4731.3395 SPECIFIC LICENSE; RADIOACTIVE DRUGS FOR MEDICAL USE; MANUFACTURE, PREPARATION, OR TRANSFER.

Subpart 1. **Approval criteria.** An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized according to parts 4731.4400 to 4731.4527 shall be approved if the applicant:

A. satisfies the general requirements specified in part 4731.3070;

B. submits evidence that the applicant is at least one of the following:

(1) registered or licensed with the United States Food and Drug Administration as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under Code of Federal Regulations, title 21, section 207.20(a);

(2) registered or licensed with a state agency as a drug manufacturer;

(3) licensed as a pharmacy by a state board of pharmacy;

(4) operating as a nuclear pharmacy within a federal medical institution; or

(5) a positron emission tomography (PET) drug production facility registered with a state agency;

C. submits the following information regarding the radionuclide:

(1) the chemical and physical form;

(2) the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and

(3) the shielding provided by the packaging to show it is appropriate for safe handling and storage of the radioactive drugs by medical use licensees; and

D. satisfies the following labeling requirements:

(1) a label must be affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution and include the radiation symbol, the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specific date and time. For a radioactive drug with a half-life greater than 100 days, the time may be omitted; and

(2) a label must be affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol, the words "CAUTION, RADIOACTIVE MATERIAL" or

"DANGER, RADIOACTIVE MATERIAL," and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

Subp. 2. **Pharmacy licensees.**

A. A licensee described in subpart 1, item B, subitem (3) or (4) may:

(1) prepare radioactive drugs for medical use, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in subitem (2) or item C, or an individual under the supervision of an authorized nuclear pharmacist, as specified in part 4731.4407; and

(2) allow a pharmacist to work as an authorized nuclear pharmacist if:

(a) the individual qualifies as an authorized nuclear pharmacist;

(b) the individual meets the requirements under parts 4731.4413 and 4731.4415 and the licensee has received an approved license amendment identifying the individual as an authorized nuclear pharmacist; or

(c) the individual is designated as an authorized nuclear pharmacist according to item C.

B. The actions authorized in item A are permitted notwithstanding more restrictive language in license conditions.

C. A licensee described in subpart 1, item B, subitem (3) or (4), may designate a pharmacist as an authorized nuclear pharmacist if the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and the individual practiced at a pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

D. No later than 30 days after the date that a licensee described in subpart 1, item B, subitem (3) or (4), allows an individual to work as an authorized nuclear pharmacist under item A, subitem (2), unit (a) or (c), the licensee must provide to the commissioner a copy of:

(1) the individual's certification by a specialty board whose certification process has been recognized as specified in part 4731.4413, subpart 1, with the written attestation signed by a preceptor as required by part 4731.4413, subpart 1; or

(2) the NRC or agreement state license, or the permit issued by an NRC master materials licensee, or the permit issued by a licensee of broad scope, or the authorization from a commercial nuclear pharmacy authorized to issue its own authorized nuclear pharmacist; or

(3) documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC; and

(4) a copy of the individual's state pharmacy licensure or registration.

Subp. 3. **Measuring radioactivity.** A licensee under this part must:

A. possess and use instrumentation to measure the radioactivity of radioactive drugs;

B. have procedures for use of the instrumentation;

C. measure, by direct measurement or a combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution;

D. perform tests before initial use, periodically, and following repair on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments when necessary; and

E. check each instrument for constancy and proper operation at the beginning of each day of use.

Subp. 4. **Other law.** Nothing in this part relieves a licensee from complying with applicable United States Food and Drug Administration, other federal, or state requirements governing radioactive drugs.

Statutory Authority: *MS s 144.1202; 144.1203*

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

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