

1 15A NCAC 11 .0309 is proposed for amendment as follows:

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3 **15A NCAC 11 .0309 GENERAL LICENSES: MEASURING GAUGING: CONTROLLING DEVICES**

4 (a) A general license shall be issued to commercial and industrial firms; research, educational and medical
5 institutions; individuals in the conduct of their business; and federal, state, or local government agencies to acquire,
6 receive, possess, use, or transfer in accordance with Paragraphs (b), (c), and (d) of this Rule, radioactive material
7 contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling
8 thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition, or
9 for producing light or an ionized atmosphere.

10 (b) The general license in Paragraph (a) of this Rule applies only to radioactive material contained in devices which
11 have been:

- 12 (1) manufactured or initially transferred and labeled in accordance with the specifications contained in
13 a specific license issued pursuant to Rule .0328 of this Section or in accordance with the
14 specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission
15 or an agreement state which authorizes distribution of the devices to persons generally licensed
16 pursuant to equivalent regulations; and
17 (2) received from one of the specific licensees referenced in Subparagraph (b)(1) of this Rule or
18 through a transfer completed in accordance with Subparagraph (c)(8) of this Rule.

19 (c) Any person who acquires, receives, possesses, uses or transfers radioactive material in a device pursuant to the
20 general license issued under Paragraph (a) of this Rule shall:

- 21 (1) ~~shall~~ assure that all labels, affixed to the device at the time of receipt and bearing a statement that
22 removal of the label is prohibited, are maintained thereon and shall comply with all instructions
23 and precautions provided by the labels;
24 (2) ~~shall~~ assure that the device is tested for leakage of radioactive material and proper operation of the
25 on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other
26 intervals as are specified in the label, except as follows:
27 (A) Devices containing only krypton need not be tested for leakage of radioactive material;
28 and
29 (B) Devices containing only tritium or not more than 100 microcuries of other beta, gamma,
30 or beta and gamma emitting material or ten microcuries of alpha emitting material and
31 devices held in storage in the original shipping container prior to initial installation need
32 not be tested for any purpose;
33 (3) ~~shall~~ assure that the tests required by Subparagraph (c)(2) of this Rule and other testing,
34 installation, servicing and removal from installation involving the radioactive materials, its
35 shielding or containment are performed:
36 (A) in accordance with the instructions provided on labels affixed to the device, except that
37 tests for leakage or contamination may be performed by the general licensee using leak

1 test kits provided and analyzed by a specific licensee who is authorized to provide leak
2 test kit services; or

3 (B) by a person holding a specific license or registration which authorizes the providing of
4 services required by this Rule and which is issued pursuant to Rules .0205 and .0306 of
5 this Chapter or equivalent regulations of the U.S. Nuclear Regulatory Commission or an
6 agreement state; State;

7 (4) ~~shall~~ maintain records, showing compliance with the requirements in Subparagraphs (c)(2) and (3)
8 of this Rule, ~~to include~~ including:

9 (A) the name of the person(s) performing the test(s) and the date(s) of the test(s);

10 (B) the name of the person(s) performing installation, servicing and removal of any
11 radioactive material, shielding or containment;

12 Retention of leakage or contamination, on-off mechanism and on-off indicator test records shall be
13 retained for three years after the next required test is performed or until the sealed source is
14 disposed of or transferred. Retention of other records of tests required in Subparagraph (c)(3) of
15 this Rule shall be retained for three years from the date of the recorded test or until the device is
16 disposed of or transferred.

17 ~~(C) — retention of leakage or contamination, on off mechanism and on off indicator test records~~
18 ~~for one year after the next required test is performed or until the sealed source is disposed~~
19 ~~of or transferred, whichever is shorter;~~

20 ~~(D) — retention of other records of tests required in Subparagraph (c)(3) of this Rule for two~~
21 ~~years from the date of the recorded test or until the device is disposed of or transferred.~~

22 (5) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or
23 damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon
24 the detection of 0.005 microcurie or more removable radioactive material, shall immediately
25 suspend operation of the device until it has been:

26 (A) repaired by the manufacturer or other person authorized to repair the device(s) by a
27 specific license issued by the agency, the U.S. Nuclear Regulatory Commission, or an
28 agreement state; or

29 (B) disposed of by transfer to a person authorized by a specific license to receive the
30 radioactive material contained in the device; and within 30 days, furnish to the agency at
31 the address in Rule .0111 of this Chapter a report containing a ~~brief~~ description of the
32 event and the remedial action taken. ~~In the event that~~ If 0.005 microcurie or more of
33 removable radioactive contamination is detected, or if the failure of or damage to a
34 source of radiation is likely to result in the contamination of the facility or the
35 environment, a plan for ensuring that the facility and the environment are acceptable for
36 unrestricted use shall be submitted to the agency at the address in Rule .0111 of this
37 Chapter.

- 1 (6) shall not abandon the device containing radioactive material;
- 2 (7) except as provided in Subparagraph (c)(8) of this Rule, shall transfer or dispose of the device
3 containing radioactive material only by export in accordance with 10 CFR Part 110 or by transfer
4 to a person holding a specific license authorizing receipt of the device; and, prior to the within 30
5 days of after transfer of a device to a specific licensee or export ~~the transfer~~ of a device ~~to a~~
6 ~~specific licensee~~, shall furnish to the agency at the address in Rule .0111 of this Chapter, a report
7 that contains:
- 8 (A) the identification of the device by manufacturer's or initial transferor's name, model
9 number, and serial number;
- 10 (B) the name, address and specific license number of the person receiving the ~~device; and~~
11 device (license number not applicable if exported); and
- 12 (C) the date of the ~~transfer.~~ transfer; and
- 13 ~~(D)~~(8) shall obtain written approval by the Agency before transferring the device to any other specific
14 licensee not identified in this Rule; however, a holder of a specific license may transfer a device
15 for possession and use under its own specific license without prior approval, if the holder:
- 16 ~~(1)~~(A) Verifies that the specific license authorizes the possession and use, or applies for
17 and obtains an amendment to the license authorizing the possession and use;
- 18 ~~(2)~~(B) Removes, alters, covers, or clearly and unambiguously augments (As defined in
19 10 CFR 31.5) the existing label otherwise required by paragraph (c)(1) of this
20 section so that the device is labeled in compliance with § .0328(a)(3) of this
21 chapter; however, the manufacturer, model number, and serial number must be
22 retained;
- 23 ~~(3)~~(C) Obtains the manufacturer's or initial transferor's information concerning
24 maintenance that be applicable under the specific license (such as leak testing
25 procedures); and
- 26 ~~(4)~~(D) Reports the transfer under paragraph (7) of this rule.
- 27 ~~(8)~~(9) shall transfer or dispose of the device only by export as provided by (c)(7) of this Rule, or by
28 transfer to another general licensee only where the device:
- 29 (A) remains in use at a particular location. In this case the transferor shall give the
30 transferee a copy of this Rule and any safety documents identified in the label of
31 the device, and the transferor shall, within 30 days of the transfer, report to the
32 agency at the address in Rule .0111 of this Chapter the manufacturer's or initial
33 transferor's name, serial number, and model number of device transferred; the
34 name and mailing address of the transferee; and the name, title, and telephone
35 number of the individual identified by the transferee pursuant to Subparagraph
36 (c)(10) of this Rule as having knowledge of and authority to take actions to
37 ensure compliance with the requirements contained in these Rules; or

1 (i) ~~In this case the transferor shall give the transferee a copy of this Section Rule~~
2 ~~and any safety documents identified in the label of the device;~~

3 (ii) ~~The transferor shall, within 30 days of the transfer, report to the agency at the~~
4 ~~address in Rule .0111 of this Chapter the manufacturer's or initial transferor's~~
5 ~~name, serial number, and model number of device transferred; the name and~~
6 ~~mailing address of the transferee; and the name, title, and telephone number of~~
7 ~~the individual identified by the transferee pursuant to Subparagraph (c)(10) of~~
8 ~~this Rule as having knowledge of and authority to take actions to ensure~~
9 ~~compliance with the requirements contained in these Rules; or~~

10 (B) is held in storage by the licensee or an intermediate person in the original shipping
11 container at its intended location of use prior to initial use by a general licensee.

12 ~~(9)(10)~~ shall comply with the provisions of Sections .0100 and .1600 of this Chapter for reporting
13 radiation incidents, theft or loss of licensed material, but ~~shall be~~ is exempt from the other
14 requirements of Section .1600 of this Chapter;

15 ~~(10)(11)~~ shall appoint an individual responsible for having knowledge of the requirements contained in
16 these Rules and the authority for taking the actions required to comply with these Rules. The
17 general licensee, through this individual, shall ensure the day-to-day compliance with these Rules.
18 The appointment of such an individual does not relieve the general licensee of any of its
19 responsibility in this regard;

20 ~~(11)(12)~~ shall register, when required by the agency, any source of radiation subject to a general license in
21 accordance with the rules in this Section. Each address for a location of use represents a separate
22 general license and requires a separate registration action;

23 ~~(12)(13)~~ shall register, on an annual basis, all devices containing, based on the activity indicated on the
24 label, at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi
25 (37MBq) of cobalt-60, 1 mCi (37 MBq) of ~~americium-241~~ americium-241, 0.1 millicurie (3.7
26 MBq) of radium-226, or any other transuranic isotope. Each address for a location of use
27 represents a separate general license and requires a separate registration action. Annual
28 registration consists of verifying, correcting, or adding to the information provided in a request for
29 annual registration within 30 days of a request from the agency. The general licensee shall furnish
30 the following information for annual registration:

31 (A) the name and mailing address of the general licensee;

32 (B) ~~specific~~ information about each device to include the manufacturer or initial transferor,
33 model number, serial number, the radioisotope, and the activity indicated on the label;

34 (C) the name, title, and telephone number of the responsible person designated as a
35 representative of the general licensee in accordance with Subparagraph (c)(10) of this
36 Rule;

1 (D) the address or location at which the device(s) are to be used or stored. For portable
2 devices that are granted a general license by the agency, the address of the primary place
3 of storage;

4 (E) certification by the responsible person designated by the general licensee that the
5 information concerning the device(s) has been verified through a physical inventory and a
6 check of label information; and

7 (F) certification by the responsible person designated by the general licensee that they are
8 aware of the requirements of the ~~general license.~~ license;

9 ~~(13)~~(14) shall report changes to the mailing address to the agency within 30 days of the effective date of the
10 change;

11 ~~(14)~~(15) shall report changes to the name of the general licensee to the agency within 30 days of the
12 effective date of the change;

13 (16) shall respond to written requests from the Agency to provide information relating to the general
14 license within 30 calendar days of the date of the request, or other time specified in the request. If
15 the general licensee cannot provide the requested information within the allotted time, it shall,
16 within that same time period, request a longer period to supply the information by providing the
17 Agency a written justification for the request. The request to extend the allotted time will be
18 granted upon agency review of the licensee request and supporting information related to the need
19 for extension;

20 ~~(15)~~ (17) shall not hold devices that are not in use for longer than two years. If devices that have
21 shutters are not in use, the shutter shall be locked in the closed position. Leak testing is
22 not required during the period of storage; however, when devices are returned to service
23 or transferred to another person, the devices must be tested for leakage and shutter
24 operation. Devices kept in standby for future use shall be excluded from the two year
25 time limit if quarterly physical inventories of these devices are performed while in
26 standby.

27 (d) The general license in Paragraph (a) of this Rule does not authorize the manufacture or ~~distribution~~ import of
28 devices containing radioactive material.

29 (e) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a),
30 .0338, .0342, .0343 and .0345 of this Chapter and to labeling requirements in Section .1600 of this Chapter.

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

33 *Eff. February 1, 1980;*

34 *Amended Eff. October 1, 2013; January 1, 2005; January 1, 1994; June 1, 1989.*