

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0301

DEADLINE FOR RECEIPT: April 17, 2024

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Line 26: Where is "byproduct material" defined?

Line 36: What does "NRC" mean? If it's an acronym, please spell it out before using. Consider making this change throughout all the rules.

On pg. 2, (20), Line 17-19: Under what circumstances "may" the agency "base the issuance of a specific license on information made pursuant to the requirements of the N.C. Department of Environmental Quality in lieu of Subpart A to 10 CFR 51?" What is the agency's authority to make this exception?

On pg. 2, (20), Line 20: You refer to "Form NRC 374". Where can this form be found? The contents of forms must be contained in rule or law. Are the contents of this form in a rule or law elsewhere?

On pg. 3, (b)(1)(D), Line 28: Change "may" to "shall."

On pg. 4, (b)(2)(G), Lines 13-14: Consider changing "may" to "shall" to be consistent with similar language in (b)(1)(D).

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1 **SECTION .0300 - LICENSING OF RADIOACTIVE MATERIAL**

2
3 10A NCAC 15 .0301 is proposed for readoption with substantive changes as follows:

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5 Codifier's Note: 10 NCAC 03G .2400 was transferred to 15A NCAC 11 .0300 effective January 4, 1990.
6 Recodification pursuant to G.S. 143B-279.3.

7
8 **10A NCAC 15 .0301 ~~PURPOSE AND SCOPE~~ GENERAL RULES APPLICABLE TO THE SPECIFIC**
9 **LICENSING OF BYPRODUCT MATERIAL**

10 ~~(a) This Section provides for the licensing of radioactive material. No person shall receive, possess, use, transfer,~~
11 ~~own, transport, manufacture and produce, or acquire radioactive material except as authorized in a specific or general~~
12 ~~license issued pursuant to, or as otherwise provided in, this Section.~~

13 ~~(b) In addition to the requirements of this Section:~~

14 (1) ~~— All licensees are subject to the requirements of Sections .1000, .1100 and .1600 of this Chapter,~~
15 ~~except as otherwise provided in the rules of this Section;~~

16 (2) ~~— Licensees engaged in industrial radiographic operations are subject to the requirements of Section~~
17 ~~.0500 of this Chapter;~~

18 (3) ~~— Licensees using sealed sources in the healing arts are subject to the requirements of Section .0700~~
19 ~~of this Chapter;~~

20 (4) ~~— Licensees engaged in the operation of radioactive waste disposal facilities are subject to the~~
21 ~~requirements of Section .1200 of this Chapter; and~~

22 (5) ~~— Licensees engaged in well logging operations are subject to the requirements of Section .1300 of~~
23 ~~this Chapter.~~

24 ~~(c) The rules in this Section do not apply to persons licensed pursuant to the rules in Section .1200 of this Chapter~~
25 ~~except as specifically provided otherwise in Section .1200.~~

26 (a) All persons using byproduct material shall comply with the provisions of 10 CFR 30, which are hereby
27 incorporated by reference including subsequent amendments and editions, as follows:

28 (1) 10 CFR 30.1, "Scope;"

29 (2) 10 CFR 30.2, "Resolution of conflict;"

30 (3) 10 CFR [30.3; 30.3(a), (c), and (d), "Activities requiring [license;]" license," except that references
31 to 10 CFR 30.3(b)(1), (b)(2), and (b)(3) shall not apply;

32 (4) 10 CFR 30.4, "Definitions," except that references in the definitions to common defense and security
33 shall not apply. The term "temporary jobsite" shall mean a location where byproduct materials are
34 used and stored other than those location(s) of use authorized on the license;

35 (5) 10 CFR 30.6, "Communications," except that notices and reports required by this Rule shall be made
36 to the agency at the address shown in Rule .0111 of this Chapter in lieu of the NRC;

37 (6) 10 CFR 30.9, "Completeness and accuracy of information;"

- 1 (7) 10 CFR 30.10, “Deliberate misconduct;”
- 2 (8) 10 CFR 30.11, “Specific exemptions;”
- 3 (9) 10 CFR 30.12, “Persons using byproduct material under certain Department of Energy and Nuclear
4 Regulatory Commission contracts;”
- 5 (10) 10 CFR 30.13, “Carriers;”
- 6 (11) 10 CFR 30.14, “Exempt concentration;”
- 7 (12) 10 CFR 30.15, “Certain items containing byproduct material;”
- 8 (13) 10 CFR 30.18, “Exempt quantities;”
- 9 (14) 10 CFR 30.19, “Self-luminous products containing tritium, krypton-85, or promethium-147;”
- 10 (15) 10 CFR 30.20, “Gas and aerosol detectors containing byproduct material;”
- 11 (16) 10 CFR 30.21(a), (b), and (d), “Radioactive drug: Capsules containing carbon-14 urea for “in vivo”
12 diagnostic use for humans;”
- 13 (17) 10 CFR 30.22, “Certain industrial devices;”
- 14 (18) 10 CFR 30.31, “Types of licenses;”
- 15 (19) 10 CFR 30.32(a) – (d) and (f) – (j), “Application for specific licenses,” except that the requirements
16 of Paragraph (b) of this Rule shall be met.
- 17 (20) 10 CFR 30.33, “General requirements for issuance of specific licenses,” except the agency may base
18 the issuance of a specific license on information and evaluations made pursuant to the requirements
19 of the N.C. Department of Environmental Quality in lieu of Subpart A to 10 CFR 51, and the agency
20 shall issue a “Radioactive Materials License” in lieu of Form NRC 374;
- 21 (21) 10 CFR 30.34(a) – (c), (e)(2), (e)(4), (f) – (k), “Terms and conditions of licenses;”
- 22 (22) 10 CFR 30.35, “Financial assurance and recordkeeping for decommissioning,” the initials “DCE”
23 shall mean “detailed cost estimate;”
- 24 (23) 10 CFR 30.36, “Expiration and termination of licenses and decommissioning of sites and separate
25 buildings or outdoor areas;”
- 26 (24) 10 CFR 30.37, “Application for renewal of licenses;”
- 27 (25) 10 CFR 30.38, “Application for amendment of licenses and registration certificates.” Licensees shall
28 submit an application for amendment to the agency to add temporary jobsites to the license as
29 authorized places of use if the duration of use or storage at the temporary jobsite exceeds 180 days
30 in any calendar year;
- 31 (26) 10 CFR 30.39, “Commission action on applications to renew or amend;”
- 32 (27) 10 CFR 30.41(a), (b)(1) – (b)(5), (b)(7), (c), (d), “Transfer of byproduct material;”
- 33 (28) 10 CFR 30.50, “Reporting requirements;”
- 34 (29) 10 CFR 30.51, “Records;”
- 35 (30) 10 CFR 30.52, “Inspections;”
- 36 (31) 10 CFR 30.53, “Tests;”
- 37 (32) 10 CFR 30.61, “Modification and revocation of licenses and registration certificates;”

- 1 (33) 10 CFR 30.62, “Right to cause the withholding or recall of byproduct material;”
2 (34) 10 CFR 30.70, “Schedule A – Exempt concentrations;”
3 (35) 10 CFR 30.71, “Schedule B.” This schedule shall also be known as the “exempt quantity table;”
4 (36) 10 CFR 30.72, “Schedule C – Quantities of radioactive materials requiring consideration of the need
5 for an emergency plan for responding to a release;”
6 (37) Appendix A to Part 30, “Criteria Relating to Use of Financial Tests and Parent Company Guarantees
7 for Providing Reasonable Assurance of Funds for Decommissioning;”
8 (38) Appendix B to Part 30, “Quantities of Licensed Material Requiring Labeling;”
9 (39) Appendix C to Part 30, “Criteria Relating to Use of Financial Tests and Self Guarantees for
10 Providing Reasonable Assurance of Funds for Decommissioning;”
11 (40) Appendix D to Part 30 “Criteria Relating To Use of Financial Tests and Self-Guarantee for
12 Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That
13 Have no Outstanding Rated Bonds;” and
14 (41) Appendix E to Part 30, “Criteria Relating to Use of Financial Tests and Self-Guarantee For
15 Providing Reasonable Assurance of Funds For Decommissioning by Nonprofit Colleges,
16 Universities, and Hospitals.”

17 (b) Applications shall be made on forms provided by the agency. One copy of the application and supporting material
18 shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of
19 this Chapter in lieu of the NRC:

- 20 (1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive
21 materials licenses, shall submit an Application for Radioactive Materials License. The following
22 information shall appear on the application:
23 (A) legal business name and mailing address;
24 (B) physical address(es) where radioactive material shall be used or possessed. The application
25 shall indicate if radioactive materials shall be used at temporary jobsites;
26 (C) the name, telephone number, and e-mail address of the Radiation Safety Officer;
27 (D) the name, telephone number, and e-mail address of the individual to be contacted about the
28 application. If this individual is same as the Radiation Safety Officer, the application may
29 so state;
30 (E) the application shall indicate if the application is for a new license, or for the renewal of an
31 existing license, by marking the corresponding check box;
32 (F) if the application is for the renewal of an existing license, the license number shall be
33 provided on the application;
34 (G) applicants shall indicate the type and category of license as shown on the form by marking
35 the corresponding check box; and

1 (H) the printed name, title, and signature of the certifying official. The certifying official shall
 2 be an individual employed by the business or licensee, who is authorized by the licensee
 3 to sign license applications on behalf of the business or licensee.

4 (2) Persons applying for an amendment to an existing license shall submit an Application for
 5 Amendment of Radioactive Materials and Accelerator Licenses. The following information shall
 6 appear on the application:

7 (A) the license number;

8 (B) amendment number of the current license;

9 (C) expiration date of the license;

10 (D) licensee name as it currently appears on the license;

11 (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;

12 (F) the name, telephone number, and e-mail address of the individual to be contacted about the
 13 application. If this individual is same as the Radiation Safety Officer, item 5b on the
 14 application may be left blank;

15 (G) applicants shall provide a description of the action requested by marking the corresponding
 16 checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief
 17 description of the action requested in the space provided in item 6b;

18 (H) explanation of the action requested; and

19 (I) the printed name, title, and signature of the certifying official. The certifying official shall
 20 be an individual employed by the business or licensee who is authorized by the licensee to
 21 sign license applications on behalf of the business or licensee.

22 (3) Applications specified in this Rule are available at:
 23 [https://radiation.ncdhhs.gov/rms/rmsforms2.htm\(Rev01\).htm](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).

24 (c) Copies of the regulations incorporated by this Rule are available free of charge at [https://www.nrc.gov/reading-](https://www.nrc.gov/reading-rm/doc-collections/cfr/part030/)
 25 [rm/doc-collections/cfr/part030/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part030/).

26
 27 History Note: *Authority G.S. 104E-7; 104E-9(8); 104E-10(b);*

28 *Eff. February 1, 1980;*

29 *Amended Eff. October 1, 2013; August 1, 1998; January 1, 1994; May 1, 1992; June 1, 1989; July*
 30 *1, 1982;*

31 *Transferred and Recodified from 15A NCAC 11 .0301 Eff. February 1, 2015. 2015;*

32 *Readopted Eff. May 1, 2024.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0302

DEADLINE FOR RECEIPT: April 17, 2024

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Lines 12-13: Add a comma after "items" and after "32."

On pg. 2, Line 2: What does "NRC" mean? If it's an acronym, please spell it out before using.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1 10A NCAC 15 .0302 is proposed for readoption with substantive changes as follows:

2
3 **10A NCAC 15 .0302 EXEMPTIONS FOR SOURCE MATERIAL GENERAL DOMESTIC LICENSES**
4 **FOR BYPRODUCT MATERIAL**

5 ~~(a) Any person possessing source material, or devices containing source material, in quantities not exceeding the~~
6 ~~limits of 10 CFR 40.13(a) through (e)(8) shall be exempt from the requirement for a radioactive materials license and~~
7 ~~shall comply with the provisions of 10 CFR 40.13.~~

8 ~~(b) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are~~
9 ~~hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are~~
10 ~~available _____ free _____ of _____ charge _____ at _____~~ http://www.ecfr.gov/cgi-bin/text-idx?SID=2beeece594411a03e50b2468ae31f89b&pid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.
11

12 (a) Persons possessing generally licensed items manufactured or initially transferred pursuant to Subpart B of 10 CFR
13 32 shall comply with the provisions of 10 CFR 31, which are hereby incorporated by reference including subsequent
14 amendments and editions, as follows:

15 (1) Reports, notifications, and responses to agency requests for information required by this Rule shall
16 be made to the agency at the address shown in Rule .0111 of this Chapter unless directed otherwise
17 by the agency;

18 (2) 10 CFR 31.1, "Purpose and scope;"

19 (3) 10 CFR 31.2, "Terms and conditions;"

20 (4) 10 CFR 31.5, "Certain detecting, measuring, gauging, or controlling devices and certain devices for
21 producing light or an ionized atmosphere," except that the fee required by 10 CFR 170.31 shall not
22 apply. Persons using devices described in 31.5(a) shall be registered with the agency. Device
23 registration shall be made in accordance with Paragraph (b) of this Rule and shall contain the
24 information required by 31.5(c)(13)(iii);

25 (5) 10 CFR 31.6, "General license to install devices generally licensed in 10 CFR 31.5;"

26 (6) 10 CFR 31.7, "Luminous safety devices in aircraft;"

27 (7) 10 CFR 31.8, "Americium-241 and radium-226 in the form of calibration or reference sources;"

28 (8) 10 CFR 31.9, "General license to own byproduct material;"

29 (9) 10 CFR 31.10, "General license for strontium 90 in ice detection devices;"

30 (10) 10 CFR 31.11, "General license for use of byproduct material for certain in vitro clinical or
31 laboratory testing," except that persons required by 31.11(b) to register devices with the agency
32 shall comply with the provisions of Paragraph (b) of this Rule;

33 (11) 10 CFR 31.12, "General license for certain items and self-luminous products containing radium-
34 226;" and

35 (12) 10 CFR 31.21, "Maintenance of records;"

36 (b) Persons registering devices shall use General License Application for Registration forms provided by the agency.
37 These forms are available free of charge at: <https://radiation.ncdhhs.gov/rms/rmsgenicforms.htm>. Applications and

1 supporting material shall be submitted to the agency by e-mail at Licensing.ram@dhhs.nc.gov, or at the address shown
2 in Rule .0111 of this Chapter in lieu of the NRC. The following information shall appear on the application:

3 (1) facility name, mailing address, physical address if different from the mailing address, and the name
4 of the county where the facility is located;

5 (2) type of device;

6 (3) device manufacturer;

7 (4) device model numbers and serial numbers;

8 (5) number of devices being registered, isotopes, and activity;

9 (6) indicate if the devices have been leak tested by checking the corresponding check box;

10 (7) if the devices have been leak tested, write down the frequency that leak tests are required;

11 (8) the name of the person or company performing the leak test;

12 (9) describe the method of device disposal; and

13 (10) the signature, printed name, title, date the form is signed and telephone number of the contact person.

14 (c) Copies of the regulations incorporated by this Rule are available free of charge at [https://www.nrc.gov/reading-](https://www.nrc.gov/reading-rm/doc-collections/cfr/part031/)
15 [rm/doc-collections/cfr/part031/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part031/).

16
17 *History Note: Authority G.S. 104E-7; 104E-10(b);*

18 *Eff. February 1, 1980;*

19 *Amended Eff. June 1, 1989; October 1, 1984; October 1, 1980;*

20 *Transferred and Recodified from 15A NCAC 11 .0302 Eff. February 1, 2015;*

21 *Amended Eff. March 1, ~~2017~~ 2017;*

22 *Adopted Eff. May 1, 2024.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0304

DEADLINE FOR RECEIPT: April 17, 2024

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Lines 13-14: How does the regulated public determine if their items or devices contain "exempt quantities or exempt concentrations of byproduct material?" Consider inserting the appropriate source(s), i.e. 10 CFR 30.70.

Lines 22-23: How does the regulated public determine if their items or devices contain "exempt quantities of byproduct material?" Consider inserting the appropriate source(s), i.e. 10 CFR 30.70.

Line 28: What does "NRC" mean? If it's an acronym, please spell it out before using.

Line 33: Add parenthesis before and after "(a)".

On pg. 3, (g)(1)(D), Line 6: Change "may" to "shall."

On pg. 3, (g)(2)(F), Line 27: Consider changing "may" to "shall" to be consistent with similar language in (g)(1)(D).

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1 10A NCAC 15 .0304 is proposed for readoption with substantive changes as follows:

2
3 **10A NCAC 15 .0304** ~~**EXEMPT QUANTITIES: OTHER THAN SOURCE MATERIAL SPECIFIC**~~
4 ~~**LICENSES: MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING**~~
5 ~~**BYPRODUCT MATERIAL**~~

6 ~~(a) Any person possessing radioactive material in individual quantities specified in 10 CFR 30.18(a) or (b) shall be~~
7 ~~exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR~~
8 ~~30.18(c) through (e).~~

9 ~~(b) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are~~
10 ~~hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are~~
11 ~~available _____ free _____ of _____ charge _____ at _____~~ http://www.ecfr.gov/cgi-bin/text-idx?SID=2beceec594411a03e50b2468ae31f89b&pid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl
12

13 (a) All persons manufacturing or initially transferring items or devices containing exempt quantities or exempt
14 concentrations of byproduct material, generally licensed and specifically licensed items or devices containing
15 byproduct material, items or devices containing byproduct material for medical use in humans, and persons requesting
16 safety evaluations of sealed sources or devices for registration with the national Sealed Source and Device Registry
17 shall comply with the following requirements of 10 CFR 32:

18 (1) 10 CFR 32.1(a), (b), and (c)(2), "Purpose and scope;"

19 (2) 10 CFR 32.2, "Definitions," the term "initially transfer" shall mean the "initial commercial transfer
20 of items and devices to an end user or a commercial or retail reseller;"

21 (3) 10 CFR 32.3, "Maintenance of records."

22 (b) All Persons manufacturing or initially transferring items or devices containing exempt quantities of byproduct
23 material shall comply with the following requirements of Subpart A – Exempt Concentrations and Items:

24 (1) 10 CFR 32.13, "Same: Prohibition of introduction;"

25 (2) 10 CFR 32.24, "Same: Table of organ doses;" and

26 (3) applications to manufacture, process, produce, prepare, package, re-package, or initially transfer
27 items or devices for commercial distribution containing exempt concentrations or exempt quantities
28 of byproduct material shall be made to the NRC in lieu of the agency.

29 (c) All persons manufacturing or initially transferring generally licensed devices containing byproduct material shall
30 comply with Paragraph (g) of this Rule and the following requirements of Subpart B – Generally Licensed Items:

31 (1) 10 CFR 32.51, "Byproduct material contained in devices for use under 10 CFR 31.5; requirements
32 for license to manufacture, or initially transfer;"

33 (2) 10 CFR 32.51a, "Same: Conditions of licenses;"

34 (3) 10 CFR 32.52, "Same: Material transfer reports and records;"

35 (4) 10 CFR 32.53, "Luminous safety devices for use in aircraft: Requirements for license to
36 manufacture, assemble, repair or initially transfer;"

37 (5) 10 CFR 32.54, "Same: Labeling of devices;"

1 (6) 10 CFR 32.55, “Same: Quality assurance; prohibition of transfer;”

2 (7) 10 CFR 32.56, “Same: Material transfer reports;”

3 (8) 10 CFR 32.57, “Calibration or reference sources containing americium-241 or radium-226:
4 Requirements for license to manufacture or initially transfer;”

5 (9) 10 CFR 32.58, “Same: Labeling of devices;”

6 (10) 10 CFR 32.59, “Same: Leak testing of each source;”

7 (11) 10 CFR 32.61, “Ice detection devices containing strontium-90; requirements for license to
8 manufacture or initially transfer;”

9 (12) 10 CFR 32.62, “Same: Quality assurance; prohibition of transfer;” and

10 (13) 10 CFR 32.71, “Manufacture and distribution of byproduct material in certain in vitro clinical or
11 laboratory testing under general license.”

12 (d) All persons manufacturing or initially transferring items or devices containing byproduct material for medical use
13 in humans shall comply with Paragraph (g) of this Rule and the following requirements of Subpart C – Specifically
14 Licensed Items:

15 (1) 10 CFR 32.72, “Manufacture, preparation, or transfer for commercial distribution of radioactive
16 drugs containing byproduct material for medical use under part 35;” and

17 (2) 10 CFR 32.74, “Manufacture and distribution of sources or devices containing byproduct material
18 for medical use.”

19 (e) All persons manufacturing sealed sources containing byproduct material in quantities equal to or greater than the
20 quantities listed in Appendix E of 10 CFR 20 shall comply with Paragraph (g) of this Rule and the requirements of 10
21 CFR 32.201.

22 (f) All persons manufacturing or initially transferring sealed sources or devices containing byproduct material under
23 this Rule for commercial distribution and persons requesting safety evaluations of sealed sources or devices for
24 registration with the national Sealed Source and Device Registry shall comply with the following requirements of
25 Subpart D – Sealed Source and Device Registration:

26 (1) 10 CFR 32.210, “Registration of product information;”

27 (2) 10 CFR 32.211, “Inactivation of certificates of registration of sealed sources and devices;” and

28 (3) requests for safety evaluations and registration of product information under this Paragraph and
29 inactivation of certificates of registration of sealed sources and devices issued by the agency shall
30 be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in
31 Rule .0111 of this Chapter in lieu of the NRC.

32 (g) Applications shall be made on forms provided by the agency. One copy of the application and supporting material
33 shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of
34 this Chapter in lieu of the NRC:

35 (1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive
36 materials licenses, shall submit an Application for Radioactive Materials License. The following
37 information shall appear on the application:

- 1 (A) legal business name and mailing address;
 2 (B) physical address(es) where radioactive material shall be used or possessed. The application
 3 shall indicate if radioactive materials shall be used at temporary jobsites;
 4 (C) the name, telephone number, and e-mail address of the Radiation Safety Officer;
 5 (D) the name, telephone number, and e-mail address of the individual to be contacted about the
 6 application. If this individual is same as the Radiation Safety Officer, the application may
 7 so state;
 8 (E) the application shall indicate if the application is for a new license, or for the renewal of an
 9 existing license, by marking the corresponding check box;
 10 (F) if the application is for the renewal of an existing license, the license number shall be
 11 provided on the application;
 12 (G) applicants shall indicate the type and category of license as shown on the form by marking
 13 the corresponding check box; and
 14 (H) the printed name, title, and signature of the certifying official. The certifying official shall
 15 be an individual employed by the business or licensee, who is authorized by the licensee
 16 to sign license applications on behalf of the business or licensee.

17 (2) Persons applying for an amendment to an existing license shall submit an Application for
 18 Amendment of Radioactive Materials and Accelerator Licenses. The following information shall
 19 appear on the application:

- 20 (A) the license number;
 21 (B) amendment number of the current license;
 22 (C) expiration date of the license;
 23 (D) licensee name as it currently appears on the license;
 24 (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;
 25 (F) the name, telephone number, and e-mail address of the individual to be contacted about the
 26 application. If this individual is same as the Radiation Safety Officer, item 5b on the
 27 application may be left blank;
 28 (G) applicants shall provide a description of the action requested by marking the corresponding
 29 checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief
 30 description of the action requested in the space provided in item 6b;
 31 (H) explanation of the action requested; and
 32 (I) the printed name, title, and signature of the certifying official. The certifying official shall
 33 be an individual employed by the business or licensee who is authorized by the licensee to
 34 sign license applications on behalf of the business or licensee.

35 (3) Applications specified in this Rule are available at:
 36 [https://radiation.ncdhhs.gov/rms/rmsforms2.htm\(Rev01\).htm](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).

1 (h) The regulations cited in this Rule from 10 CFR Part 32 are hereby incorporated by reference, including subsequent
2 amendments and editions. Copies of these regulations are available free of charge at <https://www.nrc.gov/reading->
3 [rm/doc-collections/cfr/part032/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part032/).

4
5 *History Note: Authority G.S. 104E-7; 104E-10(b); 104E-20; 10 CFR 30.71;*
6 *Eff. February 1, 1980;*
7 *Amended Eff. October 1, 2013; May 1, 1993;*
8 *Transferred and Recodified from 15A NCAC 11 .0304 Eff. February 1, 2015;*
9 *Amended Eff. March 1, ~~2017~~ 2017.*
10 *Readopted Eff. May 1, 2024.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0305

DEADLINE FOR RECEIPT: April 17, 2024

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The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

Line 21: What is meant by “engaging in activities?” Can you provide specific examples? Where is “radioactive material” defined?

Line 35: What does “NRC” mean? If it’s an acronym, please spell it out before using.

On pg. 2, Line 6: What is the purpose of the “+” in front of “Radiation?” Please delete it if it’s a typo.

On pg. 2, (b)(1)(D), Line 8: Change “may” to “shall.”

On pg. 3, (b)(2)(F), Line 30: Consider changing “may” to “shall” to be consistent with similar language in (b)(1)(D).

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1 10A NCAC 15 .0305 is proposed for readoption with substantive changes as follows:

2
3 **10A NCAC 15 .0305** **EXEMPT ITEM CONTAINING OTHER THAN SOURCE MATERIAL SPECIFIC**
4 **DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL**

5 ~~(a) Any person possessing items containing radioactive material listed in 10 CFR 30.15(a)(1) through (9) shall be~~
6 ~~exempt from the requirements for a radioactive materials license and shall comply with the provisions of 10 CFR~~
7 ~~30.15.~~

8 ~~(b) Any person possessing self luminous products listed in 10 CFR 30.19(a) shall be exempt from the requirements~~
9 ~~for a radioactive materials license and shall comply with the provisions of 10 CFR 30.19.~~

10 ~~(c) Any person possessing gas and aerosol detectors listed in 10 CFR 30.20(a) shall be exempt from the requirements~~
11 ~~for a radioactive materials license and shall comply with the provisions of 10 CFR 30.20.~~

12 ~~(d) Any person possessing radioactive drugs containing carbon 14 urea for diagnostic use in humans listed in 10 CFR~~
13 ~~30.21(a) shall be exempt from the requirements for a radioactive materials license and shall comply with the provisions~~
14 ~~of 10 CFR 30.21.~~

15 ~~(e) Any person possessing industrial devices listed in 10 CFR 30.22(a) shall be exempt from the requirements for a~~
16 ~~radioactive materials license and shall comply with the provisions of 10 CFR 30.22.~~

17 ~~(f) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are~~
18 ~~hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are~~
19 ~~available~~ ~~free~~ ~~of~~ ~~charge~~ ~~at~~ ~~http://www.ecfr.gov/cgi-bin/text~~
20 ~~idx?SID=2beeece594411a03e50b2468ae31f89b&pid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.~~

21 (a) Persons engaging in activities involving the use of more than one type of radioactive material and who have
22 established administrative controls and provisions relating to organization and management, procedures, record
23 keeping, material control and accounting, and management review that are necessary to assure safe operations in
24 compliance with the Rules of this Chapter shall comply with the provisions of 10 CFR 33, which are hereby
25 incorporated by reference including subsequent amendments and editions, as follows:

26 (1) 10 CFR 33.1, "Purpose and scope;"

27 (2) 10 CFR 33.11(a), "Types of specific licenses of broad scope;"

28 (3) 10 CFR 33.12, "Applications for specific licenses of broad scope," except that the requirements of
29 Paragraph (b) of this Rule shall be met;

30 (4) 10 CFR 33.13, "Requirements for the issuance of a Type A specific license of broad scope;"

31 (5) 10 CFR 33.16, "Application for other specific licenses;" and

32 (6) 10 CFR 33.17(a), (b), "Conditions of specific licenses of broad scope."

33 (b) Applications shall be made on forms provided by the agency. One copy of the application and supporting material
34 shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of
35 this Chapter in lieu of the NRC:

36 (1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive
37 materials licenses, shall submit an Application for Radioactive Materials License. The instructions

1 for completing the application printed on the application form shall be followed. The following
2 information shall appear on the application:

3 (A) legal business name and mailing address;

4 (B) physical address(es) where radioactive material shall be used or possessed. The application
5 shall indicate if radioactive materials shall be used at temporary jobsites;

6 (C) the name, telephone number, and e-mail address of the +Radiation Safety Officer;

7 (D) the name, telephone number, and e-mail address of the individual to be contacted about the
8 application. If this individual is same as the Radiation Safety Officer, the application may
9 so state;

10 (E) the application shall indicate if the application is for a new license, or for the renewal of an
11 existing license, by marking the corresponding check box;

12 (F) if the application is for the renewal of an existing license, the license number shall be
13 provided on the application;

14 (G) applicants shall indicate the type and category of license as shown on the form by marking
15 the corresponding check box; and

16 (H) the printed name, title, and signature of the certifying official. The certifying official shall
17 be an individual employed by the business or licensee, who is authorized by the licensee
18 to sign license applications on behalf of the business or licensee.

19 (2) Persons applying for an amendment to an existing license shall submit an Application for
20 Amendment of Radioactive Materials and Accelerator Licenses. The instructions for completing the
21 application printed on the application form shall be followed. The following information shall
22 appear on the application:

23 (A) the license number;

24 (B) amendment number of the current license;

25 (C) expiration date of the license;

26 (D) licensee name as it currently appears on the license;

27 (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;

28 (F) the name, telephone number, and e-mail address of the individual to be contacted about the
29 application. If this individual is same as the Radiation Safety Officer, item 5b on the
30 application may be left blank;

31 (G) applicants shall provide a description of the action requested by marking the corresponding
32 checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief
33 description of the action requested in the space provided in item 6b;

34 (H) explanation of the action requested; and

35 (I) the printed name, title, and signature of the certifying official. The certifying official shall
36 be an individual employed by the business or licensee who is authorized by the licensee to
37 sign license applications on behalf of the business or licensee.

1 (3) Applications specified in this Rule are available at:

2 [https://radiation.ncdhhs.gov/rms/rmsforms2.htm\(Rev01\).htm](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).

3 (c) Copies of the regulations incorporated by this Rule are available free of charge at [https://www.nrc.gov/reading-](https://www.nrc.gov/reading-rm/doc-collections/cfr/part033/)

4 [rm/doc-collections/cfr/part033/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part033/).

5
6 *History Note: Authority G.S. 104E-7; 104E-10(b); 104E-20;*

7 *Eff. February 1, 1980;*

8 *Amended Eff. October 1, 2013; April 1, 1999; June 1, 1993; October 1, 1982; September 1, 1981;*

9 *Transferred and Recodified from 15A NCAC 11 .0305 Eff. February 1, 2015;*

10 *Amended Eff. March 1, ~~2017~~ 2017;*

11 *Readopted Eff. May 1, 2024.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0307

DEADLINE FOR RECEIPT: April 17, 2024

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

On pg. 2, (c), Lines 22-23: What is the process for a clinical procedures manual to be “approved in writing by an authorized user?” Who is considered an “authorized user?”

On pg. 4, (11), Lines 23-24: How does someone become an “Authorized Medical Physicist?”

On pg. 7, (D), Line 5: Change “may” to “shall.”

On pg. 7, (F), Line 26: Consider changing “may” to “shall” to be consistent with similar language in (D).

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1 10A NCAC 15 .0307 is proposed for readoption with substantive changes as follows:

2
3 **10A NCAC 15 .0307 GENERAL LICENSES: SOURCE MATERIAL MEDICAL USE OF BYPRODUCT**
4 **MATERIAL IN HUMANS**

5 ~~(a) Any person possessing source material in quantities equal to or less than the quantities shown in 10 CFR 40.22(a)~~
6 ~~shall be issued a general license in accordance with Rule .0306(a) of this Section, and shall comply with the provisions~~
7 ~~of 10 CFR 40.22(b) through (e).~~

8 ~~(b) Any person possessing depleted uranium for the purpose authorized in 10 CFR 40.25(a) shall be issued a general~~
9 ~~license in accordance with Rule .0306(a) of this Section, and shall comply with the provisions of 10 CFR 40.25(b)~~
10 ~~through (e).~~

11 ~~(c) Reports required by 10 CFR 40.22(b)(4) or 40.25(e) shall be sent to the agency at the address shown in Rule .0111~~
12 ~~of this Chapter.~~

13 ~~(d) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are~~
14 ~~hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are~~
15 ~~available _____ free _____ of _____ charge _____ at _____~~ http://www.ecfr.gov/cgi-bin/text-idx?SID=2becece594411a03e50b2468ae31f89b&pid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.
16

17 (a) All persons using radioactive materials for medical use in humans shall comply with the general information
18 requirements of Subpart A to 10 CFR 35, as follows:

19 (1) 10 CFR 35.1, "Purpose and scope;"

20 (2) 10 CFR 35.2, "Definitions;"

21 (3) 10 CFR 35.5, "Maintenance of records;"

22 (4) 10 CFR 35.6, "Provisions for the protection of human research subjects;"

23 (5) 10 CFR 35.7, "FDA, other Federal, and State requirements;"

24 (6) 10 CFR 35.10, "Implementation;"

25 (7) 10 CFR 35.11, "License required," except that 35.11(c)(1) shall not apply;

26 (8) 10 CFR 35.12, "Application for license, amendment, or renewal," except that the requirements in
27 Paragraph (m) of this Rule shall be met;

28 (9) 10 CFR 35.13, "License amendments," except that 35.13(a)(1) shall not apply;

29 (10) 10 CFR 35.14, "Notifications," except that notifications required by this rule shall be submitted to
30 the agency at the address shown in Rule .0111 of this Chapter unless directed otherwise by the
31 agency;

32 (11) 10 CFR 35.15, "Exemptions regarding Type A specific licenses of broad scope;"

33 (12) 10 CFR 35.18, "License issuance," except 35.18(a)(2) shall not apply; and

34 (13) 10 CFR 35.19, "Specific exemptions."

35 (b) All persons using radioactive materials for medical use in humans shall comply with the general administrative
36 requirements of Subpart B to 10 CFR 35, as follows:

37 (1) 10 CFR 35.24, "Authority and responsibilities for the radiation safety program;"

1 (2) 10 CFR 35.26, "Radiation protection program changes;"

2 (3) 10 CFR 35.27, "Supervision." Persons using instrumentation for the collection of data to be used by
3 a physician shall hold active nuclear medicine technology (N) certification issued by the American
4 Registry of Radiographic Technologists (ARRT) or hold active certification issued by the Nuclear
5 Medicine Technologist Certification Board (NMTCB) within three (3) years of the effective date of
6 this readopted Rule, or shall be in training and under the supervision of an individual holding active
7 ARRT(N) or NMTCB certification or an authorized user;

8 (4) 10 CFR 35.40, "Written Directives;"

9 (5) 10 CFR 35.41, "Procedures for administrations requiring a written directive;"

10 (6) 10 CFR 35.49, "Suppliers for sealed source and devices for medical use;"

11 (7) 10 CFR 35.50, "Training for Radiation Safety Officer and Associate Radiation Safety Officer;"

12 (8) 10 CFR 35.51, "Training for an authorized medical physicist;"

13 (9) 10 CFR 35.55, "Training for an authorized nuclear pharmacist;"

14 (10) 10 CFR 35.57, "Training for experienced Radiation Safety Officer, teletherapy or medical physicist,
15 authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear
16 pharmacist;"

17 (11) 10 CFR 35.59, "Recentness of training;" and

18 (12) licensees administering radioactive materials to patients shall have a physician, a nurse practitioner,
19 or a physicians' assistant available to provide emergency life-saving assistance in the event of a
20 medical emergency. These individuals are not required to be users of radioactive materials.

21 (c) All persons administering radioactive materials to humans not requiring a written directive shall develop,
22 document, maintain, and require the use of, a clinical procedures manual. This manual shall be approved in writing
23 by an authorized user, and shall include, for each nuclear medicine procedure not requiring a written directive
24 performed at the facility:

25 (1) the range of radiopharmaceutical dosages;

26 (2) the method used to determine the dosage;

27 (3) the route of administration;

28 (4) provision of job-specific training and assistance to medical personnel in the administration of
29 radioactive material for purposes including, but not limited to, the evaluation of cardiac ischemia in
30 the emergent setting and localization of seizure foci as an adjunct to epilepsy monitoring; and

31 (5) any other information the licensee determines to be useful for patient care, and to prevent the
32 occurrence of medical events.

33 (d) All persons using radioactive materials for medical use in humans shall comply with the general technical
34 requirements of Subpart C to 10 CFR 35, as follows:

35 (1) 10 CFR 35.60, "Possession, use, and calibration of instruments used to measure the activity of
36 byproduct material;"

37 (2) 10 CFR 35.61, "Calibration of survey instruments;"

1 (3) 10 CFR 35.63, “Determination of dosages of unsealed byproduct material for medical use.” except
2 that the determination of dosages of unsealed photon emitting byproduct material shall be made
3 only by direct measurement of radioactivity. If direct measurement of the dosage is not feasible
4 because of the nature of the radiopharmaceutical, the manufacturer’s recommendations for
5 determining the dosage shall be used;

6 (4) 10 CFR 35.65, “Authorization for calibration, transmission, and reference sources;”

7 (5) 10 CFR 35.67, “Requirements for possession of sealed sources and brachytherapy sources,” except
8 that sealed sources and brachytherapy sources placed in storage may be decayed-in-storage as
9 permitted by Subparagraph (d)(10) of this Paragraph. Brachytherapy sources placed into decay-in-
10 storage shall be exempt from leak testing and the semi-annual inventory requirements of this
11 Subparagraph;

12 (6) 10 CFR 35.69, “Labeling of vials and syringes.” except that syringe shields and dose carriers used
13 to shield or transport syringes labeled in accordance with this Rule shall not be required to be labeled
14 when under the continuous direct control of the individual measuring the dose in accordance with
15 Subparagraph (d)(3) of this Rule and administering the dose to the patient;

16 (7) 10 CFR 35.70, “Surveys of ambient radiation exposure rate;”

17 (8) 10 CFR 35.75, “Release of individuals containing unsealed byproduct material or implants
18 containing byproduct material;”

19 (9) 10 CFR 35.80, “Provision of mobile medical service;” and

20 (10) 10 CFR 35.92, “Decay-in-storage.” except that licensees may hold byproduct material with a half-
21 life of less than or equal to 275 days for decay-in-storage.

22 (e) Persons using unsealed radioactive material for medical use not requiring a written directive shall comply with
23 the requirements of Subpart D to 10 CFR 35, as follows:

24 (1) 10 CFR 35.100, “Use of unsealed byproduct material for uptake, dilution, and excretion studies for
25 which a written directive is not required;”

26 (2) 10 CFR 35.190, “Training for uptake, dilution, and excretion studies;”

27 (3) 10 CFR 35.200, “Use of unsealed byproduct material for imaging and localization studies for which
28 a written directive is not required;”

29 (4) 10 CFR 35.204, “Permissible molybdenum-99, strontium-82, and strontium-85 concentrations;” and

30 (5) 10 CFR 35.290, “Training for imaging and localization studies.”

31 (f) Persons using unsealed radioactive material for medical use requiring a written directive shall comply with the
32 requirements of Subpart E to 10 CFR 35, as follows:

33 (1) 10 CFR 35.300, “Use of unsealed byproduct material for which a written directive is required;”

34 (2) 10 CFR 35.310, “Safety instruction;”

35 (3) 10 CFR 35.315, “Safety precautions;” except that patient's or human research subject's personal
36 items that cannot be effectively decontaminated to a level indistinguishable from the natural

1 background may be released to them upon discharge, provided that the patient or human research
 2 subject is instructed not to share such items with others;

3 (4) 10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is
 4 required;"

5 (5) 10 CFR 35.392, "Training for the oral administration of sodium iodide I-131 requiring a written
 6 directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries);"

7 (6) 10 CFR 35.394, "Training for the oral administration of sodium iodide I-131 requiring a written
 8 directive in quantities greater than 1.22 gigabecquerels (33 millicuries);" and

9 (7) 10 CFR 35.396, "Training for the parenteral administration of unsealed byproduct material requiring
 10 a written directive."

11 (g) Persons using sealed source radioactive material for medical use in manual brachytherapy shall comply with the
 12 requirements of Subpart F to 10 CFR 35, as follows:

13 (1) 10 CFR 35.400, "Use of sources for manual brachytherapy;"

14 (2) 10 CFR 35.404, "Surveys after source implant and removal;"

15 (3) 10 CFR 35.406, "Brachytherapy sources accountability;"

16 (4) 10 CFR 35.410, "Safety instructions;"

17 (5) 10 CFR 35.415, "Safety precautions;"

18 (6) 10 CFR 35.432, "Calibration measurements of brachytherapy sources;"

19 (7) 10 CFR 35.433, "Strontium-90 sources for ophthalmic treatments;"

20 (8) 10 CFR 35.457, "Therapy-related computer systems;"

21 (9) 10 CFR 35.490, "Training for use of manual brachytherapy sources;"

22 (10) 10 CFR 35.491, "Training for ophthalmic use of strontium-90;" and

23 (11) activities listed in Subparagraphs (g)(6) and (g)(7) of this Rule shall be approved by an Authorized
 24 Medical Physicist.

25 (h) Persons using sealed source radioactive material for medical diagnosis shall comply with the requirements of
 26 Subpart G to 10 CFR 35, as follows:

27 (1) 10 CFR 35.500, "Use of sealed sources and medical devices for diagnosis;" and

28 (2) 10 CFR 35.590, "Training for use of sealed sources and medical devices for diagnosis."

29 (i) Persons using sealed source radioactive material for medical use in remote afterloader units, teletherapy units, and
 30 gamma stereotactic radiosurgery units shall comply with the requirements of Subpart H to 10 CFR 35, as follows:

31 (1) 10 CFR 35.600, "Use of a sealed source in a remote afterloading unit, teletherapy unit, or gamma
 32 stereotactic radiosurgery unit;"

33 (2) 10 CFR 35.604, "Surveys of patients and human research subjects treated with a remote afterloader
 34 unit;"

35 (3) 10 CFR 35.605, "Installation, maintenance, and repair;"

36 (4) 10 CFR 35.610, "Safety procedures and instructions for remote afterloader units, teletherapy units,
 37 and gamma stereotactic radiosurgery units;"

- 1 (5) 10 CFR 35.615, "Safety precautions for remote afterloader units, teletherapy units, and gamma
 2 stereotactic radiosurgery units;"
 3 (6) 10 CFR 35.630, "Dosimetry equipment;"
 4 (7) 10 CFR 35.632, "Full calibration measurements on teletherapy units;"
 5 (8) 10 CFR 35.633, "Full calibration measurements on remote afterloader units;"
 6 (9) 10 CFR 35.635, "Full calibration measurements on stereotactic radiosurgery units;"
 7 (10) 10 CFR 35.642, "Periodic spot-checks for teletherapy units;"
 8 (11) 10 CFR 35.643, "Periodic spot-checks for remote afterloader units;"
 9 (12) 10 CFR 35.645, "Periodic spot-checks for on stereotactic radiosurgery units;"
 10 (13) 10 CFR 35.647, "Additional technical requirements for mobile remote afterloader units;"
 11 (14) 10 CFR 35.652, "Radiation surveys;"
 12 (15) 10 CFR 35.655, "Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery
 13 units;"
 14 (16) 10 CFR 35.657, "Therapy-related computer systems;" and
 15 (17) 10 CFR 35.690, "Training for use of remote afterloader units, teletherapy units, and gamma
 16 stereotactic radiosurgery units;"

17 (j) Persons using radioactive material for medical use, or radiation from radioactive material for medical use, that are
 18 not specifically addressed in Paragraphs (e) through (i) of this Rule shall comply with requirements of Subpart K to
 19 10 CFR 35.

20 (k) All persons licensed by the agency for the medical use of radioactive material shall maintain records required by
 21 Subpart L to 10 CFR 35, as follows:

- 22 (1) 10 CFR 35.2024, "Records of authority and responsibilities for radiation protection programs;"
 23 (2) 10 CFR 35.2026, "Records of radiation protection program changes;"
 24 (3) 10 CFR 35.2040, "Records of written directives;"
 25 (4) 10 CFR 35.2041, "Records of procedures for administrations requiring a written directive;"
 26 (5) 10 CFR 35.2060, "Records of calibrations of instruments used to measure the activity of unsealed
 27 byproduct materials;"
 28 (6) 10 CFR 35.2061, "Records of radiation survey instrument calibrations;"
 29 (7) 10 CFR 35.2063, "Records of dosages of unsealed byproduct material for medical use;"
 30 (8) 10 CFR 35.2067, "Records of leak tests of sealed sources and brachytherapy sources;"
 31 (9) 10 CFR 35.2070, "Records of surveys for ambient radiation exposure rate;"
 32 (10) 10 CFR 35.2075, "Records of the release of individuals containing unsealed byproduct material or
 33 implants containing byproduct material;"
 34 (11) 10 CFR 35.2080, "Records of mobile medical services;"
 35 (12) 10 CFR 35.2092, "Records of decay-in-storage;"
 36 (13) 10 CFR [35.2203,] 35.2204, "Records of molybdenum-99, strontium-82, and strontium-85
 37 concentrations;"

- 1 (14) 10 CFR 35.2310, "Records of safety instruction;"
 2 (15) 10 CFR 35.2404, "Records of surveys after source implant and removal;"
 3 (16) 10 CFR 35.2406, "Records of brachytherapy source accountability;"
 4 (17) 10 CFR 35.2432, "Records of calibration measurements of brachytherapy sources;"
 5 (18) 10 CFR 35.2433, "Records of decay of strontium-90 sources for ophthalmic treatments;"
 6 (19) 10 CFR 35.2605, "Records of installation, maintenance, adjustment, and repair of remote afterloader
 7 units, teletherapy units, and gamma stereotactic radiosurgery units;"
 8 (20) 10 CFR 35.2610, "Records of safety procedures;"
 9 (21) 10 CFR 35.2630, "Records of dosimetry equipment used with remote afterloader units, teletherapy
 10 units, and gamma stereotactic radiosurgery units;"
 11 (22) 10 CFR 35.2632, "Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery
 12 full calibrations;"
 13 (23) 10 CFR 35.2642, "Records of periodic spot-checks for teletherapy units;"
 14 (24) 10 CFR 35.2643, "Records of periodic spot-checks for remote afterloader units;"
 15 (25) 10 CFR 35.2645, "Records of periodic spot-checks for gamma stereotactic radiosurgery units;"
 16 (26) 10 CFR 35.2647, "Records of additional technical requirements for mobile remote afterloader
 17 units;"
 18 (27) 10 CFR 35.2652, "Records of surveys of therapeutic treatment units;" and
 19 (28) 10 CFR 35.2655, "Records of full-inspection servicing for teletherapy and gamma stereotactic
 20 radiosurgery units."

21 (l) All persons licensed by the agency for the medical use of radioactive material shall make, or cause to be made, the
 22 reports required by Subpart M to 10 CFR Part 35. Notifications made by telephone shall be made to the agency in lieu
 23 of the NRC Operations Center. Written reports and correspondence required by this Rule shall be submitted to the
 24 agency at the address shown in Rule .0111 of this Chapter unless otherwise directed by the agency, in lieu of the NRC
 25 Regional Office:

- 26 (1) 10 CFR 35.3045, "Report and notification of a medical event;"
 27 (2) 10 CFR 35.3047, "Report and notification of a dose to an embryo/fetus or a nursing child;"
 28 (3) 10 CFR 35.3067, "Report of a leaking source;" and
 29 (4) 10 CFR 35.3204, "Report and notification for an eluate exceeding permissible molybdenum-99,
 30 strontium-82, and strontium-85 concentrations."

31 (m) Applications shall be made on forms provided by the agency. One copy of the application and supporting material
 32 shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of
 33 this Chapter in lieu of the NRC:

- 34 (1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive
 35 materials licenses, shall submit an Application for Radioactive Materials License. The following
 36 information shall appear on the application:
 37 (A) legal business name and mailing address;

- 1 (B) physical address(es) where radioactive material shall be used or possessed. The application
2 shall indicate if radioactive materials shall be used at temporary jobsites;
- 3 (C) the name, telephone number, and e-mail address of the Radiation Safety Officer;
- 4 (D) the name, telephone number, and e-mail address of the individual to be contacted about the
5 application. If this individual is same as the Radiation Safety Officer, the application may
6 so state;
- 7 (E) the application shall indicate if the application is for a new license or for the renewal of an
8 existing license by marking the corresponding check box;
- 9 (F) if the application is for the renewal of an existing license, the license number shall be
10 provided on the application;
- 11 (G) applicants shall indicate the type and category of license as shown on the form by marking
12 the corresponding check box; and
- 13 (H) the printed name, title, and signature of the certifying official. The certifying official shall
14 be an individual employed by the business or licensee, who is authorized by the licensee
15 to sign license applications on behalf of the business or licensee.
- 16 (2) Persons applying for an amendment to an existing license shall submit an Application for
17 Amendment of Radioactive Materials and Accelerator Licenses. The following information shall
18 appear on the application:
- 19 (A) the license number;
- 20 (B) amendment number of the current license;
- 21 (C) expiration date of the license;
- 22 (D) licensee name as it currently appears on the license;
- 23 (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;
- 24 (F) the name, telephone number, and e-mail address of the individual to be contacted about the
25 application. If this individual is same as the Radiation Safety Officer, item 5b on the
26 application may be left blank;
- 27 (G) applicants shall provide a description of the action requested by marking the corresponding
28 checkbox in item 6a. If the check box next to "Other" is marked in item 6a, provide a brief
29 description of the action requested in the space provided in item 6b;
- 30 (H) explanation of the action requested; and
- 31 (I) the printed name, title, and signature of the certifying official. The certifying official shall
32 be an individual employed by the business or licensee who is authorized by the licensee to
33 sign license applications on behalf of the business or licensee.
- 34 (3) Applications specified in this Rule are available free of charge at:
35 [https://radiation.ncdhhs.gov/rms/rmsforms2.htm\(Rev01\).htm](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).

1 (n) The regulations cited in this Rule from 10 CFR 35 are hereby incorporated by reference, including subsequent
2 amendments and editions. Copies of these regulations are available free of charge at <https://www.nrc.gov/reading->
3 [rm/doc-collections/cfr/part035/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part035/).

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

6 *Eff. February 1, 1980;*

7 *Amended Eff. January 1, 1994; May 1, 1992;*

8 *Transferred and Recodified from 15A NCAC 11 .0307 Eff. February 1, 2015;*

9 *Amended Eff. March 1, ~~2017~~ 2017;*

10 *Readopted Eff. May 1, 2024.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0308

DEADLINE FOR RECEIPT: April 17, 2024

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

On pg. 2, Line 6: What does "NRC" mean? If it's an acronym, please spell it out before using.

On pg. 2, (b)(1)(D), Line 18: Change "may" to "shall."

On pg. 3, (b)(2)(F), Line 3: Consider changing "may" to "shall" to be consistent with similar language in (b)(1)(D).

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1 10A NCAC 15 .0308 is proposed for readoption with substantive changes as follows:

2
3 **10A NCAC 15 .0308 ~~GENERAL LICENSES: OTHER THAN SOURCE MATERIAL LICENSES AND~~**
4 **RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS**

5 ~~Any person possessing static elimination devices, or ion generating tubes containing 500 microcuries or less of~~
6 ~~Polonium 210, or ion generating tubes containing 50 millicuries or less of tritium, shall comply with Rule .0305(a) of~~
7 ~~this Section.~~

8 (a) Persons irradiating objects or materials using sealed sources containing radioactive materials shall comply with
9 the provisions of 10 CFR 36, which are hereby incorporated by reference including subsequent amendments and
10 editions, except that the requirements of 10 CFR 170 shall not apply, as follows:

11 (1) 10 CFR 36.1, "Purpose and scope;"

12 (2) 10 CFR 36.2, "Definitions," except that references to common defense and security shall not apply;

13 (3) 10 CFR 36.11, "Application for a specific license," except that the requirements of Paragraph (b) of
14 this Rule shall be met;

15 (4) 10 CFR 36.13, "Specific licenses for irradiators;"

16 (5) 10 CFR 36.15, "Commencement of construction;"

17 (6) 10 CFR 36.17, "Applications for exemptions;"

18 (7) 10 CFR 36.19, "Requests for written statements;"

19 (8) 10 CFR 36.21, "Performance criteria for sealed sources;"

20 (9) 10 CFR 36.23, "Access control;"

21 (10) 10 CFR 36.25, "Shielding;"

22 (11) 10 CFR 36.27, "Fire protection;"

23 (12) 10 CFR 36.29, "Radiation monitors;"

24 (13) 10 CFR 36.31, "Control of source movement;"

25 (14) 10 CFR 36.33, "Irradiator pools;"

26 (15) 10 CFR 36.35, "Source rack protection;"

27 (16) 10 CFR 36.37, "Power failures;"

28 (17) 10 CFR 36.39, "Design requirements;"

29 (18) 10 CFR 36.41, "Construction monitoring and acceptance testing;"

30 (19) 10 CFR 36.51, "Training;"

31 (20) 10 CFR 36.53, "Operating and emergency procedures;"

32 (21) 10 CFR 36.55, "Personnel monitoring;"

33 (22) 10 CFR 36.57, "Radiation surveys;"

34 (23) 10 CFR 36.59, "Detection of leaking sources;"

35 (24) 10 CFR 36.61, "Inspection and maintenance;"

36 (25) 10 CFR 36.63, "Pool water quality;"

37 (26) 10 CFR 36.65, "Attendance during operations;"

1 (27) 10 CFR 36.67, "Entering and leaving the radiation room;"

2 (28) 10 CFR 36.69, "Irradiation of explosive or flammable materials;"

3 (29) 10 CFR 36.81, "Records and retention periods;" and

4 (30) 10 CFR 36.83, "Reports," except that reports required by this Rule shall be made to the agency at
5 the address shown in Rule .0111 of this Chapter unless directed otherwise by the agency, in lieu of
6 the NRC.

7 (b) Applications shall be made on forms provided by the agency. One copy of the application and supporting material
8 shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of
9 this Chapter in lieu of the NRC:

10 (1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive
11 materials licenses, shall submit an Application for Radioactive Materials License. The following
12 information shall appear on the application:

13 (A) legal business name and mailing address;

14 (B) physical address(es) where radioactive material shall be used or possessed. The application
15 shall indicate if radioactive materials shall be used at temporary jobsites;

16 (C) the name, telephone number, and e-mail address of the Radiation Safety Officer;

17 (D) the name, telephone number, and e-mail address of the individual to be contacted about the
18 application. If this individual is same as the Radiation Safety Officer, the application may
19 so state;

20 (E) the application shall indicate if the application is for a new license, or for the renewal of an
21 existing license, by marking the corresponding check box;

22 (F) if the application is for the renewal of an existing license, the license number shall be
23 provided on the application;

24 (G) applicants shall indicate the type and category of license as shown on the form by marking
25 the corresponding check box; and

26 (H) the printed name, title, and signature of the certifying official. The certifying official shall
27 be an individual employed by the business or licensee, who is authorized by the licensee
28 to sign license applications on behalf of the business or licensee.

29 (2) Persons applying for an amendment to an existing license shall submit an Application for
30 Amendment of Radioactive Materials and Accelerator Licenses. The following information shall
31 appear on the application:

32 (A) the license number;

33 (B) amendment number of the current license;

34 (C) expiration date of the license;

35 (D) licensee name as it currently appears on the license;

36 (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;

1 (F) the name, telephone number, and e-mail address of the individual to be contacted about the
 2 application. If this individual is same as the Radiation Safety Officer, item 5b on the
 3 application may be left blank;

4 (G) applicants shall provide a description of the action requested by marking the corresponding
 5 checkbox in item 6a. If the check box next to “Other” is marked in item 6a, provide a brief
 6 description of the action requested in the space provided in item 6b;

7 (H) explanation of the action requested; and

8 (I) the printed name, title, and signature of the certifying official. The certifying official shall
 9 be an individual employed by the business or licensee who is authorized by the licensee to
 10 sign license applications on behalf of the business or licensee.

11 (3) Applications specified in this Rule are available at:
 12 [https://radiation.ncdhhs.gov/rms/rmsforms2.htm\(Rev01\).htm](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).

13 (c) Copies of the regulations incorporated by this Rule are available free of charge at [https://www.nrc.gov/reading-](https://www.nrc.gov/reading-rm/doc-collections/cfr/part036/)
 14 [rm/doc-collections/cfr/part036/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part036/).

15
 16 *History Note: Authority G.S. 104E-7; 104E-10(b);*

17 *Eff. February 1, 1980;*

18 *Amended Eff. January 1, 2005; January 1, 1994;*

19 *Transferred and Recodified from 15A NCAC 11 .0308 Eff. February 1, 2015;*

20 *Amended Eff. March 1, 2017; 2017;*

21 *Readopted Eff. May 1, 2024.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0309

DEADLINE FOR RECEIPT: April 17, 2024

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

On pg. 2, (18), Lines 5-7: Under what circumstances “may” the agency “require information and evaluations made pursuant to the requirements of the N.C. Department of Environmental Quality in lieu of Subpart A to 10 CFR 51?” What is the agency’s authority to make this exception?

On pg. 2, (19), Lines 9-12: Under what circumstances “may” the agency “base the issuance of a specific license on information and evaluations made pursuant to the requirements of the N.C. Department of Environmental Quality in lieu of Subpart A to 10 CFR 51?” What is the agency’s authority to make this exception?

On pg. 3, (b)(1)(D), Line 16: Change “may” to “shall.”

On pg. 3, (b)(2)(F), Line 37: Consider changing “may” to “shall” to be consistent with similar language in (b)(1)(D).

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1 10A NCAC 15 .0309 is proposed for readoption with substantive changes as follows:

2
3 **10A NCAC 15 .0309 ~~GENERAL LICENSES: MEASURING GAUGING: CONTROLLING DEVICES~~**
4 **DOMESTIC LICENSING OF SOURCE MATERIAL**

5 ~~(a) Any person possessing devices listed in 10 CFR 31.5(a) meeting the requirements of 10 CFR 31.5(b) shall be~~
6 ~~issued a general license in accordance with Rule .0306(a) of this Section, and shall comply with the provisions of 10~~
7 ~~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~~
8 ~~license under this Rule.~~

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

11 ~~(c) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are~~
12 ~~hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are~~
13 ~~available _____ free _____ of _____ charge _____ at _____ [http://www.ecfr.gov/cgi-bin/text-](http://www.ecfr.gov/cgi-bin/text-idx?SID=2becece594411a03e50b2468ae31f89b&pid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl)~~
14 ~~idx?SID=2becece594411a03e50b2468ae31f89b&pid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.~~

15 (a) Persons using source material and byproduct material as defined in this Rule shall comply with the provisions of
16 10 CFR 40, which are hereby incorporated by reference including subsequent amendments and editions, except that
17 references to importation and exportation of radioactive material and references to and requirements of 10 CFR
18 70.22(b), (c), (f) – (n), and 10 CFR 110 shall not apply, as follows:

19 (1) 10 CFR 40.1, “Purpose;”

20 (2) 10 CFR 40.2, “Scope;”

21 (3) 10 CFR 40.2a, “Coverage of inactive tailings sites;”

22 (4) 10 CFR 40.3, “Licensing requirements;”

23 (5) 10 CFR 40.4, “Definitions,” except that the definition of “foreign obligations,” “reconciliation,” and
24 references in the definitions to common defense and security shall not apply;

25 (6) 10 CFR 40.5, “Communications,” except that notices and reports shall be made to the agency at the
26 address shown in Rule .0111 of this Chapter unless directed otherwise by the agency or specified
27 otherwise in this Rule, in lieu of the NRC;

28 (7) 10 CFR 40.9, “Completeness and accuracy of information;”

29 (8) 10 CFR 40.10, “Deliberate misconduct;”

30 (9) 10 CFR 40.11, “Persons using source material under certain Department of Energy and Nuclear
31 Regulatory Commission contracts;”

32 (10) 10 CFR 40.12(a), “Carriers;”

33 (11) 10 CFR 40.13, “Unimportant quantities of source material,” except 10 CFR 40.13(c)(5)(iv);

34 (12) 10 CFR 40.14, “Specific Exemptions;”

35 (13) 10 CFR 40.20, “Types of licenses;”

36 (14) 10 CFR 40.21, “General license to receive title to source or byproduct material;”

37 (15) 10 CFR 40.22, “Small quantities of source material;”

- 1 (16) 10 CFR 40.25, “General license for use of certain industrial products or devices;”
- 2 (17) 10 CFR 40.26, “General license for possession and storage of byproduct material as defined in this
- 3 part;”
- 4 (18) 10 CFR 40.31(a), (b), (d), (f) – (i), “Application for specific licenses,” except that the requirements
- 5 of Paragraph (b) of this Rule shall be met, the agency may require information and evaluations made
- 6 pursuant to the requirements of the N.C. Department of Environmental Quality in lieu of Subpart A
- 7 to 10 CFR 51, and reports required by 10 CFR 40.31(g) shall be submitted to the NRC in lieu of the
- 8 agency;
- 9 (19) 10 CFR 40.32, “General requirements for issuance of specific licenses,” except that the agency may
- 10 base the issuance of a specific license on information and evaluations made pursuant to the
- 11 requirements of the N.C. Department of Environmental Quality in lieu of Subpart A to 10 CFR 51,
- 12 and 10 CFR 40.32(d), (g), and references to and requirements for uranium enrichment and uranium
- 13 hexafluoride facilities shall not apply;
- 14 (20) 10 CFR 40.34, “Special requirements for issuance of specific licenses;”
- 15 (21) 10 CFR 40.35, “Conditions of specific licenses issued pursuant to 10 CFR 40.34;”
- 16 (22) 10 CFR 40.36, “Financial assurance and recordkeeping for decommissioning,” the initials “DCE”
- 17 shall mean “detailed cost estimate;”
- 18 (23) 10 CFR 40.41(a) – (c), (e)(2), (e)(4), (f), “Terms and conditions of licenses;”
- 19 (24) 10 CFR 40.42, “Expiration and termination of licenses and decommissioning of sites and separate
- 20 buildings or outdoor areas;”
- 21 (25) 10 CFR 40.43, “Renewal of licenses;”
- 22 (26) 10 CFR 40.44, “Amendment of licenses at request of licensee;”
- 23 (27) 10 CFR 40.45, “Commission action on application to renew or amend;”
- 24 (28) 10 CFR 40.46, “Inalienability of licenses;”
- 25 (29) 10 CFR 40.51(a), (b)(1) – (b)(5), (b)(7), (c), (d), “Transfer of source or byproduct material;”
- 26 (30) 10 CFR 40.54, “Requirements for license to initially transfer source material for use under the ‘small
- 27 quantities of source material’ general license;”
- 28 (31) 10 CFR 40.55, “Conditions of licenses to initially transfer source material for use under the ‘small
- 29 quantities of source material’ general license: Quality control, labeling, safety instructions, and
- 30 records and reports;”
- 31 (32) 10 CFR 40.60, “Reporting requirements;”
- 32 (33) 10 CFR 40.61, “Records;”
- 33 (34) 10 CFR 40.62, “Inspections;”
- 34 (35) 10 CFR 40.63, “Tests;”
- 35 (36) 10 CFR 40.65, “Effluent monitoring reporting requirements;”
- 36 (37) 10 CFR 40.71, “Modification and revocation of licenses,” and

1 (38) Appendix A to Part 40, "Criteria Relating to the Operation of Uranium Mills and the Disposition of
2 Tailings or Wastes Produced by the Extraction or Concentration of Source Material From Ores
3 Processed Primarily for Their Source Material Content," except Criterion 11A - F and 12 shall not
4 apply.

5 (b) Applications shall be made on forms provided by the agency. One copy of the application and supporting material
6 shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of
7 this Chapter in lieu of the NRC:

8 (1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive
9 materials licenses, shall submit an Application for Radioactive Materials License. The following
10 information shall appear on the application:

11 (A) legal business name and mailing address;

12 (B) physical address(es) where radioactive material shall be used or possessed. The application
13 shall indicate if radioactive materials shall be used at temporary jobsites;

14 (C) the name, telephone number, and e-mail address of the Radiation Safety Officer;

15 (D) the name, telephone number, and e-mail address of the individual to be contacted about the
16 application. If this individual is same as the Radiation Safety Officer, the application may
17 so state;

18 (E) the application shall indicate if the application is for a new license, or for the renewal of an
19 existing license, by marking the corresponding check box;

20 (F) if the application is for the renewal of an existing license, the license number shall be
21 provided on the application;

22 (G) applicants shall indicate the type and category of license as shown on the form by marking
23 the corresponding check box; and

24 (H) the printed name, title, and signature of the certifying official. The certifying official shall
25 be an individual employed by the business or licensee, who is authorized by the licensee
26 to sign license applications on behalf of the business or licensee.

27 (2) Persons applying for an amendment to an existing license shall submit an Application for
28 Amendment of Radioactive Materials and Accelerator Licenses. The following information shall
29 appear on the application:

30 (A) the license number;

31 (B) amendment number of the current license;

32 (C) expiration date of the license;

33 (D) licensee name as it currently appears on the license;

34 (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;

35 (F) the name, telephone number, and e-mail address of the individual to be contacted about the
36 application. If this individual is same as the Radiation Safety Officer, item 5b on the
37 application may be left blank;

1 (G) applicants shall provide a description of the action requested by marking the corresponding
2 checkbox in item 6a. If the check box next to “Other” is marked in item 6a, provide a brief
3 description of the action requested in the space provided in item 6b;

4 (H) explanation of the action requested; and

5 (I) the printed name, title, and signature of the certifying official. The certifying official shall
6 be an individual employed by the business or licensee who is authorized by the licensee to
7 sign license applications on behalf of the business or licensee.

8 (3) Applications specified in this Rule are available at:
9 [https://radiation.ncdhhs.gov/rms/rmsforms2.htm\(Rev01\).htm](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).

10 (c) Copies of the regulations incorporated by this Rule are available free of charge at [https://www.nrc.gov/reading-](https://www.nrc.gov/reading-rm/doc-collections/cfr/part040/)
11 [rm/doc-collections/cfr/part040/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part040/).

12
13 *History Note: Authority G.S. 104E-7; 104E-10(b);*

14 *Eff. February 1, 1980;*

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

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

17 *Amended Eff. March 1, ~~2017~~ 2017;*

18 *Readopted Eff. May 1, 2024.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0310

DEADLINE FOR RECEIPT: April 17, 2024

PLEASE NOTE: This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may email the reviewing attorney to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following changes be made:

On pg. 2, (b)(1)(D), Line 28: Change "may" to "shall."

On pg. 3, (b)(2)(F), Line 14: Consider changing "may" to "shall" to be consistent with similar language in (b)(1)(D).

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

1 10A NCAC 15 .0310 is proposed for readoption with substantive changes as follows:

2
3 **10A NCAC 15 .0310** ~~GENERAL LICENSES: MANUFACTURE, TRANSFER, INSTALL GENERALLY~~
4 ~~LICENSED DEVICES~~ DOMESTIC LICENSING OF SPECIAL NUCLEAR
5 MATERIAL

6 ~~(a) Any person possessing a specific license issued by the agency, the U.S. Nuclear Regulatory Commission, or~~
7 ~~another Agreement State authorizing the manufacture, installation, or servicing of a device described in Rule .0309 of~~
8 ~~this Section shall be authorized to install, service, and uninstall these devices in accordance with the provisions of 10~~
9 ~~CFR 31.6.~~

10 ~~(b) 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-idx?SID=2becece594411a03e50b2468ae31f89b&pid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl
13

14 (a) Persons using special nuclear material as defined in this Rule shall comply with the provisions of 10 CFR 70,
15 which are hereby incorporated by reference including subsequent amendments and editions, as follows:

16 (1) 10 CFR 70.1(a) and (b), "Purpose;"

17 (2) 10 CFR 70.2, "Scope;"

18 (3) 10 CFR 70.3, "License requirements;"

19 (4) 10 CFR 70.4, "Definitions," except that references in the definitions to common defense and security
20 shall not apply;

21 (5) 10 CFR 70.5, "Communications," except that notices and reports shall be made to the agency at the
22 address shown in Rule .0111 of this Chapter in lieu of the NRC unless otherwise specified by the
23 agency;

24 (6) 10 CFR 70.9, "Completeness and accuracy of information;"

25 (7) 10 CFR 70.10, "Deliberate misconduct;"

26 (8) 10 CFR 70.11, "Persons using special nuclear material under certain DOE and NRC contracts;"

27 (9) 10 CFR 70.12, "Carriers;"

28 (10) 10 CFR 70.17, "Specific exemption;"

29 (11) 10 CFR 70.18, "Types of licenses;"

30 (12) 10 CFR 70.19, "General license for calibration and reference sources;"

31 (13) 10 CFR 70.20, "General license to own special nuclear material;"

32 (14) 10 CFR 70.21(a)(2), (a)(3), (b), "Filing," except that the requirements of Paragraph (b) of this Rule
33 shall be met;

34 (15) 10 CFR 70.22(a), (d), and (e), "Contents of application;"

35 (16) 10 CFR 70.23(a)(1) – (5), "Requirements for the approval of applications;"

36 (17) 10 CFR 70.25(a)(2), (b) – (h), "Financial assurance and recordkeeping for decommissioning," the
37 initials "DCE" shall mean "detailed cost estimate;"

- 1 (18) 10 CFR 70.31(a) and (b), "Issuance of license;"
 2 (19) 10 CFR 70.32(a)(2), (a)(3), (a)(8), (a)(9), (b)(2), and (b)(5), "Conditions of licenses;"
 3 (20) 10 CFR 70.33, "Applications for renewal of licenses;"
 4 (21) 10 CFR 70.34, "Amendment of licenses;"
 5 (22) 10 CFR 70.35, "Commission action on applications to renew or amend;"
 6 (23) 10 CFR 70.36, "Inalienability of licenses;"
 7 (24) 10 CFR 70.38, "Expiration and termination of licenses and decommissioning of sites and separate
 8 buildings or outdoor structures;"
 9 (25) 10 CFR 70.39, "Specific licenses for the manufacture or initial transfer of calibration sources;"
 10 (26) 10 CFR 70.41, "Authorized use of special nuclear material;"
 11 (27) 10 CFR 70.42(a), (b)(1) – (b)(5), (b)(7), (c), (d), "Transfer of special nuclear material;"
 12 (28) 10 CFR 70.50, "Reporting requirements;"
 13 (29) 10 CFR 70.51, "Records requirements;"
 14 (30) 10 CFR 70.55(a) and (b), "Inspections;"
 15 (31) 10 CFR 70.56, "Tests;" and
 16 (32) 10 CFR 70.81, "Modification and revocation of licenses."

17 (b) Applications shall be made on forms provided by the agency. One copy of the application and supporting material
 18 shall be submitted to the agency by e-mail at Licensing.RAM@dhhs.nc.gov, or at the address shown in Rule .0111 of
 19 this Chapter in lieu of the NRC:

- 20 (1) Persons applying for new radioactive materials licenses, or for the renewal of existing radioactive
 21 materials licenses, shall submit an Application for Radioactive Materials License. The following
 22 information shall appear on the application:
 23 (A) legal business name and mailing address;
 24 (B) physical address(es) where radioactive material shall be used or possessed. The application
 25 shall indicate if radioactive materials shall be used at temporary jobsites;
 26 (C) the name, telephone number, and e-mail address of the Radiation Safety Officer;
 27 (D) the name, telephone number, and e-mail address of the individual to be contacted about the
 28 application. If this individual is same as the Radiation Safety Officer, the application may
 29 so state;
 30 (E) the application shall indicate if the application is for a new license, or for the renewal of an
 31 existing license, by marking the corresponding check box;
 32 (F) if the application is for the renewal of an existing license, the license number shall be
 33 provided on the application;
 34 (G) applicants shall indicate the type and category of license as shown on the form by marking
 35 the corresponding check box; and

1 (H) the printed name, title, and signature of the certifying official. The certifying official shall
 2 be an individual employed by the business or licensee, who is authorized by the licensee
 3 to sign license applications on behalf of the business or licensee.

4 (2) Persons applying for an amendment to an existing license shall submit an Application for
 5 Amendment of Radioactive Materials and Accelerator Licenses. The following information shall
 6 appear on the application:

7 (A) the license number;

8 (B) amendment number of the current license;

9 (C) expiration date of the license;

10 (D) licensee name as it currently appears on the license;

11 (E) the name, telephone number, and e-mail address of the Radiation Safety Officer;

12 (F) the name, telephone number, and e-mail address of the individual to be contacted about the
 13 application. If this individual is same as the Radiation Safety Officer, item 5b on the
 14 application may be left blank;

15 (G) applicants shall provide a description of the action requested by marking the corresponding
 16 checkbox in item 6a. If the check box next to “Other” is marked in item 6a, provide a brief
 17 description of the action requested in the space provided in item 6b;

18 (H) explanation of the action requested; and

19 (I) the printed name, title, and signature of the certifying official. The certifying official shall
 20 be an individual employed by the business or licensee who is authorized by the licensee to
 21 sign license applications on behalf of the business or licensee.

22 (3) Applications specified in this Rule are available at:
 23 [https://radiation.ncdhhs.gov/rms/rmsforms2.htm\(Rev01\).htm](https://radiation.ncdhhs.gov/rms/rmsforms2.htm(Rev01).htm).

24 (c) Copies of the regulations incorporated by this Rule are available free of charge at [https://www.nrc.gov/reading-](https://www.nrc.gov/reading-rm/doc-collections/cfr/part070/)
 25 [rm/doc-collections/cfr/part070/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part070/).

26
 27 History Note: *Authority G.S. 104E-7; 104E-10(b);*

28 *Eff. February 1, 1980;*

29 *Amended Eff. January 1, 2005;*

30 *Transferred and Recodified from 15A NCAC 11 .0310 Eff. February 1, 2015;*

31 *Amended Eff. March 1, ~~2017~~, 2017;*

32 *Readopted Eff. May 1, 2024.*