4731.3075 TERMS AND CONDITIONS OF LICENSES.

Subpart 1. **Applicable regulation.** A license issued under this chapter is subject to all rules and orders of the commissioner.

Subp. 2. **Transfer prohibited.** No license issued or granted under this chapter nor any right under a license must be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of a license to any person, unless the commissioner, after securing full information, finds that the transfer is in accordance with this chapter and gives consent in writing.

Subp. 3. **Scope of license.** A person licensed by the commissioner under this chapter must confine the licensee's possession and use of radioactive material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued under parts 4731.3000 to 4731.7280 carries with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport of radioactive material must be according to parts 4731.0400 to 4731.0455.

Subp. 4. **Bankruptcy.**

A. A general licensee required to register under part 4731.3215, subpart 3a, and a specific licensee issued a license under this chapter must notify the commissioner, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of United States Code, title 11, by or against:

(1) the licensee;

(2) an entity, which includes a person, estate, trust, governmental unit, or United States trustee, that controls the licensee or lists the license or licensee as property; or

(3) an affiliate of the licensee, as defined under United States Code, chapter 11, section 101, clause (2).

B. The bankruptcy notification must indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

Subp. 5. **Additional conditions.**

A. The commissioner may incorporate in any license, at the time of issuance or thereafter by appropriate rule or order, such additional conditions and requirements with respect to the licensee's receipt, possession, use, and transfer of radioactive material as the commissioner deems appropriate or necessary to protect health or to minimize danger to life or property.

B. The commissioner may require reports, record keeping, and inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of this chapter.

Subp. 6. **Emergency plan.** A licensee that is required to submit an emergency plan under part 4731.3065, subpart 4, item A, must follow the emergency plan approved by the commissioner. The licensee:

A. may change the plan without commissioner approval only if the changes do not decrease the effectiveness of the plan;

B. must furnish the change to the commissioner and to affected off-site response organizations within six months after the change is made; and

C. may not implement proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan without prior application to and prior approval by the commissioner.

Subp. 7. **Molybdenum-99 requirement.** A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99 or technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators must test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, according to part 4731.4435. The licensee must record the results of each test and retain each record for three years after the record is made.

Subp. 8. **Security requirements for portable gauges.** A portable gauge licensee must use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

Subp. 9. **Authorization to produce PET.** Authorization under part 4731.3065, subpart 7, to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA requirements or other federal and state requirements governing radioactive drugs.

A. Each licensee authorized under part 4731.3065, subpart 7, to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium must:

(1) satisfy the labeling requirements in part 4731.3395, subpart 1, for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium; and

(2) possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in part 4731.3395, subpart 3.

B. A licensee that is a pharmacy authorized under part 4731.3065, subpart 7, to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium must require that any individual that prepares PET radioactive drugs must be:

(1) an authorized nuclear pharmacist that meets the requirements in part 4731.3395, subpart 2; or

(2) an individual under the supervision of an authorized nuclear pharmacist specified in part 4731.4407.

C. A pharmacy, authorized under part 4731.3065, subpart 7, to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, must meet the requirements of part 4731.3395, subpart 2.

Statutory Authority: *MS s 144.1202; 144.1203*

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

Published Electronically: *March 12, 2009*