

1 15A NCAC 11 .0309 is amended with changes as published in NCR 27:22, pp. 2031-2073, as follows:

2
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; atmosphere to:~~

- 10 (1) ~~commercial and industrial firms;~~
11 (2) ~~research, educational and medical institutions;~~
12 (3) ~~individuals in the conduct of their business; and~~
13 (4) ~~federal, state, or local government agencies.~~

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

- 16 (1) manufactured or initially transferred and labeled in accordance with the specifications contained in
17 a specific license issued pursuant to Rule .0328 of this Section or in accordance with the
18 specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission
19 or an agreement state which authorizes distribution of the devices to persons generally licensed
20 pursuant to equivalent regulations; and
21 (2) received from one of the specific licensees referenced in Subparagraph (b)(1) of this Rule or
22 through a transfer completed in accordance with Subparagraph (c)(8) or (c)(9) of this Rule.

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

- 25 (1) ~~shall~~ assure that all labels, affixed to the device at the time of receipt and bearing a statement that
26 removal of the label is prohibited, are maintained thereon and shall comply with all instructions
27 and precautions provided by the labels;
28 (2) ~~shall~~ assure that the device is tested for leakage of radioactive material and proper operation of the
29 on-off mechanism and indicator, if any, at ~~no longer than~~ six-month intervals or at alternative
30 such other intervals as are specified in the label, except as follows:
31 (A) Devices containing only krypton need not be tested for leakage of radioactive material;
32 and
33 (B) Devices containing only tritium or not more than 100 microcuries of other beta, gamma,
34 or beta and gamma emitting material or ~~ten~~ 10 microcuries of alpha emitting material and
35 devices held in storage in the original shipping container prior to initial installation need
36 not be tested for any purpose;

- 1 (3) ~~shall~~ assure that the tests required by Subparagraph (c)(2) of this Rule and other testing,
2 installation, servicing and removal from installation involving the radioactive materials, its
3 shielding or containment are performed:
- 4 (A) in accordance with the instructions provided on labels affixed to the device, except that
5 tests for leakage or contamination may be performed by the general licensee using leak
6 test kits provided and analyzed by a specific licensee who is authorized to provide leak
7 test kit services; or
- 8 (B) by a person holding a specific license or registration which authorizes the providing of
9 services required by this Rule and which is issued pursuant to Rules .0205 and .0306 of
10 this Chapter or equivalent regulations of the U.S. Nuclear Regulatory Commission or an
11 agreement state. ~~{ State; } state;~~
- 12 (4) ~~shall~~ maintain records, showing compliance with the requirements in Subparagraphs (c)(2) and (3)
13 of this Rule, ~~to include~~ including:
- 14 (A) the name of the person(s) performing the test(s) and the date(s) of the test(s);
- 15 (B) the name of the person(s) performing installation, servicing and removal of any
16 radioactive material, shielding or containment;
- 17 (C) the retention of leakage or contamination, on-off mechanism and on-off indicator test
18 records shall be retained for three years after the required test is performed or until the
19 sealed source is disposed of or transferred; and
- 20 (D) the retention of other records of tests required in Subparagraph (c)(3) of this Rule shall be
21 retained for three years from the date of the recorded test or until the device is disposed
22 of or transferred.
- 23 ~~{Retention of leakage or contamination, on off mechanism and on off indicator test records shall~~
24 ~~be retained for three years after the next required test is performed or until the sealed source is~~
25 ~~disposed of or transferred. Retention of other records of tests required in Subparagraph (c)(3) of~~
26 ~~this Rule shall be retained for three years from the date of the recorded test or until the device is~~
27 ~~disposed of or transferred. }~~
- 28 (C) ~~retention of leakage or contamination, on off mechanism and on off indicator test records~~
29 ~~for one year after the next required test is performed or until the sealed source is disposed~~
30 ~~of or transferred, whichever is shorter;~~
- 31 (D) ~~retention of other records of tests required in Subparagraph (c)(3) of this Rule for two~~
32 ~~years from the date of the recorded test or until the device is disposed of or transferred.~~
- 33 (5) upon the occurrence of a failure of or damage to, or any indication of a possible failure of or
34 damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon
35 the detection of 0.005 microcurie or more removable radioactive material, ~~shall~~ immediately
36 suspend operation of the device until it has been:

- 1 (A) repaired by the manufacturer or other person authorized to repair the device(s) by a
2 specific license issued by the agency, the U.S. Nuclear Regulatory Commission, or an
3 agreement state; or
- 4 (B) disposed of by transfer to a person authorized by a specific license to receive the
5 radioactive material contained in the device; and within 30 days, the transferor will
6 furnish to the agency at the address in Rule .0111 of this Chapter a report containing a
7 ~~brief~~ description of the event and the remedial action taken. ~~In the event that~~ If 0.005
8 microcurie or more of removable radioactive contamination is detected, or if the failure
9 of or damage to a source of radiation is likely to result in the contamination of the facility
10 or the environment, a plan for ensuring that the facility and the environment are
11 acceptable for unrestricted use shall be submitted to the agency at the address in Rule
12 .0111 of this Chapter.
- 13 (6) ~~shall~~ not abandon the device containing radioactive material;
- 14 (7) except as provided in Subparagraph (c)(8) or (c)(9) of this Rule, ~~shall~~ transfer or dispose of the
15 device containing radioactive material only by export in accordance with 10 CFR Part 110 or by
16 transfer to a person holding a specific license authorizing receipt of the device; and, ~~prior to the~~
17 within 30 days of after transfer of a device to a specific licensee or export ~~the transfer~~ of a device
18 ~~to a specific licensee~~, shall furnish to the agency at the address in Rule .0111 of this Chapter, a
19 report that contains:
- 20 (A) the identification of the device by manufacturer's or initial transferor's name, model
21 number, and serial number;
- 22 (B) the name, address and specific license number of the person receiving the ~~device; and~~
23 device {license} (the license number not applicable if exported); and
- 24 (C) the date of the ~~transfer; and~~ transfer; and
- 25 ~~(D)(8)~~ {shall} obtain written approval by the Agency before transferring the device to any other specific
26 licensee not identified in this {Rule; however,} Rule. However, a holder of a specific license may
27 transfer a device for possession and use under its own specific license without prior approval, if
28 the holder:
- 29 (A) {Verifies} verifies that the specific license authorizes the possession and use, or
30 applies for and obtains an amendment to the license authorizing the possession
31 and use;
- 32 (B) {Removes,} removes, alters, covers, or clearly and unambiguously augments
33 {As} as defined in 10 CFR 31.5) the existing label otherwise required by
34 {paragraph} Paragraph (c)(1) of this {section} Rule so that the device is labeled
35 in compliance with {§ .0328(a)(3) of this chapter;} Rule .0328(a)(3) of this
36 Chapter; however, the manufacturer, model number, and serial number must be
37 retained;

1 (C) ~~{Obtains}~~ obtains the manufacturer's or initial transferor's information
2 concerning maintenance that ~~{be}~~ are applicable under the specific license (such
3 as leak testing procedures); and

4 (D) ~~{Reports the transfer under paragraph (7) of this rule.}~~ reports the transfer under
5 Subparagraph (c)(7) of this Rule.

6 (8)(9) shall transfer or dispose of the device ~~{only}~~ by export as provided by Subparagraph (c)(7) of this
7 Rule, or by transfer to another general licensee only where the device:

8 (A) remains in use at a particular location. ~~{In this case the}~~ The transferor shall
9 give the transferee a copy of this Rule and any safety documents identified in the
10 label of the device. ~~{device, and the}~~ The transferor shall, within 30 days of the
11 transfer, report to the agency at the address in Rule .0111 of this Chapter the
12 manufacturer's or initial transferor's name, serial number, and model number of
13 device transferred; the name and mailing address of the transferee; and the
14 name, title, and telephone number of the individual identified by the transferee
15 pursuant to ~~{Subparagraph (c)(10)}~~ Subparagraph (c)(11) of this Rule; or ~~{Rule~~
16 as having knowledge of and authority to take actions to ensure compliance with
17 the requirements contained in these Rules; or }

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

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

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

29 (9)(10) shall comply with the provisions of Sections .0100 and .1600 of this Chapter for reporting
30 radiation incidents, theft or loss of licensed material, but ~~shall be~~ is exempt from the other
31 requirements of Section .1600 of this Chapter;

32 (10)(11) shall appoint an individual responsible for having knowledge of the requirements contained in
33 these Rules and the authority for taking the actions required to comply with these Rules. The
34 general licensee, through this individual, shall ensure the day-to-day compliance with these Rules.
35 The appointment of such an individual does not relieve the general licensee of any of its
36 responsibility in this regard;

1 ~~(11)~~(12) shall register, when required by the agency, any source of radiation subject to a general license in
2 accordance with the rules in this Section. Each address for a location of use represents a separate
3 general license and requires a separate registration action;

4 ~~(12)~~(13) shall register, on an annual basis, all devices containing, based on the activity indicated on the
5 label, at least 10 mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, 1 mCi
6 (37MBq) of cobalt-60, 1 mCi (37 MBq) of ~~americium-241~~ {~~americium-241, 0.1 millicurie (3.7~~
7 ~~MBq) of radium-226,~~ } americium-241, 0.1 mCi (3.7 MBq) of radium-226, or any other
8 transuranic isotope. Each address for a location of use represents a separate general license and
9 requires a separate registration action. Annual registration consists of verifying, correcting, or
10 adding to the information provided in a request for annual registration within 30 days of a request
11 from the agency. The general licensee shall furnish the following information for annual
12 registration:

- 13 (A) the name and mailing address of the general licensee;
- 14 (B) ~~specific~~ information about each device to include the manufacturer or initial transferor,
15 model number, serial number, the radioisotope, and the activity indicated on the label;
- 16 (C) the name, title, and telephone number of the responsible person designated as a
17 representative of the general licensee in accordance with ~~Subparagraph (c)(10)~~
18 Subparagraph (c)(11) of this Rule;
- 19 (D) the address or location at which the device(s) are to be used or stored. For portable
20 devices that are granted a general license by the agency, the address of the primary place
21 of storage;
- 22 (E) certification by the responsible person designated by the general licensee that the
23 information concerning the device(s) has been verified through a physical inventory and a
24 check of label information; and
- 25 (F) certification by the responsible person designated by the general licensee that they are
26 aware of the requirements of the general ~~license.~~ license;

27 ~~(13)~~(14) shall report changes to the mailing address to the agency within 30 days of the effective date of
28 the change;

29 ~~(14)~~(15) shall report changes to the name of the general licensee to the agency within 30 days of the
30 effective date of the change;

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

1 ~~(15)~~ (17) ~~shall~~ not hold devices that are not in use for longer than two years. If devices that have shutters
2 are not in use, the shutter shall be locked in the closed position. Leak testing is not required
3 during the period of storage; however, when devices are returned to service or transferred to
4 another person, the devices must be tested for leakage and shutter operation. Devices kept in
5 standby for future use shall be excluded from the two year time limit if quarterly physical
6 inventories of these devices are performed while in standby.

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

9 (e) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a),
10 .0338, .0342, .0343 and .0345 of this Chapter and to labeling requirements in Section .1600 of this Chapter.

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12 *History Note: Authority G.S. 104E-7; 104E-10(b);*
13 *Eff. February 1, 1980;*
14 *Amended Eff. October 1, 2013; January 1, 2005; January 1, 1994; June 1, 1989.*

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