

4731.4403 SPECIFIC LICENSE; MEDICAL USE OF RADIOACTIVE MATERIALS.**Subpart 1. Specific license required.**

A. Except as provided in item B, a person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer radioactive material for medical use only under a specific license issued by the NRC or an agreement state.

B. A specific license is not needed for an individual who:

(1) receives, possesses, uses, or transfers radioactive material according to this chapter under the supervision of an authorized user as provided under part 4731.4407, unless prohibited by a license condition; or

(2) prepares unsealed radioactive material for medical use according to this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided under part 4731.4407, unless prohibited by a license condition.

Subp. 2. Application for license, amendment, or renewal.

A. An application for a specific license under subpart 1 must be signed by the applicant's or licensee's management.

B. An application for a license for medical use of radioactive materials as described in parts 4731.4404, 4731.4432, 4731.4434, 4731.4440, 4731.4450, 4731.4460, and 4731.4463 must include:

(1) an original application for radioactive material license form prescribed by the commissioner that includes the facility diagram, equipment, and training and experience qualifications of the radiation safety officer, associate radiation safety officers, authorized users, authorized medical physicists, ophthalmic physicists, and authorized nuclear pharmacists; and

(2) the procedures required under parts 4731.4466 and 4731.4472 to 4731.4474, as applicable.

C. A request for a license amendment or renewal must include:

(1) an original copy of the form prescribed by the commissioner under item B or a letter requesting the amendment or renewal containing all the information in the form prescribed by the commissioner under item B; and

(2) the procedures required under parts 4731.4466 and 4731.4472 to 4731.4474, as applicable.

D. In addition to the requirements under items B and C, an application for a license or amendment for medical use of radioactive material under part 4731.4404 must include:

(1) information regarding any radiation safety aspects of the medical use of the material that is not addressed in, or differs from, parts 4731.4400 to 4731.4427 and 4731.4500 to 4731.4528;

(2) identification of and commitment to follow the applicable radiation safety program requirements in parts 4731.4432 to 4731.4479 that are appropriate for the specific medical use;

(3) any additional specific information on:

(a) radiation safety precautions and instructions;

(b) methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(c) calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

(4) any other information requested by the commissioner for review of the application.

E. An applicant that satisfies the requirements under part 4731.3530 may apply for a Type A specific license of broad scope.

Subp. 3. **License amendments.** A licensee must apply for and receive a license amendment:

A. before the licensee receives, prepares, or uses radioactive material for a type of use that is permitted under this chapter, but not authorized under the licensee's current license issued under parts 4731.4400 to 4731.4527;

B. before the licensee permits anyone to work as an authorized user, authorized nuclear pharmacist, authorized medical physicist, or ophthalmic physicist under the license, except that the licensee may permit an individual to work as an authorized user, authorized nuclear pharmacist, authorized medical physicist, or ophthalmic physicist for 60 days before being authorized on a license if the individual is an authorized user, authorized nuclear pharmacist, authorized medical physicist, or ophthalmic physicist for the same type of use:

(1) on a license issued by the commissioner, the NRC, or an agreement state or on an equivalent permit or license recognized by the commissioner, the NRC, or an agreement state that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(2) on a permit issued by the commissioner, the NRC, or an agreement state specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

(3) on a permit issued by an NRC master material licensee that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy; or

(4) by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists;

C. before the licensee changes radiation safety officers, except as provided under part 4731.4405, subpart 1, item C;

D. before the licensee permits anyone to work as an associate radiation safety officer, or before the radiation safety officer assigns duties and tasks to an associate radiation safety officer that differ from those for which the individual is authorized on the license;

E. before the licensee receives radioactive material in excess of the amount or in a form different than authorized in the license or before the licensee receives a radionuclide that is different than the radionuclide authorized in the license;

F. before the licensee adds or changes the areas of use identified in the application or in the license, except for areas of use where radioactive material is used only according to part 4731.4432 or 4731.4434;

G. before the licensee changes an address identified in the application or on the license;

H. before the licensee revises procedures required under parts 4731.4466 and 4731.4472 to 4731.4474, as applicable, when the revision reduces radiation safety; and

I. before the licensee receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license. If a licensee obtains a sealed source in accordance with this item, the licensee must submit an amendment request to add the sealed source to the licensee's radioactive materials license within 30 days after receiving the source.

Subp. 4. Notifications of changes.

A. A licensee must notify the commissioner by letter no later than 30 days after:

(1) an authorized user, authorized nuclear pharmacist, radiation safety officer, associate radiation officer, authorized medical physicist, or ophthalmic physicist has a name change;

(2) the licensee's mailing address changes;

(3) the licensee's name changes, but the name change does not constitute a transfer of control of the license as described under part 4731.3075, subpart 2;

(4) the licensee has added to or changed the areas of use identified in the application or license where radioactive material is used according to part 4731.4432 or 4731.4434;

(5) the licensee permits an individual qualified to be a radiation safety officer under parts 4731.4411 and 4731.4415, to function as a temporary radiation safety officer and to perform the functions of a radiation safety officer as described under part 4731.4405, subpart 1, item C; or

(6) the licensee permits an individual to work under the provisions of subpart 3, item B, as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist prior to being added to the license. The notification must include a copy of the commissioner, the NRC, or an agreement state license, the permit issued by an NRC master material licensee, the permit issued by the commissioner, the NRC, or an agreement state licensee of broad scope, or the permit issued by an NRC master material license broad scope permittee.

B. A licensee must mail required documents to the address under part 4731.0200, subpart 4.

Subp. 5. **Exemptions; broad scope license.** A licensee possessing a Type A specific license of broad scope for medical use, issued under parts 4731.3500 to 4731.3580, is exempt from:

A. subpart 2, item D, regarding the need to file an amendment to the license for medical use of radioactive materials under part 4731.4404;

B. subpart 3, item B;

C. subpart 3, item F, regarding additions to or changes in the areas of use at the addresses identified in the application or license;

D. subpart 4, item A, subitem (1), for an authorized user, authorized nuclear pharmacist, authorized medical physicist, or ophthalmic physicist;

E. subpart 4, item A, subitem (4), regarding additions to or changes in the areas of use identified in the application or license where radioactive material is used under part 4731.4432 or 4731.4434; and

F. part 4731.4410, item A.

Subp. 6. **License issuance.**

A. The commissioner shall issue a license for the medical use of radioactive material if:

(1) the applicant complies with subpart 2;

(2) the applicant pays any applicable fee as provided under Minnesota Statutes, section 144.1205;

(3) the commissioner finds the applicant equipped and committed to observe the safety standards established by the commissioner in this chapter for the protection of the public health and safety; and

(4) the applicant meets the requirements of parts 4731.3000 to 4731.3175.

B. The commissioner shall issue a license for mobile medical services if the applicant:

(1) meets the requirements under item A; and

(2) ensures that individuals or human research subjects to whom unsealed radioactive material or radiation from implants containing radioactive material will be administered are released following treatment according to part 4731.4427.

Subp. 7. **Specific exemptions.** The commissioner may, upon application of any interested person or upon the commissioner's own initiative, grant exemptions from parts 4731.4400 to 4731.4527 that the commissioner determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 32 SR 831; 33 SR 1440; 46 SR 791*

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