

641—37.8(136C) Requirements for registrations.

1. Any persons applying for a permit to operate ionizing radiation producing machines or administer radioactive materials shall comply with the requirements of 641—Chapter 38.
2. Any persons applying for a radioactive materials license shall comply with the licensing requirements of 641—Chapter 39 and the requirements of this chapter.
3. All mammography facilities shall comply with the registration requirements of 641—Chapter 41 and the requirements of this chapter.

37.8(1) Exemptions.

a. The following are exempt from the requirements of this chapter:

(1) Electronic equipment that produces radiation incidental to its operation for other purposes, provided the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 millirem (5 μ Sv) per hour at 5 centimeters from any accessible surface of such equipment. This exemption does not apply to the production, testing, or factory servicing of such equipment.

(2) Radiation machines while in transit or temporarily stored as part of the transit process. This exemption does not apply to the providers of radiation machines for mobile services. Facilities that have placed all radiation machines in storage, including on-site storage, and have notified the department in writing are exempt. This exemption is void if any radiation machine is energized and produces radiation.

(3) Domestic television receivers.

(4) Inoperable radiation machines. For the purposes of this chapter, “inoperable radiation machine” means a radiation machine that cannot be energized when connected to a power supply without repair or modification.

(5) Financial institutions that take possession of radiation machines as the result of foreclosure, bankruptcy, or other default of payment, to the extent that the machines are demonstrated to be operable for the sole purpose of sale, lease, or transfer.

b. Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in paragraph 37.8(3)“c” to the registrant’s radiation machine facility until such person provides evidence that the person has been registered with the department as a provider of these services.

37.8(2) Registration requirements for radiation machine facilities. Each person having a radiation machine facility shall apply for registration of such facility with the department prior to the operation of a radiation machine facility.

a. Application for registration shall be submitted to the department through the online licensing portal using the application furnished by the department. The application shall:

(1) Contain complete and accurate information as required by the department;

(2) Include the appropriate fee specified in rule 641—37.9(136C).

b. The applicant shall designate on the application form the name of an individual who will be responsible for radiation protection.

(1) All radiation machine registrants shall designate an individual who has authority to make decisions and conduct assessments related to radiation protection and regulatory compliance at the facility.

(2) Healing arts. A practitioner licensed by the respective state board of examiners and responsible for directing the operation of radiation machines shall be designated on each healing arts application. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed practitioner’s signature if the facility has more than one licensed practitioner (for example, hospitals, large clinics, or multipractitioner practices).

37.8(3) Registration requirements for radiation machine service providers. Each person who is engaged in the business of installing or offering to install radiation machines, or providing or offering to provide radiation machine servicing or services, within this state shall apply for registration with the department prior to installing, providing, or offering to provide such services.

a. *Application.* Registration shall be submitted to the department through the online licensing portal using the application furnished by the department. The application shall:

(1) Contain complete and accurate information as required by the department;

(2) Include the appropriate fee specified in rule 641—37.9(136C).

b. *Contents.* Each person applying for registration as a service provider shall specify:

- (1) That the person has read and understands the requirements of these rules;
- (2) The services for which he or she is applying for registration;
- (3) The training and experience that qualify the person to discharge the services for which the person is applying for registration;
- (4) The type of measurement instrument to be used, frequency of calibration, and source of calibration;
- (5) The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.

c. Services requiring an application. Services requiring registration include but are not limited to:

- (1) Installation and servicing of radiation machines and associated radiation machine components;
- (2) Calibration of radiation machines or radiation measurement instruments or devices;
- (3) Radiation protection or health physics consultations or surveys;
- (4) Personnel dosimetry services;
- (5) Provider of equipment;
- (6) Shielding design and evaluation;
- (7) Processor or processor servicing, or both;
- (8) Calibration and compliance surveys of external beam radiation therapy units;
- (9) Qualified expert services for CT equipment;
- (10) Qualified expert services for e-brachytherapy;
- (11) Qualified expert services for therapeutic machines.

37.8(4) *Registration requirements for qualified experts for services.* A qualified expert may perform services after registering as a radiation machines service provider, whether as an individual, as part of a corporation, or as any other entity included in the definition of “person” in this chapter.

a. Each qualified expert must possess the necessary knowledge and training to measure ionizing radiation, evaluate safety practices, and provide guidance on radiation protection. Examples of individuals who may qualify include:

- (1) Persons certified in the appropriate field by the American Board of Radiology, American Board of Medical Physics, or American Board of Health Physics or those with equivalent qualifications.
- (2) For calibration of radiation therapy equipment, persons who, in addition to the qualifications above, have training and experience in the clinical applications of radiation physics to radiation therapy, including individuals certified in therapeutic radiological physics, X-ray and radium physics by the American Board of Radiology, or those with equivalent qualifications.

b. Each qualified expert or registered radiation machines service provider must maintain documentation demonstrating that the training requirements for the services provided under this chapter have been met. This documentation must be retained and made available to the department upon request.

37.8(5) *Stated notice.* No persons shall perform services that are not specifically stated on the notice of registration issued by the department.

a. A registration may be revoked for violating or causing a facility to violate any of the rules in 641—Chapter 38 through 42.

b. Radiation therapy physicists providing services for therapeutic radiation machines must provide proof that the training requirements of rule 641—42.6(136C) have been met at the time of the application and upon request by the department.

c. Mammography physicists providing services for mammography radiation machines must provide proof that the training requirements of 641—Chapter 41 have been met at the time of the application and upon request by the department.

37.8(6) *Issuance of notice of registration.*

a. Upon a determination that an applicant meets the requirements of this chapter, the department will issue a notice of registration.

b. The department may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order such additional requirements and conditions with respect to the registrant’s receipt, possession, use, and transfer of radiation machines as it deems appropriate or necessary.

37.8(7) *Expiration of notice of registration.* Each notice of registration will expire annually.

37.8(8) *Renewal of notice of registration.* An application for renewal of registration shall be submitted annually in accordance with the requirements of this chapter.

37.8(9) *Reinstatement of registration.*

a. An application for reinstatement of registration shall be submitted to the department when a registration has not been renewed within 30 days following the expiration date in accordance with this chapter.

b. The annual registration fee, as specified in Iowa Code section 39.9, shall be submitted to the department at the time of reinstatement.

c. A reinstatement fee of \$100 shall be submitted to the department at the time of reinstatement, in addition to the annual registration fees.

37.8(10) *Report of changes.* The registrant shall notify the department in writing before making any change that would render the information contained in the application for registration or the notice of registration no longer accurate.

37.8(11) *Approval not implied.* No person, in any advertisement, shall refer to the fact that the person or the person's facility is registered with the department pursuant to the provisions of this chapter, and no person shall state or imply that any activity under such registration has been approved by the department.

37.8(12) *Assembler and transfer obligation.*

a. Any person registered under the requirements of this chapter who sells, leases, transfers, lends, disposes of, assembles, or installs radiation machines in this state shall notify the department in writing within 15 days following the completion of the service and shall include all of the following:

- (1) The name and address of persons who have received these machines;
- (2) The manufacturer, model, and serial number of each radiation machine transferred;
- (3) The date of transfer of each radiation machine.

b. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment, when properly placed in operation and used, meet the requirements of 641—Chapters 38, 39, 40 and 41.

c. In the case of diagnostic X-ray systems that contain certified components, a copy of the assembler's report prepared in accordance with the requirements of the federal diagnostic X-ray standard (21 CFR 1020.30(d)) shall be submitted to the department within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler.

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