3701:1-46-42 **Manufacture and distribution of radioactive material for certain in-vitro clinical or laboratory testing under general license.**

An application for a specific license to manufacturer or distribute radioactive material for use under the general license in rule 3701:1-46-11 of the Administrative Code will be approved if:

(A) The applicant satisfies the general requirements specified in rule 3701:1-40-15 of the Administrative Code.

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

(1) Iodine-125 in units not exceeding 0.37 megabecquerel (ten microcuries) each.

(2) Iodine-131 in units not exceeding 0.37 megabecquerel (ten microcuries) each.

(3) Carbon-14 in units not exceeding 0.37 megabecquerel (ten microcuries) each.

(4) Hydrogen-3 (tritium) in units not exceeding 1.85 megabecquerels (fifty microcuries) each.

(5) Iron-59 in units not exceeding 0.74 megabecquerel (twenty microcuries) each.

(6) Selenium-75 in units not exceeding 0.37 megabecquerel (ten microcuries) each.

(7) Mock iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each.

(8) Cobalt-57 in units not exceeding 0.37 megabecquerel (ten microcuries) each.

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

(1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 0.37 megabecquerel (ten microcuries) of iodine-131, iodine-125, selenium-75, cobalt-57, or carbon-14; 1.85 megabecquerels (fifty microcuries) of hydrogen-3 (tritium); or 0.74 megabecquerel (twenty microcuries) of iron-59; or mock iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each; and

(2) Displaying the radiation symbol described in paragraph (A) of rule 3701:1-38-18 of the Administrative Code 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 which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which 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 United States Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

(Name of manufacturer)"

(E) 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 set out in paragraph (A) of rule 3701:1-38-19 of the Administrative Code.

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CERTIFIED ELECTRONICALLY

Certification

09/18/2012

Date

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