

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

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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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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