Pertaining to Use of Radioactive Material For Certain In Vitro Clinical or Laboratory Testing under a General License

Instructions – The information provided by the State of Wisconsin, Department of Health Services (DHS), Radiation Protection Section is a summary of ***s. DHS 157.11 (2) (f),*** to be used by the registrant in order to understand the requirements that pertain to a Certificate for In Vitro Testing with Radioactive Material under General License. ***Note: The New Drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.***

s. DHS 157. 11 (2) (f)

(f) ***General license for use of radioactive material for certain in vitro clinical or laboratory testing****.*

1. A general license is issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, under the sections 2., 3., 4., 5., and 6 in this summary, the following radioactive materials in prepackaged units for use as in vitro clinical or laboratory test not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

   a. Carbon-14, in units not exceeding 370 kBq (10 microcuries) each.

   b. Cobalt-57, in units not exceeding 370 kBq (10 microcuries) each.

   c. Hydrogen-3 (tritium), in units not exceeding 1.85 MBq (50 microcuries) each.

   d. Iodine-125, in units not exceeding 370 kBq (10 microcuries) each.

   e. Mock Iodine-125 reference or calibration sources, in units not exceeding 1.85 kBq (0.05 microcurie) of Iodine-129 and 185 Bq (0.005 microcurie) of Americium-241 each.

   f. Iodine-131, in units not exceeding 370 kBq (10 microcuries) each.

   g. Iron-59, in units not exceeding 740 kBq (20 microcuries) each.

   h. Selenium-75, in units not exceeding 370 kBq (10 microcuries) each.

2. No person may receive, acquire, possess, use or transfer radioactive material under the general license established under this paragraph until the person has filed a "Certificate – In Vitro Testing with Radioactive Material Under General License" form with the department and received from the department a validated copy of the form with certification number assigned. A physician, veterinarian, clinical laboratory or hospital shall furnish on the "Certificate – In Vitro Testing with Radioactive Material Under General License" all the following information and such other information as may be required by that form:

   a. Name and address of the physician, veterinarian, clinical laboratory, or hospital.

   b. The location of use.

   c. A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized by the general license under this paragraph and that the tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(Continued)

3. A person who receives, acquires, possesses or uses radioactive material under the general license under this paragraph shall comply with all the following:

   a. The general licensee may not possess at any one time, under the general license under this paragraph, 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 7.4 MBq (200 microcuries).

   b. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

   c. The general licensee shall use the radioactive material only for the uses authorized by section 1 of this summary.

   d. The general licensee may not transfer the radioactive material to a person who is not authorized to receive it under a license issued by the department, the NRC, any agreement state or a licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

   e. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in section *1.e*. of this summary as required by ***s. DHS 157.30 " Waste Management".***

4. The general licensee shall not receive, acquire, possess, or use radioactive material under *s. DHS 157.11(2) (f)1* except in prepackaged units which are labeled under the provisions of an applicable specific license issued under *s. DHS 157.13 (4) (g)* or under the provisions of a specific license issued by the NRC, any agreement state or a licensing state which authorizes the manufacture and distribution of Iodine-125, Iodine-131, Carbon-14, Hydrogen-3 (tritium), Iron-59, Selenium-75, Cobalt-57 or Mock Iodine-125 to persons generally licensed under *s. DHS 157.11 (2) (f) 1* or its equivalent, and one of the following statements or a substantially similar statement that contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

   a. This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, 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 NRC or of a state with which commission has entered into an agreement for the exercise of regulatory authority.

   b. This radioactive material shall be received, acquired, possessed and used only by physicians, veterinarians, 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 a licensing state.

5. The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license under this paragraph shall report in writing to the department any changes in the information furnished by that person in the "Certificate – In Vitro Testing with Radioactive Material Under General License". The report shall be furnished within 30 days after the effective date of such change.

6. Any person using radioactive material under the general license under this paragraph is exempt from the requirements of ***s. DHS 157 subchs. III and X*** with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in *s. DHS 157.11 (2) (f) 1. e.* shall comply with the provisions of ***s. DHS 157.23(1) and s. DHS 157.32 (1) and (2).***

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