or clinical images, or other actions are considered by the department to be necessary to establish that the facility, machine, system, and personnel remain in compliance with the requirements of these rules. Upon department request, a facility shall provide any requested information or materials within 45 days after the request is made.

(3) If changes in information are considered to require reapplication for mammography authorization, the application shall be filed and processed in the same manner as set forth in R 333.5607 and R 333.5608.

(4) Mammography authorization that is issued by the department is not transferable between machines or between persons who own or lease a radiation machine.

R 333.5613 Authorization withdrawal; reinstatement.

Rule 613. (1) Three-year mammography authorization is subject to continued compliance with this part and the provisions of these rules. Authorization may be withdrawn based on evidence of noncompliance with this part and the provisions of these rules pursuant to 1969 PA 306, MCL 24.201 to 24.328.

(2) If the department withdraws the mammography authorization of a machine, the machine shall not be used for mammography. An application for reinstatement of a mammography authorization shall be filed and processed in the same manner as an application for mammography authorization under R 333.5607 and R 333.5608.

(3) The department shall not issue a reinstated mammography authorization until the department receives the reinspection fee, inspects the machine, and determines that the facility meets the standards in R 333.5605.

PERSONNEL

R 333.5626 Scope of personnel requirements.

Rule 626. The requirements of R 333.5627 to R 333.5634 apply to all personnel involved in any aspect of mammography, including but not limited to, the production, processing, and interpretation of mammograms and related quality assurance activities.

R 333.5627 Interpreting physician initial qualifications.

Rule 627. Before beginning to interpret mammograms independently, an interpreting physician shall meet all of the following requirements:

(a) Be licensed as a physician or osteopathic physician under article 15 of the act to practice medicine.

(b) Meet either of the following requirements:

(i) Be certified in radiology or diagnostic radiology by the American board of radiology, the American osteopathic board of radiology, or the royal college of physicians and surgeons of Canada; have been eligible for certification in radiology or diagnostic radiology for not more than 2 years; or, be certified or determined to be qualified in radiology or diagnostic radiology by another professional organization determined by the department to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography.

(ii) If the physician has been eligible for certification in radiology or diagnostic radiology for less than 2 years, he or she shall have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component of the training shall be under the direct supervision of a physician who meets the requirements of this rule.

(c) Have a minimum of 60 hours of documented medical education in mammography, including instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category 1 and at least 15 of the category 1 hours shall have been acquired within the 3 years immediately before the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography are considered as equivalent to category 1 credits and shall be accepted if documented in writing by the appropriate representative of the training institution. A physician who meets the board certification requirements of subdivision (b)(i) of this rule is deemed to have met this requirement.

(d) Have interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately before the date that the physician qualified as an interpreting physician. The interpretation or multi-reading shall be under the direct supervision of an interpreting physician. A physician who becomes appropriately board certified at the first allowable time, as defined by an eligible certifying body, shall have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any 6-month period during the last 2 years of a diagnostic radiology residency. A physician who was qualified to interpret mammograms before the effective date of this

rule is considered to have met the requirements of this subdivision.

R 333.5628 Interpreting physician continuing experience and education.

Rule 628. An interpreting physician shall maintain his or her qualifications by meeting the continuing experience and education requirements of 21 C.F.R. 900.12(a)(1)(ii), "Personnel – Interpreting physicians – Continuing experience and education" (2000).

R 333.5629 Interpreting physician reestablishment of qualifications.

Rule 629. An interpreting physician who failed to maintain the required continuing experience or continuing education requirements of R 333.5628 shall reestablish his or her qualifications before resuming the independent interpretation of mammograms by meeting the reestablishing qualifications requirements of 21 C.F.R. 900.12(a)(1)(iv), "Personnel – Interpreting physicians – Reestablishing qualifications" (2000).

R 333.5630 Radiologic technologists.

Rule 630. All mammographic examinations shall be performed by a radiologic technologist who meets the general requirements, mammography requirements, continuing education requirements, and continuing experience requirements of 21 C.F.R. 900.12(a)(2), "Radiologic technologists" (2000), with the exception of 21 C.F.R. 900.12(a)(2)(i)(A).

R 333.5634 Medical physicists.

Rule 634. A medical physicist who conducts surveys of mammography facilities and provides oversight of a facility's quality assurance program shall meet the initial qualifications, continuing qualifications, and reestablishing qualification requirements of 21 C.F.R. 900.12(a)(3), "Medical physicists" (2000).

R 333.5635 Retention of personnel records.

Rule 635. A mammography facility shall maintain records to document the qualifications of all personnel who work at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records shall be made available for review during department inspections. Records of personnel no longer employed by the mammography facility shall be kept on file until the next inspection following the employee's termination has been completed, and the department determines that the facility complies with the personnel requirements.

X-RAY EQUIPMENT

R 333.5637 X-ray equipment; requirements.

Rule 637. (1) The mammographic x-ray equipment shall be maintained in compliance with the applicable regulations in 21 C.F.R. 1020.30, "Diagnostic x-ray systems and their major components" (2007), and 21 C.F.R. 1020.31, "Radiographic equipment" (2005).

(2) The mammography machine, x-ray film, intensifying screens, film processing solutions, film illumination, and film masking devices shall meet the requirements of 21 C.F.R. 900.12(b), "Equipment" (2000).

R 333.5655 Enclosure requirements; use of mobile equipment.

Rule 655. (1) A fixed x-ray equipment enclosure shall meet the requirements of R 333.5331.

(2) For mammography, the operator's barrier shall provide radiation protection that is equivalent to not less than 0.5 millimeter of lead when the maximum tube potential is less than or equal to 35 kilovolts and 0.8 millimeter of lead when the maximum tube potential is greater than 35 kilovolts.

(3) An individual operating a mobile or portable mammography machine shall wear a protective apron of a minimum 0.5 millimeter lead equivalence unless shielding is provided as specified in subrule (2) of this rule.

(4) Mobile or portable mammography equipment used routinely in 1 location shall be considered a fixed installation and shall meet the requirements of R 333.5331.

(5) Mobile or portable mammography equipment shall not be used for routine mammography in hospitals or private offices of practitioners of the healing arts. This equipment shall be used only when it is medically inadvisable to move a patient to a fixed mammographic installation.

R 333.5656 Conditions of operation.

Rule 656. The operation of a mammography x-ray machine shall meet the requirements of R 333.5333.

MEDICAL RECORDS AND MAMMOGRAPHY REPORTS

R 333.5657 Medical records and mammography reports.

Rule 657. A mammography facility shall comply with 21 C.F.R. 900.12(c), "Medical records and mammography reports" (2000), except that the reference to retention of records in 21 C.F.R. 900.12(c)(4)(i) is changed from "not less than 5 years" to "not less than 7 years" pursuant to MCL 333.20175.

QUALITY ASSURANCE

R 333.5658 Quality assurance - general.

Rule 658. A mammography facility shall comply with 21 C.F.R. 900.12(d), "Quality assurance general" (2000).

R 333.5667 Quality assurance – equipment.

Rule 667. A mammography facility shall comply with 21 C.F.R. 900.12(e), "Quality assurance – equipment" (2000).

R 333.5668 Quality assurance - mammography medical outcomes audit; mammographic procedure and techniques for mammography of patients with breast implants; consumer complaint mechanism; clinical image quality.

Rule 668. A mammography facility shall comply with 21 C.F.R. 900.12(f), "Quality assurance – mammography medical outcomes audit" (2000); 21 C.F.R. 900.12(g), "Mammographic procedure and techniques for mammography of patients with breast implants" (2000); 21 C.F.R. 900.12(h), "Consumer complaint mechanism" (2000) and 21 C.F.R. 900.12(i), "Clinical image quality" (2000).

R 333.5669 Alternative requirements for personnel, x-ray equipment, medical records and mammography reports, and quality assurance.

Rule 669. The department may accept alternatives to a quality standard under 21 C.F.R. 900.12 that have been approved by the U.S. food and drug administration under 21 C.F.R. 900.18, "Alternative requirements for § 900.12 quality standards" (2000).

STEREOTACTIC BREAST BIOPSY

PERSONNEL

R 333.5674 Radiologic technologists.

Rule 674. All stereotactic breast biopsy procedures shall be performed by a radiologic technologist who meets all of the following requirements:

(a) Initial qualifications. Before beginning to perform stereotactic breast biopsy procedures independently, a technologist shall do all of the following:

(i) Meet the requirements of R 333.5630.

(ii) Have 3 hours of category A continuing education units in stereotactic breast biopsy.

(iii) Have performed 5 stereotactic breast biopsy procedures under supervision of a stereotactic breast biopsy physician or a qualified stereotactic breast biopsy technologist.

(b) Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the initial qualifications of subdivision (a) of this rule were completed, the stereotactic breast biopsy technologist shall have performed at least 24 stereotactic breast biopsy procedures during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the 2. The facility shall choose 1 of these dates to determine the 24-month period.

(c) Continuing education. A technologist shall comply with the requirements of the American registry of radiologic technologists for continuing education for the imaging modality in which he or she performs services. The continuing education shall include credits pertinent to stereotactic breast biopsy.

R 333.5675 Medical physicists.

Rule 675. A stereotactic breast biopsy medical physicist shall meet all of the following requirements:

(a) Initial qualifications. Before independently performing surveys of stereotactic breast biopsy facilities a medical physicist shall have complied with all of the following:

(i) Met the requirements of R 333.5634.

(ii) Have performed 1 hands-on stereotactic breast biopsy physics survey under a qualified stereotactic breast biopsy medical physicist or 3 independent stereotactic breast biopsy surveys before April 17, 2013.

(b) Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the initial qualifications of subdivision (a) of this rule were completed, the stereotactic breast biopsy medical physicist shall have performed at least 2 stereotactic breast biopsy physics surveys during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the

inspection or any date in between the 2. The facility shall choose 1 of these dates to determine the 24-month period.

(c) Continuing education. Following the third anniversary date of the end of the calendar quarter in which the initial qualifications of subdivision (a) of this rule were completed, the stereotactic breast biopsy medical physicist shall have completed at least 3 continuing medical education credits in stereotactic breast biopsy during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the 2. The facility shall choose 1 of these dates to determine the 36-month period.

X-RAY EQUIPMENT

R 333.5676 Equipment requirements.

Rule 676. (1) The mammographic x-ray equipment shall be maintained in compliance with the applicable regulations in 21 C.F.R. 1020.30, "Diagnostic x-ray systems and their major components" (2007), and 21 C.F.R. 1020.31, "Radiographic equipment" (2005).

(2) A machine that is used for stereotactic breast biopsy shall be 1 of the following:

(a) A radiation machine that is specifically designed to perform stereotactic breast biopsy.

(b) A mammography machine with a specially designed add-on device for breast biopsy.

(c) A mammography machine that exclusively uses lateral arm devices if the needle can be seen in 2 ways in relation to the target lesion.

R 333.5677 Enclosures; use of mobile equipment.

Rule 677. (1) A fixed x-ray equipment enclosure shall comply with R 333.5331.

(2) For stereotactic breast biopsy, the operator's barrier shall provide radiation protection that is equivalent to not less than 0.5 millimeter of lead when the maximum tube potential is less than or equal to 35 kilovolts and 0.8 millimeter of lead when the maximum tube potential is greater than 35 kilovolts.

(3) An individual operating mobile or portable stereotactic breast biopsy equipment shall wear a protective apron of a minimum 0.5 millimeter lead equivalence unless shielding is provided as specified in subrule (2) of this rule.

(4) Mobile or portable stereotactic breast biopsy equipment used routinely in 1 location shall be considered a fixed installation and shall comply with the requirements of R 333.5331.

(5) Mobile or portable stereotactic breast biopsy equipment shall not be used for routine mammography in hospitals or private offices of physicians or osteopathic physicians. This equipment shall be used only when it is medically inadvisable to move a patient to a fixed mammographic installation.

R 333.5678 Conditions of operation.

Rule 678. The operation of a mammography x-ray machine shall comply with R 333.5333.

MEDICAL RECORDS AND STEREOTACTIC BREAST BIOPSY REPORTS

R 333.5679 Report contents.

Rule 679. A stereotactic breast biopsy facility shall prepare a written report of the results

of each stereotactic breast biopsy procedure. The stereotactic breast biopsy report shall include all of the following information:

(a) The name of the patient and an additional unique patient identifier.

(b) The date of the procedure.

(c) The name of the stereotactic breast biopsy physician who conducted the procedure.

(d) The procedure performed.

(e) Designation of the left or right breast.

(f) Description and location of the lesion.

R 333.5681 Communication of stereotactic breast biopsy results to health care providers.

Rule 681. When a patient has a referring health care provider or a patient has named a health care provider, the stereotactic breast biopsy facility shall provide a written report of the stereotactic breast biopsy procedure, including the items listed in R 333.5679, to that health care provider not later than 30 days after the date that the stereotactic breast biopsy procedure was performed.

R 333.5682 Record keeping.

Rule 682. (1) A facility that performs stereotactic breast biopsy procedures shall comply with both of the following:

(a) Maintain stereotactic breast biopsy images and reports in a permanent medical record of the patient for a period of not less than 7 years, or not less than 10 years if no additional stereotactic breast biopsy procedures of the patient are performed at the facility.

(b) Upon request by, or on behalf of, a patient, permanently or temporarily transfer the original stereotactic breast biopsy images and copies of the patient's reports to any of the following:

(i) A medical institution.

(ii) A patient’s physician.

(iii) The patient directly.

(2) Any fee a facility charges a patient for providing the services specified in subrule (1)(b) of this rule shall not exceed the documented costs associated with this service.

R 333.5683 Stereotactic breast biopsy image identification.

Rule 683. A stereotactic breast biopsy image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(a) Name of patient and an additional unique patient identifier.

(b) Date of the procedure.

(c) Designation of left or right breast.

(d) Cassette identification, if applicable.

(e) Stereotactic breast biopsy unit identification if there is more than 1 unit in the facility.

QUALITY ASSURANCE

R 333.5684 Quality assurance – general.

Rule 684. A stereotactic breast biopsy facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of stereotactic breast

biopsy services performed at the facility.

R 333.5685 Responsible individuals.

Rule 685. Responsibility for the quality assurance program and for each of its elements shall be assigned to the following individuals who are qualified for their assignments:

(a) Lead stereotactic breast biopsy physician. The facility shall identify a lead stereotactic breast biopsy physician who shall be responsible for ensuring that the quality assurance program meets all requirements of R 333.5684 to R 333.5697. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead stereotactic breast biopsy physician has determined that the individual is qualified to perform the assignment.

(b) Stereotactic breast biopsy physicians. All stereotactic breast biopsy physicians conducting stereotactic breast biopsy procedures for the facility shall do both of the following:

(i) Follow the facility's procedures for corrective action when the images they are asked to interpret are of poor quality.

(ii) Participate in the facility's medical outcomes audit program.

(c) Medical physicist. The facility shall have the services of a medical physicist available to survey stereotactic breast biopsy equipment and oversee the equipment-related quality assurance practices of the facility. The medical physicist shall be responsible for performing the surveys and stereotactic breast biopsy equipment evaluations and providing the facility with the reports described in R 333.5693 and R 333.5694.

(d) Quality control technologist. Responsibility for tasks within the quality assurance program not assigned to the lead stereotactic breast biopsy physician or the medical physicist shall be assigned to a quality control technologist. The tasks are to be performed by the quality control technologist, but may be delegated to other qualified personnel by the quality control technologist. When other personnel are utilized for these tasks, the quality control technologist shall ensure that they were completed in compliance with R 333.5687.

R 333.5686 Quality assurance records.

Rule 686. (1) The lead stereotactic breast biopsy physician, quality control technologist, and medical physicist shall ensure that records concerning the following items are properly maintained and updated:

(a) Stereotactic breast biopsy techniques and procedures.

(b) Quality control, including monitoring data and corrective actions taken.

(c) Safety.

(d) Employee qualifications to meet assigned quality assurance tasks.

(2) The quality assurance records specified in subrule (1) of this rule shall be kept for each test specified in R 333.5684 to R 333.5697 until the next annual inspection has been completed and the department has determined that the facility is in compliance with the quality assurance requirements, or until the test has been performed 2 additional times at the required frequency, whichever is longer.

R 333.5687 Radiologic technologist quality control tests.

Rule 687. A stereotactic breast biopsy facility shall have a radiologic technologist perform the following quality control tests at the intervals specified in this rule:

(a) A localization accuracy test shall be performed daily before the equipment is used on patients. Each of the indicated needle tip coordinates shall be within 1 millimeter of the actual preset needle tip location.

(b) A phantom image evaluation shall be performed at least weekly. The phantom image shall achieve at least the minimum score established in R 333.5689.

(c) A hard copy output quality test shall be performed at least monthly, if hard copies are produced from digital data.

(d) A compression test shall be performed at least semiannually. The maximum compression force for the power drive mode shall be between 25 pounds and 45 pounds.

(e) A repeat analysis shall be performed at least semiannually. If the overall repeat or reject rate exceeds 20% based on an image volume of not less than 150 patients, the reason for the change shall be determined. A repeat analysis shall be assessed semiannually even if fewer than 150 patients are examined during that period.

(f) If stereotactic breast biopsy is performed using a screen-film system, the following tests shall be required:

(i) A processor quality control test shall be performed at least daily. Film processors used to develop stereotactic breast biopsy films shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed at the beginning of each operational day before processing any clinical images. The test shall use the mammography film used clinically at the facility and shall include an assessment of base plus fog density, mid-density, and density difference as follows:

(A) The base plus fog density shall be within 0.03 of the established operating level.

(B) The mid-density shall be within plus or minus 0.15 of the established operating level.

(C) The density difference shall be within plus or minus 0.15 of the established operating level.

(ii) An analysis of fixer retention in film assessed at least quarterly. The residual fixer shall be not more than 5 micrograms per square centimeter.

(iii) A screen-film contact test shall be performed at least semiannually. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for stereotactic breast biopsy shall be tested.

(iv) A test of darkroom fog shall be performed at least semiannually. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of not less than 1.2 optical density, is exposed to typical darkroom conditions for 2 minutes while the film is placed on the counter top emulsion side up.

R 333.5688 Annual medical physicist's quality control tests.

Rule 688. Before the radiation machine is used on patients and at least annually thereafter, a stereotactic breast biopsy facility shall have the medical physicist perform all of the following quality control tests:

(a) Collimation assessment that meets either of the following:

(i) For screen-film systems, the x-ray field shall be contained within the image receptor on all 3 sides except the chest wall edge. The x-ray field shall not extend beyond the chest wall edge of the image receptor by more than 2% of the source-image receptor distance.

(ii) For digital image receptors, the x-ray field may extend beyond the edge of the image

receptor on all 4 sides, but no edge of the x-ray field shall extend beyond the image receptor by more than 5 millimeters on any side. Distances shall be measured in, or referred to, the plane of the digital image receptor.

(b) Focal spot performance and system limiting spatial resolution. Assess consistency of system-limiting resolution over time and in comparison to acceptance testing results using a line pair test pattern.

(c) Peak tube potential (kVp) accuracy and reproducibility. The tube potential shall be accurate to within 5% of the indicated or selected potential. The coefficient of variation of reproducibility of the potential shall be less than or equal to 0.02 at the most commonly used clinical settings.

(d) Beam quality assessment. The half-value layer shall be greater than or equal to the value kVp/100 in units of millimeter of aluminum.

(e) Automatic exposure control system or manual exposure performance assessment that meets either of the following:

(i) For screen-film systems, the image optical density shall be within 0.15 of the mean optical density when thicknesses of a homogeneous material is varied over a range of 4 to 8 centimeters using the clinical techniques for each thickness. If the optical densities do not meet this criterion, the medical physicist shall develop a technique chart which meets this criterion.

(ii) For digital systems, the signal value at the center of the digital field of view shall remain within 20% of the signal obtained for the 4 centimeter phantom when thicknesses of a homogeneous material is varied over a range of 4 to 8 centimeters using the clinical techniques for each thickness. If the signal values do not meet this criterion, the medical physicist shall develop a technique chart which meets this criterion.

(f) Image receptor speed uniformity that meets 1 of the following:

(i) For screen-film systems, the difference between the maximum and minimum optical densities of all the cassettes in the facility shall not exceed 0.30.

(ii) For digital systems, the signal-to-noise ratios (SNR) measured in each corner of the image shall be within 15% of the SNR measured at the center of the field of view.

(iii) For digital systems that are not equipped with region of interest signal measurements, the machine shall meet the receptor uniformity requirements specified by the manufacturer.

(g) Breast entrance exposure, average glandular dose, and exposure reproducibility. The coefficient of variation for both air kerma and current-time product (mAs) shall not exceed 0.05. The average glandular dose delivered during a single exposure of a department-approved phantom simulating a standard breast shall not exceed 3.0 milligrays (300 millirads) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

(h) Image quality evaluation. An image of a department-approved phantom shall achieve at least the minimum score established in R 333.5689.

(i) Artifact evaluation. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the full area of the exposed image receptor on the breast support assembly.

(j) Localization accuracy test. Using a phantom made of gelatin or similar material, the biopsy needle shall capture the intended object in the phantom.

R 333.5689 Phantom image scores.

Rule 689. A stereotactic breast biopsy phantom image score for the tests required in R 333.5687(b) and R 333.5688(h) shall be not less than the values specified in table 689:

TABLE 689

Image System	Standard Mammography Phantom			Mini Stereotactic Phantom		
	Fibers	Speck Groups	Masses	Fibers	Speck Groups	Masses
Screen-film	4.0	3.0	3.0	2.0	2.0	2.0
Digital	5.0	4.0	3.5	3.0	3.0	2.5

R 333.5690 Dosimetry.

Rule 690. The average glandular dose delivered during a single exposure of a department-approved phantom simulating a standard breast shall not exceed 3.0 milligrays (300 millirads) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

R 333.5691 Quality assurance for mobile units.

Rule 691. A stereotactic breast biopsy facility shall verify that mammography units used to produce interventional mammograms at more than 1 location meet the requirements in R 333.5687 to R 333.5690. At each examination location and before any examinations are conducted, the facility shall verify satisfactory performance of these units by using a test method that establishes the adequacy of the image quality produced by the unit.

R 333.5692 Use of quality assurance test results.

Rule 692. (1) After completion of tests specified in R 333.5687 to R 333.5691, the facility shall compare the test results to the corresponding specified action limits or the limits established by the facility to verify the image quality of mobile units following a move.

(2) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken within the following time frames:

(a) Before any further examinations are performed or any films are processed using a component of the mammography system that failed any of the tests described in R 333.5687(a),(b),(d),(f)(i), (f)(iii), (f)(iv); R 333.5688(g) and (h); or R 333.5691.

(b) Within 30 days of the test date for all other tests described in R 333.5687 to R 333.5691.

R 333.5693 Medical physicist surveys.

Rule 693. (1) A stereotactic breast biopsy facility shall annually undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. The survey shall include, at a minimum, the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in R 333.5688 and the weekly phantom image quality test as provided in R 333.5687(b).

(2) The results of all tests conducted by the facility pursuant to R 333.5687 to R 333.5691 and written documentation of any corrective actions taken and their results shall be evaluated for adequacy by the medical physicist performing the survey.

(3) The medical physicist shall prepare a survey report that includes a summary of this

review and recommendations for necessary improvements.

(4) The survey report shall be provided to the facility within 30 days of the date of the survey.

(5) The survey report shall be dated and signed by the medical physicist who performed or supervised the survey. If the survey was performed entirely or in part by an individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall be identified in the survey report.

R 333.5694 Mammography equipment evaluations.

Rule 694. (1) Additional evaluations of stereotactic breast biopsy units or image processors shall be conducted when a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a stereotactic breast biopsy unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of R 333.5676 to R 333.5678 and R 333.5687 to R 333.5691, as applicable. Problems revealed by the evaluation shall be corrected before the new or changed equipment is put into service for procedures or film processing.

(2) The equipment evaluations specified in subrule (1) of this rule shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

R 333.5695 Cleanliness in facilities using screen-film systems.

Rule 695. (1) A stereotactic breast biopsy facility shall establish and implement protocols for maintaining darkroom, screen, and view box cleanliness.

(2) The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

R 333.5696 Calibration of air kerma measuring instruments.

Rule 696. Instruments used by a medical physicist in his or her annual survey to measure the air kerma or air kerma rate from a stereotactic breast biopsy unit shall be calibrated once every 2 years and each time the instrument is repaired. The instrument calibration shall be traceable to a national standard and calibrated with an accuracy of plus or minus 6% (95% confidence level) in the mammography energy range.

R 333.5697 Infection control.

Rule 697. A stereotactic breast biopsy facility shall establish and comply with procedures to be followed for cleaning and disinfecting stereotactic breast biopsy equipment after contact with blood or other potentially infectious materials. The procedures shall include methods for documenting facility compliance with the infection control procedures.

PART 15. COMPUTED TOMOGRAPHY INSTALLATIONS

R 333.5701 Purpose and scope.

Rule 701. (1) This part establishes requirements governing the use of computed tomography (CT) scanners by, or on behalf of, a health practitioner licensed under article 15 of the act, MCL 333.1101 to 333.25211.

(2) This part applies to all registrants who use a CT scanner for the intentional exposure of

humans for diagnostic imaging.

(3) A CT scanner is exempt from this part if the scanner meets 1 of the following:

(a) Generates a peak power of 5 kilowatts or less as certified by the manufacturer.

(b) Is used only for attenuation corrections and anatomical markers as part of a positron emission tomography (PET/CT) or single photon emission computed tomography (SPECT/CT) study.

(c) Is used as a simulator solely for treatment planning purposes in conjunction with a megavoltage radiation therapy unit.

(d) Is used solely for intra-operative guidance tomography.

(4) In addition to the requirements of this part, all registrants are subject to applicable parts of these rules and the certificate of need review standards for computed tomography scanner services.

R 333.5703 Definitions.

Rule 703. (1) As used in this part the definitions in 21 C.F.R. 1020.33, "Computed tomography (CT) equipment" (June 10, 2005), are adopted by reference. Copies of these regulations are available for no cost from either of the following sources:

(a) The website of the Michigan department of licensing and regulatory affairs, radiation safety section at http://www.michigan.gov/rss.

(b) The website of the United States department of health & human services, U.S. food and drug administration at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.

(2) As used in this part the following definitions apply:

(a) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data. Computed tomography includes the capability of producing axial tomograms.

(b) "CT medical event" means an unintended event where a physician determines that actual damage has occurred to an organ or a physiological system of an individual due to or suspected to be due to exposure to diagnostic radiation from a CT scanner.

(c) "CT scanner" means a CT machine capable of performing CT scans of the head, other body parts, or full body patient procedures including PET/CT and SPECT/CT scanner hybrids if used for CT only procedures.

(d) "Medical physicist" means an individual trained in evaluating the performance of CT scanners, related equipment, and facility quality assurance programs and who meets the requirements in R 333.5707.

(e) "Positron emission tomography (PET)" means an imaging technique that uses positron-emitting radionuclides to produce 3-dimensional images of functional processes in the body.

(f) "Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and who meets the requirements in R 333.5705.

(g) "Single photon emission computed tomography (SPECT)" means an imaging technique that uses radionuclides to produce 3-dimentional images of functional processes in the body.

(h) "Tomogram" means the depiction of the attenuation properties of a section through a body.

R 333.5705 CT operators.

Rule 705. All CT examinations shall be performed by a radiologic technologist who meets all of the following requirements or by a physician or osteopathic physician licensed under article 15 of the act.

(a) Initial qualifications. Before beginning to perform CT examinations independently, a technologist shall meet both of the following:

(i) Be currently registered by the American registry of radiologic technologists (ARRT), the Canadian association of medical radiation technologists (CAMRT), or the Nuclear Medicine Technology Certification Board (NMTCB).

(ii) Document at least 20 hours of training and experience in operating CT equipment, radiation physics, and radiation protection or have the advanced certification in computed tomography from the ARRT.

(b) Continuing education. A technologist shall be in compliance with the ARRT requirements for continuing education for the imaging modality in which he or she performs services. The continuing education shall include credits pertinent to CT.

R 333.5707 Medical physicist.

Rule 707. A registrant with 1 or more CT scanners shall employ or contract with a medical physicist to review the quality and safety of the operation of the CT scanner. The medical physicist shall meet all of the following:

(a) Initial qualifications. Before beginning to independently provide consultation to a CT facility, a medical physicist shall meet 1 of the following:

(i) Be certified in diagnostic radiological physics or radiological physics by the American board of radiology, or in diagnostic imaging physics by the American board of medical physics, or in diagnostic radiology physics by the Canadian college of physicists in medicine.

(ii) Have a graduate degree in medical physics, radiological physics, physics, or other relevant physical science or engineering discipline from an accredited institution and have formal coursework in the biological sciences with at least 1 course in biology or radiation biology and 1 course in anatomy, physiology, or similar topics related to the practice of medical physics, and have 3 years of documented experience in a clinical CT environment. An accredited institution is a college or university accredited by a regional accrediting organization that has been recognized either by the U.S. department of education (USDE) or by the council for higher education accreditation (CHEA) or both. Individuals with non-U.S. degrees shall provide documentation that their foreign degrees are equivalent to those granted from an approved institution in the U.S. and that the granting institution is equivalent to a regionally accredited institution in the U.S.

(b) Continuing experience. Within 24 months following the date when the requirements of subdivision (a) of this rule were completed, the medical physicist shall have evaluated at least 2 CT scanners in the prior 24-month period.

(c) Continuing education. Within 36 months following the date when the requirements of subdivision (a) of this rule were completed, the medical physicist shall have earned at least 15 continuing medical education units, at least half shall be category 1, in the prior 36-month period. The continuing education shall include credits pertinent to CT.

(d) Reestablishing qualifications. A medical physicist who fails to maintain the required continuing experience or continuing education requirements shall reestablish his or her qualifications before resuming the independent evaluation of CT scanners and facilities, as follows:

(i) A medical physicist who fails to meet the continuing experience requirements of subdivision (b) of this rule shall evaluate a sufficient number of CT scanners, under the supervision of a medical physicist, to meet the requirements of subdivision (b) of this rule.

(ii) A medical physicist who fails to meet the continuing education requirements of subdivision (c) of this rule shall obtain a sufficient number of additional continuing education credits to meet the requirements of subdivision (c) of this rule.

R 333.5709 Equipment requirements.

Rule 709. (1) The regulations in 21 C.F.R. 1020.33(c), (d), (f), (g), (h), (i), and (j), "Computed tomography (CT) equipment" (June 10, 2005), are adopted by reference.

Copies of these regulations are available for no cost from either of the following sources:

(a) The website of the Michigan department of licensing and regulatory affairs, radiation safety section at http://www.michigan.gov/rss.

(b) The website of the United States department of health & human services, U.S. food and drug administration at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.

(2) CT equipment shall be maintained in compliance with the requirements of subrule (1) of this rule.

R 333.5711 Enclosures.

Rule 711. (1) A fixed CT scanner 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 a CT scanner 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) Protective barriers shall be provided in the ceiling, floor, and walls of a fixed CT scanner enclosure.

(4) The control panel for a fixed CT scanner shall be shielded by a protective barrier which cannot be removed from a protective position between the operator and the radiation source during machine operation.

(5) Movable barriers with electrical interlocks shall not be approved in place of compliance with subrule (4) of this rule.

(6) The operator of a fixed CT scanner 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 in which it is installed.

(7) Mobile or portable CT scanners used routinely in 1 location shall be considered a fixed installation and shall meet the requirements of subrules (1) to (6) of this rule.

R 333.5713 Conditions of operation.

Rule 713. (1) The CT facility shall establish scanning protocols in consultation with the medical physicist.

(2) The CT operator shall check the display panel before and after performing each scan to make sure the amount of radiation delivered is appropriate for the technique and individual patient. This may be accomplished by reviewing dose indicator devices, if available, or dose indices such as the technique factors. Dose indicators or indices outside of expected values shall be documented and reviewed by an interpreting physician or medical physicist.

(3) A fixed CT scanner shall be operated from a shielded position behind a protective barrier pursuant to R 333.5711(4).

(4) Staff personnel routinely working with or around radiation sources shall not be required by the registrant to restrain patients during CT examinations. If the procedure is permitted personnel exposure shall not exceed the limits in R 333.5057 to R 333.5059 or the procedure is prohibited.

(5) When a patient must be held in position for CT, mechanical supporting or restraining devices shall be used unless contraindicated. If the patient is held by an individual, this individual shall wear protective gloves and a protective apron of 0.5 millimeter minimum lead equivalence and 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.

(6) Only individuals whose presence is necessary are allowed in a fixed CT scanner room during exposure. Each individual, except the patient, shall be protected by at least 0.5 millimeter lead equivalent aprons or a whole body protective barrier.

(7) Personnel monitoring is required in controlled areas for each individual occupationally exposed to ionizing radiation from CT scanner equipment. Individual monitoring devices shall be permanently assigned to each occupationally exposed individual. 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 all other body parts shall meet the requirements of 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) A CT scanner shall not be left unattended without locking the apparatus, room, or building in some manner which prevents use of the apparatus by unauthorized persons.

R 333.5715 Report and notification of CT medical event.

Rule 715. (1) A CT facility shall report all CT medical events.

(2) The registrant shall submit a written report to the department within 15 days after a physician of the CT facility discovers the CT medical event or within 15 days after the CT facility is notified of the CT medical event by another physician, whichever comes first.

(3) The written report shall include all of the following:

(a) The registrant's name, address, facility registration number, and machine registration tag number as they appear on the registration certificate.

(b) The name of the physician who determined a CT medical event occurred.

(c) The dates of occurrence and discovery of the CT medical event.

(d) A narrative description of the CT medical event.

(e) The cause of the CT medical event.

(f) The effect on the individual who received the exposure.

(g) A narrative detailing corrective action taken or planned to prevent a recurrence.

(h) Certification that the registrant notified the individual or the individual's responsible relative or guardian and, if not, why not.

(i) The name and signature of the person preparing the report.

(4) The report shall not contain the name of the individual who is the subject of the CT

medical event or any other information that could lead to identification of the individual.

(5) The registrant shall provide notification of the CT medical event to the referring physician and shall notify the individual who is the subject of the CT medical event not later than 1 week after its discovery, unless the referring physician personally informs the registrant that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The notification of the individual who is the subject of the CT medical event may be made instead to that individual's responsible relative or guardian. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 1 week, the registrant shall notify the individual as soon as possible thereafter. The registrant shall not delay appropriate medical care for the individual, including all necessary remedial care as a result of the CT medical event, because of a delay in notification. If a verbal notification is made, the registrant shall inform the individual or appropriate responsible relative or guardian that a written description of the CT medical event can be obtained from the registrant upon request. The registrant shall provide a written description if requested.

R 333.5717 Quality control program.

Rule 717. (1) A CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following:

(a) Image quality.

(b) Patient radiation dose.

(c) Personnel radiation protection.

(d) Compliance with the provisions of this part.

(e) Ongoing quality control.

(2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits.

(3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule.

R 333.5719 Initial and annual medical physicist performance evaluations.

Rule 719. (1) A medical physicist shall complete an initial performance evaluation of the CT scanner before use on human patients and annually thereafter.

(2) A calibrated dosimetry system shall be used to measure the radiation output of a CT scanner. Calibration of the dosimetry system shall be within the preceding 24 months and shall be traceable to a national standard as specified in R 333.5012(1).

(3) A performance evaluation should include the following:

(a) Alignment light accuracy.

(b) Alignment of table to gantry.

(c) Table and gantry tilt.

(d) Slice localization from scanned projection radiograph.

(e) Table increment accuracy.

(f) Slice thickness.
(g) Image quality, including the following:
(i) High-contrast resolution.
(ii) Low-contrast resolution.
(iii) Image uniformity.
(iv) Noise.
(v) Artifact evaluation.
(h) CT number accuracy and linearity.
(i) Dosimetry, including the following:
(i) Dose indicator such as computed tomography dose index (CTDI).
(ii) Patient radiation dose for representative examinations.
(j) Safety evaluation, including the following:
(i) Visual inspection.
(ii) Audible and visual signals.
(iii) Posting requirements.
(iv) Scattered radiation measurements.
(k) Review of the ongoing quality control program, including test results and corrective action.

(4) The medical physicist shall prepare a report that includes all of the following:
(a) A summary of the performance evaluation required under subrule (1) of this rule.
(b) Recommendations for necessary improvements.
(c) Type of dosimetry system used, including the date of the last calibration.

(5) The report required under subrule (4) of this rule shall be provided to the CT facility within 30 days after completion of the evaluation.

R 333.5721 Records and report retention.

Rule 721. A CT facility shall maintain records and reports on file and shall make the records and reports available for review by the department as follows:

(a) Records of personnel no longer employed by the CT facility shall be kept on file until the next inspection following the employee's termination has been completed and the department has determined that the facility is in compliance with the CT personnel requirements.

(b) A report of a CT medical event required under R 333.5715 shall be maintained on file for at least 7 years.

(c) Initial and annual medical physicist performance evaluation reports required under R 333.5719(4) shall be maintained on file for at least 5 years.

(d) Records of the results from the ongoing quality control evaluation required under R 333.5717 shall be maintained on file for at least 2 years.