

1 10A NCAC 15 .0331 is amended with changes as published in 31:07 NCR, pp. 549-582, as follows:

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3 **10A NCAC 15 .0331 SPECIFIC LICENSES-MANUFACTURE OF IN VITRO TEST KITS**

4 An application for a specific license authorizing the manufacture and initial transfer of devices containing byproduct
5 material to persons generally licensed under Rule .0314 of this Section shall comply with the provisions of Rule
6 .0317(a), (b)(2), (c), and (d) of this Section as applicable to the licensed activities.

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

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

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

11 (a) ~~— iodine 125 in units not exceeding 10 microcuries each;~~

12 (b) ~~— iodine 131 in units not exceeding 10 microcuries each;~~

13 (c) ~~— carbon 14 in units not exceeding 10 microcuries each;~~

14 (d) ~~— hydrogen 3 (tritium) in units not exceeding 50 microcuries each;~~

15 (e) ~~— iron 59 in units not to exceed 20 microcuries each;~~

16 (f) ~~— cobalt 57 in units not to exceed 10 microcuries each;~~

17 (g) ~~— selenium 75 in units not exceeding 10 microcuries each; or~~

18 (h) ~~— mock iodine 125 in units not exceeding 0.05 microcurie of iodine 129 and 0.005~~
19 ~~microcurie of americium 241 each.~~

20 (3) ~~— Each prepackaged unit bears a durable, visible label:~~

21 (a) ~~— identifying the radioactive contents as to chemical form and radionuclide, and indicating~~
22 ~~that the amount of radioactivity does not exceed the appropriate limit in Item (2) of this~~
23 ~~Rule; and~~

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

27 (4) ~~— The following statement, or a statement which contains the information called for in the following~~
28 ~~statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure~~
29 ~~which accompanies the package:~~

30 ~~This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or~~
31 ~~hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the~~
32 ~~material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer~~
33 ~~are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or a state with which~~
34 ~~the Commission has entered into an agreement for the exercise of regulatory authority. (Name of Manufacturer.)~~

35 (5) ~~— The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains~~
36 ~~information as to the precautions to be observed in handling and storing such radioactive material.~~
37 ~~In the case of the mock iodine 125 reference or calibration source, the information accompanying~~

1 ~~the source must also contain directions to the licensee regarding the waste disposal requirements set~~
2 ~~out in Rule .1628 of this Chapter.~~

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4 *History Note: Authority G.S. 104E-7; 104E-10(b);*

5 *Eff. February 1, 1980;*

6 *Amended Eff. October 1, 2013; January 1, 1994;*

7 *Transferred and Recodified from 15A NCAC 11 .0331 Eff. February 1, ~~2015.~~ 2015.*

8 *Amended Eff. March 1, 2017.*