

136C.15 Radiation machines used for mammography — registration standards and requirements — application for authority — inspection.

1. A person shall not use a radiation machine to perform mammography unless the radiation machine is registered with the department pursuant to the department's rules and is specifically authorized for use for mammography as provided in this section.

2. The department shall authorize a radiation machine for use for mammography if the radiation machine meets all of the following:

a. The radiation machine meets the criteria for a mammography accreditation program approved by the United States food and drug administration. 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 such an approved accreditation program as evidence that a radiation machine meets those criteria. If at any time the department determines that it will not accept any evaluation reports issued by such an approved accreditation program as evidence that a radiation machine meets those criteria, the department shall promptly notify each person who has registered a radiation machine under this paragraph.

b. The radiation machine, the film or other image receptor used in the radiation machine, and the facility where 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 radiation machine is used in a facility that does all of the following:

(1) 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 section and the rules adopted pursuant to this section.

(2) Maintains for at least seven years, records of the consultation required in subparagraph (1) and the findings of the consultation.

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

f. The radiation machine is operated only by an individual who can demonstrate to the department that the individual is specifically trained in mammography and meets the standards established in this section, or an individual who is a physician or an osteopathic physician.

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 meets the standards set forth in subsection 2 for approval for mammography. A temporary authorization granted under this subsection shall be effective for no more than twelve months. The department may withdraw a temporary authorization prior to its expiration if the radiation machine does not meet one 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 one radiation machine used for mammography shall obtain authorization for each radiation machine. The department shall process and respond to an application within thirty 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 the mammography authorization. A mammography authorization is effective for three years.

5. The department shall annually inspect each authorized 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

written proof of inspection or a similar document identifying the facility and radiation machine inspected and providing a record of the date the radiation machine was inspected.

7. The department may withdraw the mammography authorization for a radiation machine if it does not meet one 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 section or the rules adopted pursuant to this section 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 five working days after issuance of the order. The order shall be 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 registration specifying the mammography authorization until the department 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 sixty days after receiving a proper application for reinstatement of a mammography authorization.

11. The department shall establish fees pursuant to section 136C.10 for the application for authorization and the inspection related to a radiation machine used for mammography.

92 Acts, ch 1054, §2; 93 Acts, ch 139, §4; 2008 Acts, ch 1058, §8, 9

Referred to in §136C.3