4731.3245 GENERAL LICENSE; IN VITRO CLINICAL OR LABORATORY TESTING USE.

Subpart 1. **License issued.** A physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital is issued a general license to receive, acquire, possess, transfer, or use, according to this part, the following radioactive materials in prepackaged units for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

A. iodine-125, in units not exceeding ten microcuries (0.37 MBq) each;

B. iodine-131, in units not exceeding ten microcuries (0.37 MBq) each;

C. carbon-14, in units not exceeding ten microcuries (0.37 MBq) each;

D. hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each;

E. iron-59, in units not exceeding 20 microcuries (0.74 MBq) each;

F. selenium-75, in units not exceeding ten microcuries (0.37 MBq) each;

G. mock iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (0.185 kBq) of americium-241 each; and

H. cobalt-57, in units not exceeding ten microcuries (0.37 MBq) each.

Subp. 2. **License requirements.** A person must not receive, acquire, possess, use, or transfer radioactive material under the general license issued under subpart 1 unless the person:

A. has filed a registration certificate in vitro testing with radioactive material under general license form, as prescribed by the commissioner, with the commissioner and received from the commissioner a validated copy of the form with a registration number assigned; or

B. has a license that authorizes the medical use of radioactive material issued under parts 4731.4400 to 4731.4527.

Subp. 3. **Additional requirements.** A person who receives, acquires, possesses, or uses radioactive material under the general license issued under subpart 1 must:

A. not possess at any one time, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, or cobalt-57 in excess of 200 microcuries (7.4 MBq);

B. store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection;

C. use the radioactive material only for the uses authorized under subpart 1;

D. not transfer the radioactive material, except by transfer to a person who is authorized to receive it under a license issued by the commissioner, the NRC, or an agreement state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier; and

E. dispose of the mock iodine-125 reference or calibration sources described in subpart 1, item G, as required under part 4731.2400.

Subp. 4. **Limitation.** A general licensee under this part must not receive, acquire, possess, or use radioactive material:

A. except as prepackaged units that are labeled according to:

(1) a specific license issued under part 4731.3390; or

(2) a specific license issued by the NRC or an agreement state that authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, mock iodine-125, or cobalt-57 to persons generally licensed by the NRC or an agreement state; and

B. unless the following statement, or a substantially similar statement that contains the information called for, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure that accompanies the package:

"This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the rules of and a general license issued by the Nuclear Regulatory Commission or a state with which the Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority.

(Name of manufacturer)"

Subp. 5. **Changes in registration.** A registrant possessing or using radioactive material under the general license issued under subpart 1 must report in writing to the commissioner any changes in the information provided in the form under subpart 2, item A. The report must be furnished within 30 days after the effective date of the change.

Subp. 6. **Exemptions.** A person using radioactive material under the general license issued under subpart 1 is exempt from parts 4731.1000 to 4731.2950 and Code of Federal Regulations, title 10, part 21, with respect to radioactive material covered by the general

license, except that persons using mock iodine-125 under subpart 1, item G, must comply with parts 4731.2400, 4731.2600, and 4731.2610.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 33 SR 1440*

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