WAC 246-235-097 Manufacture and distribution of radioactive material for certain in vitro clinical or laboratory testing under general license. An application for a specific license to manufacture or distribute radioactive material for use under the general license of WAC 246-233-040 will be approved if:

(1) The applicant satisfies the general requirements specified in WAC 246-235-020;

(2) The radioactive material is to be prepared for distribution in prepackaged units of:

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

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

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

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

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

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

(g) Selenium-75 in units not exceeding 370 kilobecquerels (10 microcuries) each;

(h) Mock Iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 185 becquerels (0.005 microcurie) of americium-241 each.

(3) Each prepackaged unit bears a durable, clearly visible label:

(a) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 370 kilobecquerels (10 microcuries) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 1850 kilobecquerels (50 microcuries) of hydrogen-3 (tritium); 740 kilobecquerels (20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 185 becquerels (0.005 microcurie) of americium-241 each; and

(b) Displaying the radiation caution symbol described in WAC 246-221-120 (1)(a) and the words, "CAUTION, RADIOACTIVE MATERIAL," and "Not for internal or external use in humans or animals."

(4) 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:

(a) This radioactive material may 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 the NRC has entered into an agreement for the exercise of regulatory authority.

.....
Name of manufacturer

(b) This radioactive material may 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 an agreement state.

.....
Name of manufacturer

(5) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements in WAC 246-221-170 of these rules.

[Statutory Authority: RCW 70.98.050. WSR 13-24-025, § 246-235-097, filed 11/22/13, effective 12/23/13. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 09-06-003, § 246-235-097, filed 2/18/09, effective 3/21/09. Statutory Authority: RCW 70.98.050. WSR 04-04-055, § 246-235-097, filed 1/30/04, effective 3/1/04; WSR 98-13-037, § 246-235-097, filed 6/8/98, effective 7/9/98.]