Ohio Administrative Code

Rule 3701:1-46-11 General license for use of radioactive material for certain in-vitro clinical or laboratory testing.

Effective: October 4, 2010

(A) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (B) to (F) of this rule, the following radioactive materials in prepackaged units:

(1) Iodine-125, in units not exceeding three hundred seventy kilobecquerels (ten 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.

(2) Iodine-131, in units not exceeding three hundred seventy kilobecquerels (ten 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.

(3) Carbon-14, in units not exceeding three hundred seventy kilobecquerels (ten 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.

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

(5) Iron-59, in units not exceeding seven hundred forty kilobecquerels (twenty 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.

(6) Selenium-75, in units not exceeding three hundred seventy kilobecquerels (ten 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.

(7) Mock iodine-125 reference or calibration sources, in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and one hundred eighty-five 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.

(8) Cobalt-57, in units not exceeding three hundred seventy kilobecquerels (ten 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) A person shall not receive, acquire, possess, use, or transfer radioactive material under the general license established by paragraph (A) of this rule unless that person:

(1) Has filed the radioactive materials in-vitro testing form with the director; or

(2) Has a license that authorizes the medical use of radioactive material that was issued under rules for medical uses of radioactive material.

(C) A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by paragraph (A) of this rule shall comply with the following:

(1) The general licensee shall not possess at any one time, pursuant to the general license in paragraph (A) of this rule, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, iron-59, and/or cobalt-57 in excess of 7.4 megabecquerels (two hundred microcuries).

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

(3) The general licensee shall use the radioactive material only for the uses authorized by paragraph (A) of this rule.

(4) The general licensee shall not transfer the radioactive material except by transfer to a person

authorized to receive it by a license pursuant to this chapter, from the United States nuclear regulatory commission, or from an agreement state or transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(5) The general licensee shall dispose of the mock iodine-125 reference or calibration sources described in paragraph (A)(7) of this rule as required by rule 3701:1-38-19 of the Administrative Code.

(D) The general licensee shall not receive, acquire, possess or use radioactive material pursuant to paragraph (A) of this rule:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of rule 3701:1-46-42 of the Administrative Code or in accordance with the provisions of a specific license issued by the United States nuclear regulatory commission or an agreement state that authorizes manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, mock iodine-125, or cobalt-57 for distribution to persons generally licensed by the United States nuclear regulatory commission or an agreement state.

(2) Unless 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: This 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 licensee possessing or using radioactive materials under the general license of paragraph (A) of this rule shall report in writing to the director any changes in the information furnished by the licensee in department form HEA-5518, "In-Vitro Testing With Radioactive Material Form." The report shall be furnished within thirty days after the effective date of such change.

(F) Any person using radioactive material pursuant to the general license of paragraph (A) of this rule is exempt from the requirements of Chapter 3701:1-38 of the Administrative Code with respect to radioactive materials covered by that general license, except that such persons using the mock iodine-125 described in paragraph (A)(7) of this rule shall comply with the provisions of paragraph (A) of rule 3701:1-38-19 of the Administrative Code and paragraphs (A) and (B) of rule 3701:1-38-21 of the Administrative Code.