4731.3390 SPECIFIC LICENSE; MATERIAL FOR IN VITRO CLINICAL OR LABORATORY TESTING; MANUFACTURE AND DISTRIBUTION.

An application for a specific license to manufacture or distribute radioactive material for use under the general license under part 4731.3245 shall be approved if:

A. the applicant satisfies the general requirements of part 4731.3070;

B. the radioactive material is prepared for distribution in prepackaged units of:

(1) iodine-125 in units not exceeding ten microcuries (370 kBq) each;

(2) iodine-131 in units not exceeding ten microcuries (370 kBq) each;

(3) carbon-14 in units not exceeding ten microcuries (370 kBq) each;

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

(5) iron-59 in units not exceeding 20 microcuries (740 kBq) each;

(6) selenium-75 in units not exceeding ten microcuries (370 kBq) each;

(7) mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; and

(8) cobalt-57 in units not exceeding ten microcuries (370 kBq) each;

C. each prepackaged unit bears a durable, clearly visible label that:

(1) identifies the radioactive contents as to chemical form and radionuclide; and

(2) indicates that the amount of radioactivity does not exceed:

(a) ten microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, or selenium-75;

(b) 50 microcuries (1.85 MBq) of hydrogen-3 (tritium);

(c) 20 microcuries (740 kBq) of iron-59;

(d) mock iodine-125 in units not exceeding 0.05 microcuries (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each; or

(e) cobalt-57 in units not exceeding ten microcuries (370 kBq); and

(3) displays the radiation caution symbol described in part 4731.2300, and the words "Caution, Radioactive Material" and "Not for Internal or External Use in Humans or Animals";

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

"The 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 regulations and a general license of the Minnesota commissioner of health, 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)"; and

E. the label affixed to the unit, or the leaflet or brochure that accompanies the package, contains adequate information as to the precautions to be observed in handling and storing the radioactive material. In the case of a mock iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements under part 4731.2400.

Statutory Authority: *MS s 144.1202; 144.1203*

History: *29 SR 755; 33 SR 1440*

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