

## CHAPTER 136C

## RADIATION MACHINES AND RADIOACTIVE MATERIALS

Referred to in §135.11

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**136C.1 Definitions.**

As used in [this chapter](#), unless the context otherwise requires:

1. “*Decommissioning*” means final operational activities at a site to dismantle site structures, to decontaminate site surfaces and remaining structures, to stabilize and contain residual radioactive material, and to carry out any other activities to prepare the site for postoperational care.

2. “*Department*” means the Iowa department of public health.

3. “*Director*” means the director of public health or the director’s designee.

4. “*Licensed professional*” means a person licensed or otherwise authorized by law to practice medicine, osteopathic medicine, podiatry, chiropractic, dentistry, dental hygiene, or veterinary medicine.

5. “*Radiation*” means energy forms capable of causing ionization including alpha particles, beta particles, gamma rays, X rays, neutrons, high-speed protons, and other atomic particles, but does not include sound or radio waves, or visible light, or infrared or ultraviolet light.

6. “*Radiation machine*” means a device capable of producing radiation except those that produce radiation solely from radioactive material.

7. “*Radioactive material*” means a solid, liquid, or gaseous material that emits radiation spontaneously including accelerator-produced and naturally occurring material, and byproduct, source, and special nuclear material as defined in the Atomic Energy Act of 1954 as amended to July 1, 1984.

[C79, 81, §136C.1]

[84 Acts, ch 1286, §10](#); [2009 Acts, ch 133, §37](#)

Referred to in [§455B.315](#)

**136C.2 Applicability.**

[This chapter](#) applies to radiation machines and radioactive material located in this state. The provisions of [this chapter](#) do not supersede or duplicate the authority and programs of any other agency of the state or the United States government. To avoid duplication and promote coordination of radiation protection activities, the department may enter into agreements pursuant to [chapter 28E](#) with other state and federal agencies, or with private organizations or individuals, to administer [this chapter](#).

[C79, 81, §136C.2]

[84 Acts, ch 1286, §11](#)

**136C.3 Duties of department.**

The department is designated the state radiation control agency and is responsible for regulating the installation and use of radiation machines and the use of radioactive materials in this state as provided in [this chapter](#). The department shall:

1. Establish minimum criteria and safety standards for the installation, operation, and use of radiation machines and radioactive materials.

2. Establish minimum training standards including continuing education requirements, and administer examinations and disciplinary procedures for operators of radiation machines and users of radioactive materials. A state of Iowa license to practice medicine, osteopathic medicine, chiropractic, podiatry, dentistry, dental hygiene, or veterinary medicine, or licensure as a physician assistant pursuant to [chapter 148C](#), or certification by the dental board in dental radiography, or by the board of podiatry in podiatric radiography, or enrollment in a program or course of study approved by the Iowa department of public health which includes the application of radiation to humans satisfies the minimum training standards for operation of radiation machines only.

3. Develop programs for evaluation and control of hazards associated with the use of sources of radiation with due regard for compatibility of a proposed program with federal programs regulating byproduct, source, and special nuclear materials and considering consistency of a proposed program with federal programs for regulation of radiation machines.

4. Adopt, publish, and amend rules in accordance with [chapter 17A](#) as necessary for the implementation and enforcement of [this chapter](#). The rules may provide for the licensing and control of radioactive materials with due regard for compatibility with federal regulatory programs.

5. Issue orders as necessary in connection with licensing and registration of radiation machines and radioactive materials and the operators or users thereof.

6. Advise, consult, and cooperate with other agencies of the state, the federal government, other states and interstate agencies, political subdivisions, and other organizations concerned with control of sources of radiation.

7. Encourage, participate in, or conduct studies, investigations, training, research, and demonstrations relating to control of sources of radiation.

8. Collect and disseminate information relating to control of sources of radiation. The department shall maintain the following information on file:

a. License applications, issuances, denials, amendments, transfers, renewals, modifications, suspensions, and revocations.

b. A list of persons possessing sources of radiation requiring registration under [this chapter](#) and any administrative or judicial action involving each person.

c. Departmental rules relating to regulation of sources of radiation, existing or pending, and related actions.

9. Adopt rules requiring the keeping of such records with respect to activities under licenses and registration certificates issued pursuant to [this chapter](#) as the department determines necessary to effect the purposes of [this chapter](#).

10. a. Adopt rules specifying the minimum training and performance standards for an individual using a radiation machine for mammography, and other rules necessary to implement [section 136C.15](#). The rules shall complement federal requirements applicable to similar radiation machinery and shall not be less stringent than those federal requirements.

b. (1) Adopt rules, in collaboration with appropriate stakeholders, to require that, by January 1, 2018, a facility at which mammography services are performed shall include information on breast density in mammogram reports sent to all mammography patients, pursuant to regulations implementing the federal Mammography Quality Standards Act of 1992, Pub. L. No. 102-539, as amended. The mammogram report shall include information on a patient's breast density, as categorized by an interpreting physician at the facility based on standards as defined in nationally recognized guidelines or systems for breast imaging reporting of mammography screening, including the breast imaging reporting and data system of the American college of radiology. For patients categorized as having heterogeneously dense breasts or extremely dense breasts, or an equivalent determination by another nationally recognized density gradient system, the report to the patient shall include evidence-based information on dense breast tissue, the increased risk associated with dense breast tissue, and the effects of dense breast tissue on screening mammography.

(2) Nothing in this paragraph "b" shall be construed to modify the existing liability of a facility where mammography services are performed beyond the duty to provide the information set forth in this paragraph "b". Notwithstanding any other provision of law to

the contrary, this paragraph “b” shall not create a cause of action or create a standard of care, obligation, or duty that provides grounds for a cause of action.

(3) Nothing in this paragraph “b” shall be deemed to require a notice or the provision of information that is inconsistent with the provisions of the federal Mammography Quality Standards Act of 1992, Pub. L. No. 102-539, as amended, or any regulations promulgated pursuant to that Act.

[C79, 81, §136C.3]

84 Acts, ch 1286, §1; 86 Acts, ch 1217, §1; 88 Acts, ch 1225, §1; 90 Acts, ch 1233, §6; 92 Acts, ch 1054, §1; 92 Acts, ch 1163, §36; 99 Acts, ch 141, §12; 2007 Acts, ch 10, §23; 2007 Acts, ch 218, §195; 2009 Acts, ch 133, §38; 2010 Acts, ch 1031, §397; 2012 Acts, ch 1113, §25; 2017 Acts, ch 61, §1, 2

Referred to in §136C.5, 136C.10

#### **136C.4 Penalties.**

1. It is unlawful to operate or use radiation machines or radioactive material in violation of [this chapter](#) or of any rule adopted pursuant to [this chapter](#). Persons convicted of violating a provision of [this chapter](#) are guilty of a serious misdemeanor.

2. In addition to criminal penalties, the department may impose a civil penalty not to exceed one thousand dollars on a person who violates a provision of [this chapter](#) or a rule or order issued under [this chapter](#), or a term, condition, or limitation of a license or registration certificate issued under [this chapter](#), or who commits a violation for which a license or registration certificate may be revoked under rules issued pursuant to [this chapter](#). Each day of continuing violation constitutes a separate offense in computing the civil penalty.

3. The department shall notify a person of the intent to impose a civil penalty against the person. The notice shall be by registered or certified mail to the person’s last known address and shall state the date, facts, the nature of the act or omission leading to the charge, the specific statute, rule, or license or registration provision involved, and the amount of the penalty the department proposes to impose. The notice shall advise the person that upon failure to pay the civil penalty, the penalty may be collected by civil action. The person shall have the opportunity to respond in writing, within a reasonable time as the department shall establish by rule, why the civil penalty should not be imposed.

4. The department may compromise, mitigate, or remit a civil penalty imposed under [this section](#). A person upon whom a civil penalty is imposed may appeal the action pursuant to [chapter 17A](#). The department shall remit moneys collected from civil penalties to the treasurer of state who shall deposit the moneys in the general fund of the state.

[C79, 81, §136C.4]

84 Acts, ch 1286, §12; 2002 Acts, ch 1108, §10

#### **136C.5 Enforcement.**

1. Upon determination by the department that [this chapter](#) or any rule adopted pursuant to [this chapter](#) has been or is being violated, the department may order that the radiation machine or radioactive material not be used until the necessary corrective action has been taken. If the use of the radiation machine or radioactive material continues in violation of the order of the department, the department may request the county attorney or the attorney general to make an application in the name of the state to the district court of the county in which the violations may have occurred for an order to enjoin the violations or practices.

2. The department may impound or order the impounding of radioactive material in the possession of a person who is not equipped to observe or fails to observe a provision of [this chapter](#) or of a rule adopted under [this chapter](#).

3. The department may enter at reasonable times any private or public property to determine whether there is a violation of a provision of [this chapter](#) or of a rule issued under [this chapter](#). However, the department must have the consent of the federal government before entering an area under the jurisdiction of the federal government.

4. The department may inspect records required to be kept under [section 136C.3](#),

[subsection 9](#). Upon request of the department a person shall submit the records to the department for inspection.

[C79, 81, §136C.5]

[84 Acts, ch 1286, §13](#)

Referred to in [§331.756\(26\)](#)

**136C.6** Reserved.

**136C.7 Acceptance of funds.**

The department may accept from any source loans, grants, gifts, or other funds to be used for programs authorized by [this chapter](#).

[84 Acts, ch 1286, §2](#)

**136C.8 Inspections.**

The department may inspect radiation machines and radioactive materials located in this state, for the purpose of detecting, abating, or eliminating excessive radiation exposure hazards. The inspection shall include but shall not be limited to an evaluation of the radiation machine or radioactive material as well as the immediate environment to ensure that in using the machines or materials all unnecessary hazards for patients, personnel, and other persons who may be exposed to radiation produced by the machine or materials are avoided. All defects and deficiencies noted by the inspector shall be fully disclosed and discussed with the responsible persons at the time of inspection. The department shall establish rules prescribing operating procedures for radiation machines and radioactive materials which ensure minimum radiation exposure to patients, personnel, and other persons in the immediate environment.

[84 Acts, ch 1286, §3](#); [2012 Acts, ch 1113, §26](#)

**136C.9 Registration and license requirements.**

1. The department shall establish by rule a system for the registration of the possession of radiation machines and for the licensing of radioactive materials in the state. The rules may provide for the issuance of the following licenses:

a. General licenses which do not require the filing of an application or the issuance of a document but do permit designated persons to transfer, acquire, own, possess, or use quantities of or equipment using radioactive materials.

b. Specific licenses issued upon application to a person named in the license to use, manufacture, produce, transfer, receive, acquire, or possess quantities of or equipment using radioactive material. Applicants requesting radioactive materials in quantities of concern, as identified by the United States nuclear regulatory commission, shall submit fingerprints to the United States nuclear regulatory commission for a background check of all individuals authorized for unescorted access to such material.

2. The department may exempt certain sources of radiation or kinds of uses or users from the licensing or registration requirements when the department finds that the exemption of the source of radiation, use, or users will not pose a significant risk to the health and safety of the public. The rules may provide for recognition of other state or federal licenses as the department may allow, subject to registration requirements as the department may prescribe.

3. A person shall not use, manufacture, produce, distribute, sell, transport, transfer, install, repair, receive, acquire, own, or possess any radioactive material without a license from the department as provided in [this chapter](#).

[84 Acts, ch 1286, §4](#); [2008 Acts, ch 1058, §7](#)

**136C.10 Fees.**

1. a. The department shall establish and collect fees for the licensing and amendment of licenses for radioactive materials, the registration of radiation machines, the periodic inspection of radiation machines and radioactive materials, and the implementation of [section 136C.3, subsection 2](#). Fees shall be in amounts sufficient to defray the cost

of administering [this chapter](#). The license fee may include the cost of environmental surveillance activities to assess the radiological impact of activities conducted by licensees.

b. When a registrant or licensee fails to pay the applicable fee the department may suspend or revoke the registration or license or may issue an appropriate order. Fees for the license, amendment of a license, and inspection of radioactive material shall not exceed the fees prescribed by the United States nuclear regulatory commission.

2. The department may establish and collect a fee related to transporting radioactive material if the fee is used for a purpose related to transporting radioactive material, including enforcement and planning, developing, and maintaining a capability for emergency response. The fees shall be established by rules adopted pursuant to [chapter 17A](#).

3. The department may establish and collect fees from persons providing mammography services to assure compliance with applicable rules and the federal Mammography Quality Standards Act of 1992, Pub. L. No. 102-539, as amended. Fees shall be in an amount determined by the department by rule and all fees collected shall be used to support the department's mammography program.

4. Fees collected pursuant to [this section](#) shall be retained by the department, shall be considered repayment receipts as defined in [section 8.2](#), and shall be used for the purposes described in [this section](#), including but not limited to the addition of full-time equivalent positions for program services and investigations. Notwithstanding [section 8.33](#), moneys retained by the department pursuant to [this subsection](#) are not subject to reversion to the general fund of the state.

[84 Acts, ch 1286, §5](#); [86 Acts, ch 1217, §2](#); [2004 Acts, ch 1167, §3](#); [2005 Acts, ch 175, §81](#); [2006 Acts, ch 1155, §1, 15](#)

Referred to in [§136C.15](#)

#### **136C.11 Federal-state agreements.**

1. The governor, on behalf of the state, may enter into an agreement with the United States nuclear regulatory commission pursuant to section 274b of the Atomic Energy Act of 1954, as amended to July 1, 1984, providing for the discontinuation of certain federal licensing and related regulatory authority over byproduct, source, and special nuclear material and the assumption of regulatory authority over these materials by the state.

2. A person who, on the effective date of an agreement made under [subsection 1](#), possesses a license issued by the United States nuclear regulatory commission for radioactive material that comes under the agreement is considered to possess the license required under [this chapter](#). The license shall expire either ninety days after receipt from the department of a notice of expiration of the license, or on the date of expiration specified in the license issued by the nuclear regulatory commission, whichever is earlier.

[84 Acts, ch 1286, §6](#)

#### **136C.12 Conflicting laws.**

[This chapter](#) does not preempt ordinances, resolutions, or rules of a local government or of a state agency relating to radioactive material that are consistent with [this chapter](#). [This chapter](#) does not give the department the authority to regulate a facility for the disposal of low-level radioactive waste as defined in article II of [section 457B.1](#).

[84 Acts, ch 1286, §7](#)

#### **136C.13 Emergencies.**

If the department finds that an emergency exists involving radioactive material or radiation machines that requires immediate action to protect the public health and safety, the department may, without notice or hearing, issue an order stating that an emergency exists and requiring that action be taken as necessary to meet the emergency. An emergency order shall be effective immediately. A person to whom the order is directed shall comply with the order immediately, but on application to the department shall be afforded a hearing within ten days of the date application is made. The emergency order may be continued, modified, or revoked within thirty days after the hearing, based on the evidence presented at the hearing.

[84 Acts, ch 1286, §8](#)

**136C.14 Qualified operators — credentials available upon request.**

1. A person, other than a licensed professional, shall not operate a radiation machine or use radioactive materials for medical treatment or diagnostic purposes unless that person has completed a course of instruction approved by the department or has otherwise met the minimum training requirement established by the department.

2. A person, other than a licensed professional, who operates a radiation machine or uses radioactive materials for medical treatment or diagnostic purposes shall make available upon request the credentials which indicate that person's qualification to operate the machine or use the materials. A person who owns or controls the machine or materials shall not employ a person to operate the machine or use the materials for medical treatment or diagnostic purposes except as provided in [this section](#).

[84 Acts, ch 1286, §9; 85 Acts, ch 195, §17; 2012 Acts, ch 1113, §27](#)

**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](#)