

1 10A NCAC 15 .0309 is proposed for amendment as follows:

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3 **10A NCAC 15 .0309 GENERAL LICENSES: MEASURING GAUGING: CONTROLLING DEVICES**

4 (a) Any person possessing devices listed in 10 CFR 31.5(a) meeting the requirements of 10 CFR 31.5(b) shall be
5 issued a general license in accordance with Rule .0306(a) of this Section, and shall comply with the provisions of 10
6 CFR 31.5(c) and (d), except that the fees specified in 10 CFR 31.5(c)(13)(ii) shall not apply to persons issued a general
7 license under this Rule.

8 (b) Reports, requests for prior approval to transfer devices authorized under this Rule, and any other correspondence
9 required by 10 CFR 31.5 shall be sent to the agency at the address listed in Rule .0111 of this Chapter.

10 (c) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are
11 hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are
12 available free of charge at [http://www.ecfr.gov/cgi-bin/text-](http://www.ecfr.gov/cgi-bin/text-idx?SID=2beece594411a03e50b2468ae31f89b&pid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl)
13 [idx?SID=2beece594411a03e50b2468ae31f89b&pid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?SID=2beece594411a03e50b2468ae31f89b&pid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl).

14 ~~(a) A general license shall be issued to acquire, receive, possess, use, or transfer in accordance with Paragraphs (b),~~
15 ~~(c), and (d) of this Rule, radioactive material contained in devices designed and manufactured for the purpose of~~
16 ~~detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation leakage, or~~
17 ~~qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere to:~~

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

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

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

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

- 33 (1) ~~assure that all labels, affixed to the device at the time of receipt and bearing a statement that removal~~
34 ~~of the label is prohibited, are maintained thereon and shall comply with all instructions and~~
35 ~~precautions provided by the labels;~~

- 1 ~~(2) — assure that the device is tested for leakage of radioactive material and proper operation of the on-off~~
2 ~~mechanism and indicator, if any, at six-month intervals or at alternative intervals as are specified in~~
3 ~~the label, except as follows:~~
- 4 ~~(A) — Devices containing only krypton need not be tested for leakage of radioactive material; and~~
5 ~~(B) — Devices containing only tritium or not more than 100 microcuries of other beta, gamma, or~~
6 ~~beta and gamma emitting material or 10 microcuries of alpha emitting material and devices~~
7 ~~held in storage in the original shipping container prior to initial installation need not be~~
8 ~~tested for any purpose;~~
- 9 ~~(3) — assure that the tests required by Subparagraph (c)(2) of this Rule and other testing, installation,~~
10 ~~servicing and removal from installation involving the radioactive materials, its shielding or~~
11 ~~containment are performed:~~
- 12 ~~(A) — in accordance with the instructions provided on labels affixed to the device, except that~~
13 ~~tests for leakage or contamination may be performed by the general licensee using leak test~~
14 ~~kits provided and analyzed by a specific licensee who is authorized to provide leak test kit~~
15 ~~services; or~~
- 16 ~~(B) — by a person holding a specific license or registration which authorizes the providing of~~
17 ~~services required by this Rule and which is issued pursuant to Rules .0205 and .0306 of~~
18 ~~this Chapter or equivalent regulations of the U.S. Nuclear Regulatory Commission or an~~
19 ~~agreement state;~~
- 20 ~~(4) — maintain records, showing compliance with the requirements in Subparagraphs (c)(2) and (3) of this~~
21 ~~Rule, including:~~
- 22 ~~(A) — the name of the person(s) performing the test(s) and the date(s) of the test(s);~~
23 ~~(B) — the name of the person(s) performing installation, servicing and removal of any radioactive~~
24 ~~material, shielding or containment;~~
- 25 ~~(C) — the retention of leakage or contamination, on-off mechanism and on-off indicator test~~
26 ~~records shall be retained for three years after the required test is performed or until the~~
27 ~~sealed source is disposed of or transferred; and~~
- 28 ~~(D) — the retention of other records of tests required in Subparagraph (c)(3) of this Rule shall be~~
29 ~~retained for three years from the date of the recorded test or until the device is disposed of~~
30 ~~or transferred.~~
- 31 ~~(5) — upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage~~
32 ~~to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the~~
33 ~~detection of 0.005 microcurie or more removable radioactive material, immediately suspend~~
34 ~~operation of the device until it has been:~~
- 35 ~~(A) — repaired by the manufacturer or other person authorized to repair the device(s) by a specific~~
36 ~~license issued by the agency, the U.S. Nuclear Regulatory Commission, or an agreement~~
37 ~~state; or~~

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

- 1 ~~number of device transferred; the name and mailing address of the transferee; and the name,~~
2 ~~title, and telephone number of the individual identified by the transferee pursuant to~~
3 ~~Subparagraph (c)(11) of this Rule; or~~
- 4 ~~(B) is held in storage by the licensee or an intermediate person in the original shipping~~
5 ~~container at its intended location of use prior to initial use by a general licensee;~~
- 6 ~~(10) comply with the provisions of Sections .0100 and .1600 of this Chapter for reporting radiation~~
7 ~~incidents, theft or loss of licensed material, but is exempt from the other requirements of Section~~
8 ~~.1600 of this Chapter;~~
- 9 ~~(11) appoint an individual responsible for having knowledge of the requirements contained in these Rules~~
10 ~~and the authority for taking the actions required to comply with these Rules. The general licensee,~~
11 ~~through this individual, shall ensure the day to day compliance with these Rules. The appointment~~
12 ~~of such an individual does not relieve the general licensee of any of its responsibility in this regard;~~
- 13 ~~(12) register, when required by the agency, any source of radiation subject to a general license in~~
14 ~~accordance with the rules in this Section. Each address for a location of use represents a separate~~
15 ~~general license and requires a separate registration action;~~
- 16 ~~(13) register, on an annual basis, all devices containing, based on the activity indicated on the label, at~~
17 ~~least 10 mCi (370 MBq) of cesium 137, 0.1 mCi (3.7 MBq) of strontium 90, 1 mCi (37MBq) of~~
18 ~~cobalt 60, 1 mCi (37 MBq) of americium 241, 0.1 mCi (3.7 MBq) of radium 226, or any other~~
19 ~~transuranic isotope. Each address for a location of use represents a separate general license and~~
20 ~~requires a separate registration action. Annual registration consists of verifying, correcting, or~~
21 ~~adding to the information provided in a request for annual registration within 30 days of a request~~
22 ~~from the agency. The general licensee shall furnish the following information for annual~~
23 ~~registration:~~
- 24 ~~(A) the name and mailing address of the general licensee;~~
- 25 ~~(B) information about each device to include the manufacturer or initial transferor, model~~
26 ~~number, serial number, the radioisotope, and the activity indicated on the label;~~
- 27 ~~(C) the name, title, and telephone number of the responsible person designated as a~~
28 ~~representative of the general licensee in accordance with Subparagraph (c)(11) of this Rule;~~
- 29 ~~(D) the address or location at which the device(s) are to be used or stored. For portable devices~~
30 ~~that are granted a general license by the agency, the address of the primary place of storage;~~
- 31 ~~(E) certification by the responsible person designated by the general licensee that the~~
32 ~~information concerning the device(s) has been verified through a physical inventory and a~~
33 ~~check of label information; and~~
- 34 ~~(F) certification by the responsible person designated by the general licensee that they are~~
35 ~~aware of the requirements of the general license;~~
- 36 ~~(14) report changes to the mailing address to the agency within 30 days of the effective date of the~~
37 ~~change;~~

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

3 ~~(16) respond to written requests from the agency to provide information relating to the general license~~
4 ~~within 30 calendar days of the date of the request, or other time specified in the request. If the~~
5 ~~general licensee cannot provide the requested information within the allotted time, it shall, within~~
6 ~~that same time period, request a longer period to supply the information by providing the agency a~~
7 ~~written justification for the request;~~

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

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

16 ~~(e) The general license in Paragraph (a) of this Rule is subject to the provisions of Rules .0107 to .0111, .0303(a),~~
17 ~~.0338, .0342, .0343 and .0345 of this Chapter and to labeling requirements in Section .1600 of this Chapter.~~

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

20 *Eff. February 1, 1980;*

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

22 *Transferred and Recodified from 15A NCAC 11 .0309 Eff. February 1, 2015. 2015;*

23 *Amended Eff. March 1, 2017.*