

REQUEST FOR TECHNICAL CHANGE

AGENCY: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .0359

DEADLINE FOR RECEIPT: Friday, February 10, 2017

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 call this office to inquire concerning the staff recommendation.

In reviewing these rules, the staff determined that the following technical changes need to be made:

,DOLERXOGLWUHDGG LUHFWDPHDXUHPHWR IUDGLRDFWLYLWWRPLUURUWWRKSRUGRHRXU
UHJXODWHGSEOLFQGHUWDQLWDZLWWHQ

,WHLWRUWRWHGRRXGHWRUHWDLQGHHRXDUHGHOHWLQBDUDJUDEFRUGR
RXDWRUHWDLQWGXHWKODQDJHLQKSLWK5XOH"

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

Amanda J. Reeder
Commission Counsel
Date submitted to agency: January 30, 2017

1 10A NCAC 15 .0359 is amended as published in 31:07 NCR, pp. 549-582, as follows:

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3 **10A NCAC 15 .0359 MEASUREMENTS/DOSAGES OF UNSEALED RADIOACTIVE MATERIAL**
 4 **FOR MEDICAL USE**

5 (a) Licensees shall comply with the provisions of 10 CFR 35.63, except that dosage determination shall be made by
 6 direct measurement for all unsealed photon-emitting radioactive drugs prior to administration to any person. Licensees
 7 shall ensure that instruments used to measure dosages under this Rule are calibrated in accordance with the provisions
 8 of 10 CFR 35.60.

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-](http://www.ecfr.gov/cgi-bin/text-idx?SID=2beece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl)
 12 [idx?SID=2beece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?SID=2beece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl).

13 ~~(a) A licensee shall possess and use a dose calibrator to measure the radioactivity of dosages of photon-emitting~~
 14 ~~radionuclides prior to administration to each individual. A licensee shall:~~

15 ~~(1) — develop, maintain, and implement written procedures for use of the dose calibrator;~~

16 ~~(2) — calibrate each dose calibrator in accordance with the requirements of 10 CFR 35.60(b).~~

17 ~~(b) A licensee shall retain a record of each check, test, and calibration performed in accordance with this Rule for a~~
 18 ~~period of three years following the test.~~

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

21 *Eff. April 1, 1999;*

22 *Amended Eff. November 1, 2007;*

23 *Transferred and Recodified from 15A NCAC 11 .0359 Eff. February 1, 2015; 2015;*

24 *Amended Eff. March 1, 2017.*

1 10A NCAC 15 .0521 is amended as published in 31:07 NCR, pp. 549-582, as follows:

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3 **10A NCAC 15 .0521 PERFORMANCE REQUIREMENTS FOR RADIOGRAPHY EQUIPMENT**

4 (a) Equipment used in industrial radiographic operations shall meet the performance requirements of 10 CFR 34.20.

5 (b) Notwithstanding Rule .0117 of this Chapter, the regulations cited in this Rule from 10 CFR Chapter I (2015) are
6 hereby incorporated by reference, excluding subsequent amendments and editions. Copies of these regulations are
7 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)
8 [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).

9 ~~Equipment used in industrial radiographic operations shall meet the following minimum criteria:~~

10 ~~(1) — Each radiographic exposure device, source assembly or sealed source, and all associated equipment~~
11 ~~shall meet the requirements specified in American National Standard N432-1980 "Radiological~~
12 ~~Safety for the Design and Construction of Apparatus for Gamma Radiography". This publication~~
13 ~~is incorporated by reference in Rule .0117 of this Chapter.~~

14 ~~(2) — Engineering analysis may be submitted to the agency to demonstrate the applicability of previously~~
15 ~~performed testing on similar individual radiography equipment components. Upon review by the~~
16 ~~agency, this may be an acceptable alternative to actual testing of the component pursuant to the~~
17 ~~above referenced standard.~~

18 ~~(3) — In addition to the requirements specified in Item (1) of this Rule, the following requirements apply~~
19 ~~to radiographic exposure devices, source changers, source assemblies, and sealed sources:~~

20 ~~(a) — Each radiographic exposure device shall have attached to it by the user a durable, legible,~~
21 ~~clearly visible label bearing the following:~~

22 ~~(i) — Chemical symbol and mass number of the radionuclide in the device;~~

23 ~~(ii) — Activity and the date on which this activity was last measured;~~

24 ~~(iii) — Model number (or product code) and serial number of the sealed source;~~

25 ~~(iv) — Manufacturer's identity of the sealed source; and~~

26 ~~(v) — Licensee's name, address, and telephone number.~~

27 ~~(b) — Radiographic exposure devices intended for use as Type B transport containers shall meet~~
28 ~~the applicable requirements of 10 CFR Part 71.~~

29 ~~(c) — Modification of radiographic exposure devices, source changers and source assemblies and~~
30 ~~associated equipment is prohibited, unless the design of any replacement component,~~
31 ~~including sealed source holder, source assembly, controls or guide tubes would not~~
32 ~~compromise the design safety features of the system.~~

33 ~~(4) — In addition to the requirements specified in Items (1) and (3) of this Rule, the following requirements~~
34 ~~apply to radiographic exposure devices, source assemblies, and associated equipment that allow the~~
35 ~~sealed source to be moved out of the device for radiographic operations or to source changers.~~

36 ~~(a) — The coupling between the source assembly and the control cable shall be designed in such~~
37 ~~a manner that the source assembly will not become disconnected if cranked outside the~~

- 1 ~~guide tube. The coupling shall be such that it cannot be unintentionally disconnected under~~
2 ~~normal and reasonably foreseeable abnormal conditions.~~
- 3 (b) ~~— The device shall automatically secure the source assembly when it is cranked back into the~~
4 ~~fully shielded position within the device. This securing system shall be designed to only~~
5 ~~allow release of the sealed source by means of a deliberate operation on the exposure~~
6 ~~device.~~
- 7 (c) ~~— The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device~~
8 ~~shall be equipped with safety plugs or covers which shall be installed during storage and~~
9 ~~transportation to protect the source assembly from water, mud, sand or other foreign matter.~~
- 10 (d) ~~— Each sealed source or source assembly shall have attached to it or engraved in it, a durable,~~
11 ~~legible, visible label with the words: "DANGER RADIOACTIVE." The label shall not~~
12 ~~interfere with the safe operation of the exposure device or associated equipment.~~
- 13 (e) ~~— The guide tube must be able to withstand a crushing test that closely approximates the~~
14 ~~crushing forces that are likely to be encountered during use, and be able to withstand a~~
15 ~~kinking resistance test that closely approximates the kinking forces that are likely to be~~
16 ~~encountered during use.~~
- 17 (f) ~~— Guide tubes shall be used when moving the sealed source out of the device.~~
- 18 (g) ~~— An exposure head or similar device designed to prevent the source assembly from passing~~
19 ~~out of the end of the guide tube shall be attached to the outermost end of the guide tube~~
20 ~~during radiographic operations.~~
- 21 (h) ~~— The guide tube exposure head connection shall be able to withstand the tensile test for~~
22 ~~control units specified in ANSIN432.~~
- 23 (i) ~~— Source changers shall provide a system for assuring that the sealed source will not be~~
24 ~~accidentally withdrawn from the changer when connecting or disconnecting the drive cable~~
25 ~~to or from a source assembly.~~
- 26 (5) ~~— All associated equipment acquired after January 10, 1996 shall be labeled to identify that the~~
27 ~~components have met the requirements of this Rule.~~

29 *History Note: Filed as a Temporary Adoption Eff. August 20, 1994, for a period of 180 days or until the permanent*
30 *rule becomes effective, whichever is sooner;*

31 *Authority G.S. 104E-7;*

32 *Filed as a Temporary Adoption Eff. August 20, 1994, for a period of 180 days or until the permanent*
33 *rule becomes effective, whichever is sooner;*

34 *Eff. May 1, 1995;*

35 *Amended Eff. April 1, 1999;*

36 *Transferred and Recodified from 15A NCAC 11 .0521 Eff. February 1, 2015; 2015;*

37 *Amended Eff. March 1, 2017.*

1 10A NCAC 15 .1004 is amended as published in 31:07 NCR, pp. 549-582, as follows:

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3 **10A NCAC 15 .1004 NOTIFICATIONS AND REPORTS TO INDIVIDUALS**

4 (a) Licensees and registrants shall report radiation exposure data for any occupationally exposed person to that person
5 or their designee in accordance with the provisions of 10 CFR 19.13, except that the report shall contain the following
6 statement in lieu of the statement appearing in 19.13(a): "This report is furnished to you under the provisions of 10A
7 NCAC 15 Section .1000: NOTICES: INSTRUCTIONS: REPORTS AND INSPECTIONS. You should preserve this
8 report for future reference."

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-](http://www.ecfr.gov/cgi-bin/text-idx?SID=2beece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl)
12 idx?SID=2beece594411a03e50b2468ae31f89b&pitd=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl.

13 ~~(a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of~~
14 ~~radioactive material deposited or retained in the body of any individual shall be reported to the individual as specified~~
15 ~~in this Rule. The information reported shall include data and results obtained pursuant to rules of this Chapter, orders,~~
16 ~~or license conditions, as shown in records maintained by the licensee or registrant pursuant to provisions of this~~
17 ~~Chapter. Each notification and report shall:~~

18 (1) ~~be in writing;~~

19 (2) ~~include identifying data such as the name of the licensee or registrant, the name of the individual,~~
20 ~~and the individual's social security number;~~

21 (3) ~~include the individual's exposure information; and~~

22 (4) ~~contain the following statement: This report is furnished to you under the provisions of Section 15A~~
23 ~~NCAC 11 .1000: NOTICES: INSTRUCTIONS: REPORTS AND INSPECTIONS. You should~~
24 ~~preserve this report for further reference.~~

25 ~~(b) Each licensee or registrant shall make dose information available to workers as shown in records maintained by~~
26 ~~the licensee or registrant under the provisions of Rule .1640 of this Chapter. The licensee or registrant shall provide~~
27 ~~an annual report to each individual monitored under Rule .1614 of this Chapter of the dose received in that monitoring~~
28 ~~year if:~~

29 (1) ~~the individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any~~
30 ~~individual organ or tissue; or~~

31 (2) ~~the individual requests his or her annual dose report.~~

32 ~~(c) At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or~~
33 ~~registrant shall furnish to the worker a report of the worker's radiation dosage and exposure to radioactive materials.~~
34 ~~The report shall:~~

35 (1) ~~be furnished within 30 days from the time any request is made, or within 30 days after the~~
36 ~~information has been obtained by the licensee or registrant, whichever is later;~~

- 1 ~~(2) — cover, within the period of time specified in the request, each calendar quarter in which the worker's~~
2 ~~activities involved exposure to radiation from radioactive material licensed by, or radiation~~
3 ~~machines registered with the agency; and~~
4 ~~(3) — include the dates and locations of work under the license or registration in which the worker~~
5 ~~participated during this period.~~

6 ~~(d) When a licensee or registrant is required pursuant to Rules .1646, .1647, or .1648 of this Chapter to report to the~~
7 ~~agency any overexposure of an individual to radiation or radioactive material, the licensee or the registrant shall also~~
8 ~~provide the individual a report on his or her exposure data included in the report to the agency. The reports shall be~~
9 ~~transmitted at a time no later than the transmittal to the agency.~~

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11 *History Note:* *Authority G.S. 104E-7; 104E-10(b); 104E-12;*
12 *Eff. February 1, 1980;*
13 *Amended Eff. October 1, 2013; January 1, 1994;*
14 *Transferred and Recodified from 15A NCAC 11 .1004 Eff. February 1, ~~2015~~ 2015;*
15 *Amended Eff. March 1, 2017.*

1 10A NCAC 15 .1613 is amended as published in 31:07 NCR, pp. 549-582, as follows:

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3 **10A NCAC 15 .1613 SURVEYS**

4 (a) Licensees and registrants shall conduct surveys, and monitor for radiation and radiation exposure in accordance
5 with the provisions of 10 CFR 20.1501.

6 (b) The exposure of individual monitoring devices, individual monitoring equipment, or personnel monitoring
7 equipment to radiation from any source for the purpose of falsifying exposure records shall be prohibited.

8 (c) 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-](http://www.ecfr.gov/cgi-bin/text-idx?SID=2beece594411a03e50b2468ae31f89b&pid=20160101&tpl=/ecfrbrowse/Title10/10tab_02.tpl)
11 [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).

12 ~~(a) Each licensee or registrant shall make or cause to be made, surveys that:~~

13 ~~(1) — may be necessary for the licensee or registrant to comply with the rules in this Section; and~~

14 ~~(2) — are reasonable under the circumstances to evaluate:~~

15 ~~(A) — the magnitude and extent of radiation levels;~~

16 ~~(B) — concentrations or quantities of radioactive material; and~~

17 ~~(C) — the potential radiological hazards that could be present.~~

18 ~~(b) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation~~
19 ~~measurements (e.g., dose rate and effluent monitoring) are calibrated at the frequency committed to in accordance~~
20 ~~with the requirements of Rules .0207 or .0317 of this Chapter for the radiation measured.~~

21 ~~(c) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters~~
22 ~~used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used~~
23 ~~by licensees or registrants to comply with Rule .1604 of this Section, with other applicable provisions of this Chapter,~~
24 ~~or with conditions specified in a license shall be processed and evaluated by a dosimetry processor:~~

25 ~~(1) — Holding current personnel dosimetry accreditation from the National Voluntary Laboratory~~
26 ~~Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and~~

27 ~~(2) — Approved in this accreditation process for the type of radiation or radiations included in the NVLAP~~
28 ~~program that most closely approximates the type of radiation or radiations for which the individual~~
29 ~~wearing the dosimeter is monitored.~~

30 ~~(d) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.~~

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32 *History Note: Authority G.S. 104E-7(a)(2);*

33 *Eff. January 1, 1994;*

34 *Amended Eff. August 1, 2002;*

35 *Transferred and Recodified from 15A NCAC 11 .1613 Eff. February 1, 2015; 2015;*

36 *Amended Eff. March 1, 2017.*

- 1 (i) ~~participation by representatives of a broad cross section of community interests~~
- 2 ~~who may be affected by the decommissioning;~~
- 3 (ii) ~~an opportunity for a comprehensive, collective discussion of the issues by the~~
- 4 ~~participants represented; and~~
- 5 (iii) ~~a publicly available summary of the results of such discussions, including a~~
- 6 ~~description of the extent of agreement and disagreement among the participants~~
- 7 ~~on the issues.~~

8 (2) ~~The use of alternate criteria to terminate a license requires the consideration of any comments~~

9 ~~provided by any other interested state agencies and any public comments submitted pursuant to~~

10 ~~Paragraph (e) of this Rule.~~

11 (e) ~~Upon the receipt of a license termination plan or decommissioning plan from the licensee, or a proposal by the~~

12 ~~licensee for release of a site pursuant to Paragraphs (e) and (d) of this Rule, or whenever the agency deems such notice~~

13 ~~to be in the public interest, the agency shall notify and solicit comments from:~~

14 (1) ~~local governments in the vicinity of the site, appropriate state agencies, the U.S. Environmental~~

15 ~~Protection Agency, and any Indian Nation or other indigenous people that have treaty or statutory~~

16 ~~rights that could be affected by the decommissioning; and~~

17 (2) ~~publish a notice in a forum, such as local newspapers, letters to state or local organizations or other~~

18 ~~appropriate forum that is readily accessible to individuals in the vicinity of the site, and solicit~~

19 ~~comments from affected parties.~~

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21 *History Note: Authority G.S. 104E-7(a)(2); 104E-10(b);*

22 *Eff. April 1, 1999;*

23 *Transferred and Recodified from 15A NCAC 11 .1653 Eff. February 1, 2015; 2015;*

24 *Amended Eff. March 1, 2017.*