WAC 246-233-040 General license for use of radioactive material for certain *in vitro* clinical or laboratory testing.* (1) A general license is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of subsections (2), (3), (4), (5), and (6) of this section the following radioactive material in prepackaged units:

(a) Iodine-125, in units not exceeding 370 kilobecquerels (10 microcuries) each 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.

(b) Iodine-131, in units not exceeding 370 kilobecquerels (10 microcuries) each 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.

(c) Carbon-14, in units not exceeding 370 kilobecquerels (10 microcuries) each 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.

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

(e) Iron-59, in units not exceeding 740 kilobecquerels (20 microcuries) each 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.

(f) Cobalt-57, in units not exceeding 370 kilobecquerels (10 microcuries) each 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.

(g) Selenium-75, in units not to exceed 370 kilobecquerels (10 microcuries) each 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.

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

*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.

(2) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established by subsection (1) of this section until that person has received a validated copy of department Form RHF-15 "Certificate *in vitro* testing with radioactive material under general license." Annual validation requires annual resubmittal of revised department Form RHF-15 and submittal of the annual fee to the department. The physician, veterinarian, clinical laboratory or hospital shall furnish on department Form RHF-15 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; and

(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 under the general license in subsection (1) of this section and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

(3) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established by subsection (1) of this section shall comply with the following:

(a) The general licensee shall not possess at any one time, pursuant to the general license in subsection (1) of this section 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 megabecquerels (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 subsection (1) of this section.

(d) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the department, 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.

(e) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in subsection (1)(h) of this section as required by WAC 246-221-170.

(4) The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to subsection (1) of this section:

(a) Except as prepackaged units which are labeled in accordance with the provision of an applicable specific license issued pursuant to WAC 246-235-097 or in accordance with the provisions of a specific license issued by the NRC, or an agreement 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 this subsection or its equivalent; and

(b) Unless one of the following statements, as appropriate, or a substantially similar statement which 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:

> 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 rules and a general license of an agreement state or the NRC.
>
> .....
> Name of manufacturer

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 rules and a general license of an agreement state or the NRC.

.....
Name of manufacturer

(5) The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general license of subsection (1) of this section shall report in writing to the department, any changes in the information previously furnished in the "Certificate *in vitro* testing with radioactive material under general license," department Form RHF-15. The report shall be furnished within thirty days after the effective date of such change.

(6) This general license is subject to the provisions of WAC 246-220-020, 246-220-030, 246-220-040, 246-220-060, 246-220-070, 246-220-090 and 246-220-100. In addition, any person using radioactive material pursuant to the general license of subsection (1) of this section is exempt from the requirements of chapters 246-221 and 246-222 WAC with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in subsection (1)(h) of this section shall comply with the provisions of WAC 246-221-170, 246-221-240, and 246-221-250 and of these rules.

[Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-233-040, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-233-040, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 04-04-055, § 246-233-040, filed 1/30/04, effective 3/1/04.]