

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.13523 Radiation machine; registration; temporary authorization; authorization; standards; application; certificate; inspections; denial or withdrawal of authorization; hearing; emergency order; reinstatement of authorization; fine; notice; rules; definitions.

Sec. 13523.

(1) Beginning August 16, 1989, a person shall not use a radiation machine to perform mammography unless the radiation machine is registered with the department under department rules for registration of radiation machines and is specifically authorized under this section for use for mammography.

(2) The department shall authorize a radiation machine for use for mammography if the radiation machine, the personnel operating the radiation machine, and the facility in which the radiation machine is used meet all of the following standards:

(a) The radiation machine and the facility in which the radiation machine is used meet the criteria for the American college of radiology mammography accreditation program dated August, 1993 and published by the American college of radiology in the documents entitled "overview, mammography accreditation program, and ACR standards for the performance of screening mammography", which documents and criteria are incorporated by reference, excluding the physician interpreter and the accreditation fee schedule. The department shall make copies of those criteria available to the public and may by rule adopt modified criteria. The department may accept an evaluation report issued by the American college of radiology as evidence that a radiation machine, the personnel operating the radiation machine, and the facility in which the radiation machine is used meet those criteria. If at any time the department determines that it will not accept any evaluation reports issued by the American college of radiology as evidence that a radiation machine, the personnel operating the radiation machine, and the facility in which the radiation machine is used meet those criteria, the department shall promptly notify each person who has registered a radiation machine used exclusively to perform mammography under this part and the rules promulgated under this part.

(b) The radiation machine, the film or other image receptor used in the radiation machine, and the facility in which the radiation machine is used meet the requirements set forth in department rules for radiation machines.

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

(d) The facility in which the radiation machine is used does all of the following:

(i) At least annually has a qualified radiation physicist provide on-site consultation to the facility, including, but not limited to, a complete evaluation of the entire mammography system to ensure compliance with this part and the rules promulgated under this part.

(ii) Maintains for at least 7 years records of the consultation required in subparagraph (i) and the findings of the consultation.

(iii) Designates a physician or osteopathic physician licensed under article 15 to provide medical direction for the delivery of mammography services and to be responsible for the clinical aspects of the x-ray examinations and other procedures related to mammography. The physician designated under this subparagraph is responsible for conducting an on-site visit to each mammography station within the facility at least monthly for the purpose of providing professional feedback regarding clinical image quality and quality assurance procedures, for review of quality control documentation, and for ensuring that safe operating procedures are used in the delivery of mammographic services. If the physician designated under this subparagraph practices primarily outside of the facility, the physician shall keep a log of each on-site visit signed by the physician. The chief administrative officer of the facility or his or her designee may request to view the log at any time. The physician designated under this subparagraph shall meet the requirements of subdivision (g)(i) and (ii) or, until January 1, 1996, the requirements of subdivision (g)(ii) and (iii).

(e) The radiation machine is used according to department rules on patient radiation exposure and radiation dose levels.

(f) Each individual who operates the radiation machine can demonstrate to the department that he or she is specifically trained in mammography or an individual who is a physician or an osteopathic physician, and beginning 60 days after the rules required under section 13521(3) are promulgated, each individual who operates the radiation machine can demonstrate to the department that he or she meets the standards required by those rules or an individual who is a physician or an osteopathic physician.

(g) The x-ray images of each mammographic examination performed with the radiation machine are interpreted by a mammography interpreter who is a physician or osteopathic physician licensed under article 15 and who meets the requirements of subparagraphs (i), (ii), (iii), (iv), and (v):

(i) Except as otherwise provided in this subparagraph, is certified in radiology or diagnostic radiology by the American board of radiology or the American osteopathic board of radiology, has been eligible for certification in

radiology or diagnostic radiology for not more than 2 years, or is certified or determined to be qualified in radiology or diagnostic radiology by another professional organization approved by the radiation advisory board appointed under section 13531. Until the expiration of 2 years after the effective date of the amendatory act that added this subdivision, a physician or osteopathic physician licensed under article 15 who has been eligible for certification in radiology or diagnostic radiology for more than 2 years shall be considered to meet the requirement of this subparagraph.

(ii) Shall successfully complete or teach not less than 15 hours of continuing medical education every 3 years after the effective date of the amendatory act that added this subdivision in the technical aspects or clinical aspects, or both, of mammography in courses or programs approved by the individual's respective specialty organization and licensing board and has documentation of successful completion or teaching that is satisfactory to the department.

(iii) Shall have successfully completed not less than 2 months of formal training in reading mammograms with instruction in medical radiation physics, radiation effects, and radiation protection and has documentation of successful completion of the training that is satisfactory to the department. For purposes of this subparagraph, the department may accept time spent in a residency program that includes specific training in mammography if the individual has documentation of the residency program that is satisfactory to the department.

(iv) Interprets not less than 520 mammographic examinations each year.

(v) Maintains annual records concerning outcome data for correlation of positive mammograms to biopsies done, and the number of cancers detected.

(3) The department may issue a nonrenewable temporary authorization for a radiation machine for use for mammography if additional time is needed to allow submission of evidence satisfactory to the department that the radiation machine, the personnel operating the radiation machine, and the facility in which the radiation machine is used meet the standards set forth in subsection (2) for approval for mammography. A temporary authorization granted under this subsection after February 16, 1991 is effective for no more than 12 months. The department may withdraw a temporary authorization before its expiration if the radiation machine, the personnel operating the radiation machine, or the facility in which the radiation machine is used does not meet 1 or more of the standards set forth in subsection (2).

(4) To obtain authorization from the department to use a radiation machine for mammography, the person who owns or leases the radiation machine or an authorized agent of the person shall apply to the department for mammography authorization on an application form provided by the department and shall provide all of the information required by the department as specified on the application form. A person who owns or leases more than 1 radiation machine used for mammography shall obtain authorization for each radiation machine. The department shall process and respond to an application within 30 days after the date of receipt of the application. Upon determining to grant mammography authorization for a radiation machine, the department shall issue a certificate of registration specifying mammography authorization for each authorized radiation machine. A mammography authorization is effective for 3 years contingent upon the radiation machine, the personnel operating the radiation machine, and the facility in which the radiation machine is operated for which the mammography authorization is issued meeting 1 of the following requirements:

(a) Maintaining continued accreditation by the American college of radiology.

(b) Having an active accreditation application in process with the American college of radiology.

(c) Maintaining approval or being in the process of obtaining approval under a department evaluation process equivalent to that described in subdivisions (a) and (b).

(5) No later than 60 days after initial mammography authorization of a radiation machine under this section, the department shall inspect the radiation machine. After that initial inspection, the department shall annually inspect the radiation machine and may inspect the radiation machine more frequently. The department shall make reasonable efforts to coordinate the inspections under this section with the department's other inspections of the facility in which the radiation machine is located.

(6) After each satisfactory inspection by the department, the department shall issue a certificate of radiation machine inspection or a similar document identifying the facility and radiation machine inspected and providing a record of the date the radiation machine was inspected. The facility shall post the certificate or other document near the inspected radiation machine.

(7) The department may withdraw the mammography authorization for a radiation machine if it does not meet 1 or more of the standards set forth in subsection (2).

(8) The department shall provide an opportunity for a hearing in connection with a denial or withdrawal of mammography authorization.

(9) Upon a finding that a deficiency in a radiation machine used for mammography or a violation of this part or the rules promulgated under this part seriously affects the health, safety, and welfare of individuals upon whom the radiation machine is used for mammography, the department may issue an emergency order summarily withdrawing the mammography authorization of the radiation machine. The department shall incorporate its findings in the order and shall provide an opportunity for a hearing within 5 working days after issuance of the order. The order is effective during the proceedings.

(10) If the department withdraws the mammography authorization of a radiation machine, the radiation 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 subsection (4), except that the department shall not issue a reinstated certificate of mammography registration until the department receives the reinspection fee required under section 13522(5), inspects the radiation machine, and determines that it meets the standards set forth in subsection (2). The department shall conduct an inspection required under this subsection no later than 60 days after receiving a proper application for reinstatement of a mammography authorization.

(11) In addition to the penalties provided in section 13535 and the reinspection fee required under section 13522(5), if a person violates subsection (1), the department may impose an administrative fine against the owner of the radiation machine or, if a lessee of the radiation machine has effective control of the radiation machine, the lessee, of not more than \$500.00 for each calendar week in which a mammography is performed in violation of subsection (1). If a person continues to violate subsection (1) for a period of 2 weeks after a fine is imposed under this subsection, the department shall post a conspicuous notice on the unauthorized radiation machine and at the entry to the facility where the radiation machine is located warning the public that the facility is performing mammography using a radiation machine that is a substantial hazard to the public health.

(12) The department may promulgate rules necessary to implement this section after consultation with the radiation advisory board established under section 13531.

(13) As used in this section:

(a) "Radiation machine" means a machine, other than those exempted by department rule, that emits ionizing radiation.

(b) "Mammography system" means the radiation machine used for mammography; automatic exposure control devices; films, screens, and cassettes; image processor; darkroom; and viewboxes.

History: Add. 1989, Act 56, Imd. Eff. June 16, 1989 ;-- Am. 1994, Act 100, Imd. Eff. Apr. 18, 1994

Compiler's Notes: For transfer of powers and duties of Michigan indoor radon program from department of health and human services to department of environmental quality, see E.R.O. No. 2017-3, compiled at MCL 333.26254.

Popular Name: Act 368

Admin Rule: R 325.5001 et seq. of the Michigan Administrative Code.