10A NCAC 15 .0314 GENERAL LICENSES: IN VITRO CLINICAL OR LABORATORY TESTING

(a) A general license shall be issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer or use the following radioactive materials for IN VITRO clinical or laboratory tests not involving internal or external administration of radioactive material, or radiation therefrom, to human beings or animals:

(1) iodine-125 in units not exceeding ten microcuries each;
(2) iodine-131 in units not exceeding ten microcuries each;
(3) carbon-14 in units not exceeding ten microcuries each;
(4) hydrogen-3 (tritium) in units not exceeding 50 microcuries each;
(5) iron-59 in units not exceeding 20 microcuries each;
(6) cobalt-57 in units not exceeding ten microcuries each;
(7) selenium-75 in units not exceeding ten microcuries each;
(8) mock iodine-125 reference or calibration sources in units not exceeding 0.05 microcuries of iodine-129 and 0.005 microcurie of americium-241 each. This general license is subject to the provisions of Paragraphs (b) to (f) of this Rule.

(b) No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general license established in Paragraph (a) of this Rule until he has filed agency form "Certificate IN VITRO Testing with Radioactive Material Under General License", with the agency and received from the agency a validated copy of the agency form with certification number assigned. The physician, clinical laboratory or hospital shall furnish on the agency form the following information and such other information as may be required by the form:

(1) name and address of the physician, clinical laboratory or hospital;
(2) the location of use;
(3) a statement that the physician, 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 Paragraph (a) of this Rule and that these tests will be performed only by personnel competent in the use of the instruments and in the handling of the radioactive material.

(c) A person who receives, acquires, possesses or uses radioactive material pursuant to the general license established in Paragraph (a) of this Rule:

(1) 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, and iron-59 in excess of 200 microcuries;
(2) shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection;
(3) shall use the radioactive material only for the uses authorized in Paragraph (a) of this Rule;
(4) shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the agency, the U.S. Nuclear Regulatory Commission, 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; and
(5) shall dispose of the mock iodine-125 reference or calibration sources described in Subparagraph (a)(8) of this Rule as required by Rule .1628 of this Chapter.

(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 by the U.S. Nuclear Regulatory Commission, or an agreement state which authorizes the manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, mock iodine-125 (of iodine-129 and americium-241), or iron-59 for distribution to persons generally licensed under Paragraph (a) of this Rule or its equivalent; and
(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:
    (A) This radioactive material may be received, acquired, possessed, and used only by physicians, 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.
    (B) 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 physician, clinical laboratory or hospital possessing or using radioactive material under the general license in Paragraph (a) of this Rule shall report in writing to the agency, any changes in the information furnished in the "Certificate IN VITRO Testing with Radioactive Material Under General License" agency form within 30 days after the effective date of the changes.

(f) Any person using radioactive material pursuant to the general license in Paragraph (a) of this Rule is exempt from the requirements of Sections .1000 and .1600 of these Rules with respect to radioactive material covered by the general license. 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.

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