15A NCAC 11 .0331 is proposed for amendment as follows:

15A NCAC 11 .0331 SPECIFIC LICENSES-MANUFACTURE OF IN VITRO TEST KITS

An application for a specific license to manufacture or distribute radioactive material for use under the general license in Rule .0314 of this Section ~~will~~ shall be approved if the following requirements are satisfied:

(1) The applicant satisfies the general requirements specified in Rule .0317 of this Section.

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

(a) iodine-125 in units not exceeding ten microcuries each;

(b) iodine-131 in units not exceeding ten microcuries each;

(c) carbon-14 in units not exceeding ten microcuries each;

(d) hydrogen-3 (tritium) in units not exceeding 50 microcuries each;

(e) iron-59 in units not to exceed 20 microcuries each;

(f) cobalt-57 in units not to exceed ten microcuries each;

(g) selenium-75 in units not exceeding 10 microcuries ~~0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.~~ each; or

(h) mock iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 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 the appropriate limit in Item (2) of this Rule, and

(b) displaying the radiation caution symbol described in Rule .1623 of this Chapter and the words, "CAUTION, RADIOACTIVE MATERIAL", and "NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS".

(4) 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, 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 U.S. Nuclear Regulatory Commission or a state with which the Commission has entered into an agreement for the exercise of regulatory authority. (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 set out in Rule .1628 of this Chapter.

History Note: *Authority G.S. 104E-7; 104E-10(b);*
Eff. February 1, 1980;
Amended Eff. October 1, 2013; January 1, 1994.