Subject: FW: Submission of Permanent Rule RRC Changes - 10A NCAC 15

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>

Sent: Friday, September 8, 2023 6:02 PM

To: Liebman, Brian R <bri> Liebman@oah.nc.gov>

Cc: Albright, James <james.albright@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: Submission of Permanent Rule RRC Changes - 10A NCAC 15

Thank you, Brian!

Nadine Pfeiffer

Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811 Fax: 919-733-2757

nadine.pfeiffer@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building 2701 Mail Service Center Raleigh, NC 27699-2701

From: Liebman, Brian R <bri> Sprian.liebman@oah.nc.gov>

Sent: Friday, September 8, 2023 10:59 AM

To: Pfeiffer, Nadine < nadine.pfeiffer@dhhs.nc.gov >

Cc: Albright, James <james.albright@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: Submission of Permanent Rule RRC Changes - 10A NCAC 15

Hi Nadine, James,

Thanks for making the edits on these. I will recommend approval of both rules. Unless I hear an objection, I'll send them over to Alex and Dana for filing as the final rules.

Thanks, and have a great weekend! Brian

Brian Liebman Counsel to the North Carolina Rules Review Commission Office of Administrative Hearings (984)236-1948

brian.liebman@oah.nc.gov

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From: Pfeiffer, Nadine < nadine.pfeiffer@dhhs.nc.gov>

Sent: Friday, September 1, 2023 11:21 AM

Subject: Submission of Permanent Rule RRC Changes - 10A NCAC 15

Brian,

We were notified of the technical changes on August 23, 2023 pursuant to G.S. 150B-21.10 for the Radiation Protection Commission Rules 10A NCAC 15 .0101 and .1601. In preparation for the September 21, 2023 RRC meeting, attached to this email you will find the amended text for those rules as requested in the Request for Changes document received. The Agency's responses to the concerns raised in the "Request for Changes" document may be seen in bold black font on the attached document.

Should you have any questions regarding the attachments, or should you have any follow up questions or concerns, please feel free to contact me.

Thank you,

Nadine Pfeiffer

Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811 Fax: 919-733-2757

nadine.pfeiffer@dhhs.nc.gov

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Subject: FW: Submission of Permanent Rule RRC Changes - 10A NCAC 15

From: Liebman, Brian R <bri> Sprian.liebman@oah.nc.gov>

Sent: Friday, September 8, 2023 10:59 AM

To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>

Cc: Albright, James <james.albright@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: Submission of Permanent Rule RRC Changes - 10A NCAC 15

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Brian Liebman
Counsel to the North Carolina Rules Review Commission
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(984)236-1948
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Subject: FW: Submission of Permanent Rule RRC Changes - 10A NCAC 15

Attachments: 10A NCAC 15 .1001.docx; 10A NCAC 15 .1601.docx; RRC Requests for Changes 15 RP

Responses.docx

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>

Sent: Friday, September 1, 2023 11:21 AM

To: Liebman, Brian R < brian.liebman@oah.nc.gov <a href="mailto:Cc: Albright, James james.albright@dhhs.nc.gov

Subject: Submission of Permanent Rule RRC Changes - 10A NCAC 15

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We were notified of the technical changes on August 23, 2023 pursuant to G.S. 150B-21.10 for the Radiation Protection Commission Rules 10A NCAC 15 .0101 and .1601. In preparation for the September 21, 2023 RRC meeting, attached to this email you will find the amended text for those rules as requested in the Request for Changes document received. The Agency's responses to the concerns raised in the "Request for Changes" document may be seen in bold black font on the attached document.

Should you have any questions regarding the attachments, or should you have any follow up questions or concerns, please feel free to contact me.

Thank you,

Nadine Pfeiffer

Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811 Fax: 919-733-2757

nadine.pfeiffer@dhhs.nc.gov

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Email correspondence to and from this address may be subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized state official.

1 2	10A NCAC 15 .1	001 is amended with changes as published in 37:19 NCR 1923-1927 as follows:
3	SE	CTION .1000 - NOTICES: INSTRUCTIONS: REPORTS AND INSPECTIONS
4		
5	Codifier's Note:	10 NCAC 03G .3100 was transferred to 15A NCAC 11 .1000 effective January 4, 1990.
6	Recodification p	arsuant to G.S. 143B-279.3.
7		
8	10A NCAC 15.	1001 SCOPE NOTICES, INSTRUCTIONS, AND REPORTS TO EMPLOYEES
9	This Section esta	blishes requirements for notices, instructions and reports by licensees or registrants to individuals
10	engaged in work	under a license or registration and options available to such individuals in connection with agency
11	inspections of lie	rensees or registrants to ascertain compliance with the provisions of the Act and rules, orders and
12	licenses issued the	nereunder regarding radiological working conditions. The rules in this Section apply to all persons
13	who receive, pos	sess, use, own or transfer sources of radiation licensed by or registered with the agency pursuant to
14	the rules in Secti	ons .0200, .0300, .0900 and .1200 of this Chapter.
15	(a) Persons regi	stered with the agency pursuant to the rules in Section .0200 of this Chapter and persons licensed
16	under the rules in	Sections .0300, .0900, .1200, and .1300 of this Chapter shall comply with the provisions of 10 CFR
17	19 as follows, wh	ich are hereby incorporated by reference including subsequent amendments and editions, except that
18	references to and	requirements for 10 CFR 2, 50, 52, 54, 60, 63, 72, and 76 shall not apply:
19	(1)	10 CFR 19.1, "Purpose;"
20	(2)	10 CFR 19.2, "Scope;"
21	(3)	10 CFR 19.3, "Definitions," except that the definition of "regulated activities" and "regulated
22		entities" shall not apply. For persons registered with the agency pursuant to the rules in Section
23		.0200 of this Chapter, the following terms used in [19.3] 10 CFR 19 shall have the following
24		<u>substitutions:</u>
25		(A) "license" shall have the same meaning as "registration" as defined in Rule .0104(131) of
26		this Chapter;
27		(B) "licensed" means registered pursuant to the rules in Section .0200 of this Chapter;
28		(C) "licensee" shall have the same meaning as "registrant" as defined in Rule .0104(130) of
29		this Chapter:
30		[(E)](D) "materials" shall have the same meaning as "radiation machine" as defined in Rule
31		<u>.0104(122) of this Chapter:</u>
32		[F] (E) "NRC-licensed" means registered pursuant to the rules in Section .0200 of this Chapter;
33		<u>and</u>
34		[(D)](F) "radioactive material" shall have the same meaning as "radiation machine" as defined
35		in Rule .0104(122) of this Chapter;

1	<u>(4)</u>	10 CFR 19.5, "Communications," except that licensees and registrants shall address
2		communications and reports to the agency [at the address shown in] as instructed by Rule .0111 of
3		this Chapter in lieu of the NRC;
4	(5)	10 CFR 19.11, "Posting of notices to workers," except that 19.11(b) and (e) shall not apply;
5		(A) NRC Form 3 shall not be used in lieu of the Notice to Employees issued by the agency,
6		except as authorized by the agency in writing;
7		(B) licensees and registrants shall not post other notices, postings, notes, or other materials
8		over the [notice to employees,] Notice to Employees, nor shall equipment be placed in such
9		a manner that the [notice to employees] Notice to Employees is obscured or hidden by that
10		equipment; and
11		(C) additional copies of the Notice to Employees may be obtained free of charge from the
12		agency by contacting the agency at the [address] addresses shown in Rule [.0111].
13		of this Chapter in lieu of the NRC, or online at https://radiation.ncdhhs.gov/;
14	(6)	10 CFR 19.12, "Instructions to workers;"
15	<u>(7)</u>	10 CFR 19.13, "Notifications and reports to individuals;"
16	<u>(8)</u>	10 CFR 19.14, "Presence of representatives of licensees and regulated entities, and workers during
17		[inspections;"] inspections," except that 19.14(a) shall not apply:
18	<u>(9)</u>	10 CFR 19.15, "Consultation with workers during inspections;"
19	(10)	10 CFR 19.16, "Requests by workers for inspections." Requests for inspections shall be [submitted]
20		mailed or delivered to the agency [at the address shown in] as instructed by Rule [.0111] .0111(a)
21		of this Chapter in lieu of the NRC;
22	(11)	10 CFR 19.17, "Inspections not warranted; informal review." Communications regarding the
23		agency's decisions with respect to a request for inspection submitted to the agency under
24		Subparagraph (a)(10) shall be [submitted] mailed or delivered to the agency [at the address shown
25		in as instructed by Rule [-0111] .0111(a) of this Chapter in lieu of the NRC;
26	(12)	10 CFR 19.18, "Sequestration of witnesses and exclusion of counsel in interviews conducted under
27		subpoena;"
28	(13)	10 CFR 19.20, "Employee protection;"
29	(14)	10 CFR 19.31, "Application for exemptions," except that the request for exemption shall be made
30		on the licensee's or registrant's business letterhead. Requests for exemptions from the requirements
31		of this Rule shall be made to the agency at the [address] addresses shown in Rule [.0111] .0111(a)
32		of this Chapter in lieu of the NRC or as otherwise instructed by the agency. To request an exemption,
33		the following information shall be submitted to the agency:
34		(A) licensee or registrant name;
35		(B) license or registration number;
36		(C) name of the individual requesting the exemption;
37		(D) contact information for the individual requesting the exemption;

1	(E) a description of the exemption being requested; and
2	(F) an explanation describing why the exemption is necessary.
3	(b) Notwithstanding Subparagraph (a)(5) of this Rule, registrants temporarily working in North Carolina and license
4	working in North Carolina under reciprocity may post the Notice to Employees, NRC Form 3, or an equivalent for
5	issued under the authority of the regulatory agency issuing the registration or license.
6	(c) Copies of these regulations are available free of charge at https://www.nrc.gov/reading-rm/do
7	collections/cfr/part019/.
8	
9	History Note: Authority G.S. 104E-7; 104E-12;
10	Eff. February 1, 1980;
11	Amended Eff. May 1, 1993; June 1, 1989;
12	Transferred and Recodified from 15A NCAC 11 .1001 Eff. February 1, 2015;
13	Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. June 2
14	2019. <u>2019;</u>
15	Amended Eff. October 1, 2023.

1	10A NCAC 15 .1601 is readopted with changes as published in 37:19 NCR 1923-1927 as follows:
2	
3	SECTION .1600 - STANDARDS FOR PROTECTION AGAINST RADIATION
4	
5	10A NCAC 15 .1601 PURPOSE AND SCOPE STANDARDS FOR PROTECTION AGAINST
6	<u>RADIATION</u>
7	(a) The rules in this Section establish standards for protection against ionizing radiation resulting from activities
8	conducted under licenses and registrations issued by the agency pursuant to the rules in this Chapter.
9	(b) It is the purpose of the rules in this Section to control the receipt, possession, use, transfer, and disposal of sources
10	of radiation by any licensee or registrant in such a manner that the total dose to an individual, including doses resulting
11	from all sources of radiation other than background radiation, does not exceed the standards for protection against
12	$radiation\ prescribed\ in\ the\ rules\ in\ this\ Section.\ However, nothing\ in\ this\ Section\ shall\ be\ construed\ as\ limiting\ actions$
13	that may be necessary to protect health and safety.
14	(c) The rules in this Section apply to persons licensed or registered by the agency to receive, possess, use, transfer, or
15	dispose of radioactive material or other sources of radiation. The limits in this Section do not apply to doses due to
16	background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to voluntary
17	participation in medical research programs, or to exposure from individuals administered radioactive material and
18	released in accordance with Rule .0358 of this Chapter.
19	(d) Nothing in this Section shall relieve a licensee engaged in operation of a radioactive waste disposal facility, as
20	defined in Rule .0104 of this Chapter, from responsibility for complying with the requirements in Section .1200 of
21	this Chapter.
22	(e) Effective January 1, 1994 all licensees and registrants shall comply with the rules in this Section and cease to
23	comply with the requirements in Section .0400 of this Chapter, except as provided otherwise in Rule .1602 of this
24	Section.
25	(a) Persons registered with the agency pursuant to the rules in Section .0200 of this Chapter and persons licensed
26	pursuant to the rules in Section .0300, .0900, .1200, or .1300 of this Chapter shall comply with the provisions of 10
27	CFR 20 as follows, which are hereby incorporated by reference including subsequent amendments and editions, except
28	references to and requirements for 10 CFR 50, 52, 60, 63, 72, 73, and 76 shall not apply:
29	(1) 20.1001, "Purpose," except that non-ionizing radiation from radiation machines registered in
30	accordance with the rules in Section .0200 of this Chapter shall also be regulated by this Rule;
31	(2) 20.1002, "Scope;"
32	(3) 20.1003, "Definitions," except that for persons registered with the agency pursuant to the rules in
33	Section .0200 of this Chapter, the following terms used in [20.1003] 10 CFR 20 shall have the
34	following substitutions:
35	(A) "license" shall have the same meaning as "registration" as defined in Rule .0104(131) of
36	this Chapter;
37	(B) "licensed" means registered pursuant to the rules in Section .0200 of this Chapter;

l		(C) "licensed material" shall have the same meaning as "radiation machine" as defined in Rule
2		.0104(122) of this Chapter, and
3		(D) "licensee" shall have the same meaning as "registrant" as defined in Rule .0104(130) of
4		this Chapter:
5	<u>(4)</u>	20.1004, "Units of radiation dose;"
6	<u>(5)</u>	20.1005, "Units of radioactivity;"
7	<u>(6)</u>	20.1007, "Communications," except that licensees and registrants shall address communications
8		regarding these rules, notifications, and reports to the agency [at the address shown in] as instructed
9		by Rule .0111 of this Chapter in lieu of the NRC;
10	<u>(7)</u>	20.1101, "Radiation protection programs;"
11	(8)	20.1201, "Occupational dose limits for adults;"
12	<u>(9)</u>	20.1202, "Compliance with requirements for summation of external and internal doses;"
13	(10)	20.1203, "Determination of external dose from airborne radioactive material;"
14	<u>(11)</u>	20.1204, "Determination of internal exposure;"
15	(12)	20.1206, "Planned special exposures;"
16	(13)	20.1207, "Occupational dose limits for minors;"
17	<u>(14)</u>	20.1208, "Dose equivalent to an embryo/fetus;"
18	(15)	20.1301, "Dose limits for individual members of the public;"
19	(16)	20.1302, "Compliance with dose limits for individual members of the public;"
20	<u>(17)</u>	20.1401, "General provisions and scope;"
21	<u>(18)</u>	20.1402, "Radiological criteria for unrestricted use;"
22	(19)	20.1403, "Criteria for license termination under restricted conditions;"
23	(20)	20.1404, "Alternate criteria for license termination;"
24	(21)	20.1405, "Public notification and public participation," except the agency shall not publish a notice
25		in the Federal Register;
26	(22)	20.1406, "Minimization of [contamination;"] contamination," except that 20.1406(b) shall not
27		apply;
28	(23)	20.1501, "General;"
29	(24)	20.1502, "Conditions requiring individual monitoring of external and internal occupational dose;"
30	(25)	20.1601, "Control of access to high radiation areas;"
31	(26)	20.1602, "Control of access to very high radiation areas;"
32	(27)	20.1701, "Use of process or other engineering controls;"
33	(28)	20.1702, "Use of other controls;"
34	(29)	20.1703, "Use of individual respiratory protection equipment;"
35	(30)	20.1704, "Further restrictions on the use of respiratory equipment;"
36	(31)	20.1705, "Application for use of higher assigned protection factors;"
37	(32)	20 1801 "Security of stored material."

1	(33)	20.1802, "Control of material not in storage;"
2	(34)	20.1901, "Caution signs;"
3	(35)	20.1902, "Posting requirements;"
4	(36)	20.1903, "Exceptions to posting requirements;"
5	(37)	20.1904, "Labeling containers;"
6	(38)	20.1905, "Exemptions to labeling [requirements;"] requirements," except that 20.1905(g) shall not
7		apply:
8	(39)	20.1906, "Procedures for receiving and opening packages;"
9	(40)	20.2001, "General requirements;"
10	<u>(41)</u>	20.2002, "Method for obtaining approval of proposed disposal procedures;"
11	(42)	20.2003, "Disposal by release to sanitary sewerage;"
12	(43)	20.2004, "Treatment or disposal by incineration;"
13	(44)	20.2005, "Disposal of specific wastes;"
14	(45)	20.2006, "Transfer for disposal and manifests;"
15	(46)	20.2007, "Compliance with environmental and health protection regulations;"
16	(47)	20.2008, "Disposal of certain byproduct material;"
17	(48)	20.2101, "General provisions;"
18	(49)	20.2102, "Records of radiation protection programs;"
19	(50)	20.2103, "Records of surveys;"
20	(51)	20.2104, "Determination of prior occupational dose;"
21	(52)	20.2105, "Records of planned special exposures;"
22	<u>(53)</u>	20.2106, "Records of individual monitoring results;"
23	<u>(54)</u>	20.2107, "Records of dose to individual members of the public;"
24	<u>(55)</u>	20.2108, "Records of waste disposal;"
25	<u>(56)</u>	20.2110, "Form of records;"
26	<u>(57)</u>	20.2201, "Reports of theft or loss of material." Persons registered with the agency pursuant to the
27		rules in Section .0200 of this Chapter shall make telephone reports of the theft or loss of radiation
28		machines in accordance with 20.2201(a)(1)(i):
29	<u>(58)</u>	20.2202, "Notifications of incidents;"
30	<u>(59)</u>	20.2203, "Reports of exposures, radiation levels, and concentrations of radioactive material
31		exceeding the constraints or [limits;"] limits," except that 20.2203(c) shall not apply;
32	<u>(60)</u>	20.2204, "Reports of planned special exposures;"
33	<u>(61)</u>	20.2205, "Reports to individuals exceeding dose limits;"
34	(62)	20.2206, "Reports of individual monitoring," except [20.2206(a)(3).] that 20.2206(a)(1), and
35		20.2206(a)(3) through (a)(5) shall not apply. The report required by 20.2206(b) shall be submitted
36		upon request by the agency in lieu of the requirements of 20.2206(c);

1	<u>(63)</u>	20.2207, "Reports of transactions involving nationally tracked sources." Notwithstanding
2		Subparagraph (a)(6) of this Rule, reports required by this Subparagraph shall be made in accordance
3		with 20.2207(f) and (g);
4	<u>(64)</u>	20.2301, "Application for exemptions," except that the request for exemption shall be made on the
5		licensee's or registrant's business letterhead. Requests for exemptions from the requirements of this
6		Rule shall be made to the agency at the [address] addresses shown in Rule [.0111] .0111(a) of this
7		Chapter in lieu of the NRC or as otherwise instructed by the agency. To request an exemption, the
8		following information shall be submitted to the agency:
9		(A) licensee or registrant name;
10		(B) license or registration number;
11		(C) name and contact information for the individual requesting the exemption;
12		(D) a description of the exemption being requested, and
13		(E) an explanation describing why the exemption is necessary;
14	<u>(65)</u>	20.2302, "Additional requirements;"
15	<u>(66)</u>	Appendix A to Part 20, "Assigned Protection Factors for Respirators;"
16	<u>(67)</u>	Appendix B to Part 20, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs)
17		of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release
18		to Sewerage;"
19	(68)	Appendix C to Part 20, "Quantities of Radioactive Material Requiring Labeling;"
20	<u>(69)</u>	Appendix E to Part 20, "Nationally Tracked Source Thresholds," and
21	<u>(70)</u>	Appendix G to Part 20, "Requirements for Transfers of Low-Level Radioactive Waste Intended for
22		Disposal at Licensed Land Disposal Facilities and Manifests."
23	(b) Exposure of	a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.
24	(c) Licensees as	nd registrants shall continue to perform all activities required by the rules of this Chapter, license or
25	registration cond	dition, and shall pay annual fees as instructed on an invoice issued by the agency until the license or
26	registration is te	erminated. Registrants shall maintain registration of all radiation machines under their control until
27	those units are d	lisposed.
28	(d) Nothing in t	he rules of this Chapter shall relieve any person of responsibility for complying with other applicable
29	North Carolina l	laws and rules.
30	(e) Copies	of these regulations are available free of charge at https://www.nrc.gov/reading-rm/doc-
31	collections/cfr/p	vart020/.
32		
33	History Note:	Authority G.S. 104E-7(a)(2);
34		Eff. January 1, 1994;
35		Amended Eff. August 1, 1998;
36		Transferred and Recodified from 15A NCAC 11 .1601 Eff. February 1, 2015. <u>2015:</u>
37		Readopted Eff. October 1, 2023.

Request for Changes Pursuant to N.C. Gen. Stat. § 150B-21.10

Staff reviewed these Rules to ensure that each Rule is within the agency's statutory authority, reasonably necessary, clear and unambiguous, and adopted in accordance with Part 2 of the North Carolina Administrative Procedure Act. Following review, staff has issued this document that may request changes pursuant to G.S. 150B-21.10 from your agency or ask clarifying questions.

If the request includes questions, please contact the reviewing attorney to discuss.

In order to properly submit rewritten rules, please refer to the following Rules in the NC Administrative Code:

- Rule 26 NCAC 02C .0108 The Rule addresses general formatting.
- Rule 26 NCAC 02C .0404 The Rule addresses changing the introductory statement.
- Rule 26 NCAC 02C .0405 The Rule addresses properly formatting changes made after publication in the NC Register.

Note the following general instructions:

- 1. You must submit the revised rule via email to oah.rules@oah.nc.gov. The electronic copy must be saved as the official rule name (XX NCAC XXXX).
- 2. For rules longer than one page, insert a page number.
- 3. Use line numbers; if the rule spans more than one page, have the line numbers reset at one for each page.
- 4. Do not use track changes. Make all changes using manual strikethroughs, underlines and highlighting.
- 5. You cannot change just one part of a word. For example:
 - Wrong: "aAssociation"
 - Right: "association Association"
- 6. Treat punctuation as part of a word. For example:
 - Wrong: "day; and"
 - Right: "day, day; and"
- 7. Formatting instructions and examples may be found at: www.ncoah.com/rules/examples.html

If you have any questions regarding proper formatting of edits after reviewing the rules and examples, please contact the reviewing attorney.

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

AGENCY: North Carolina Radiation Protection Commission

RULE CITATION: 10A NCAC 15.1001

DEADLINE FOR RECEIPT: Wednesday, September 6, 2023.

<u>PLEASE NOTE:</u> 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:

Throughout the Rule, there are many instances where licensees and registrants are directed to address communications and report to the agency "at the address shown in Rule .0111 of this Chapter...." In Rule .0111, there is both a street and a mailing address. Please consider specifying how you want to receive these communications, and/or specifying "addresses" in this Rule.

The agency gave this recommendation considerable thought and revised the Rule language to provide clarity to licensees, registrants, and workers. The agency assumes that licensees and registrants are familiar with how rules are structured and how to comply with the rules and assumes that workers are probably not as familiar. Thus, for licensees and registrants, the agency specified "addresses" as suggested and pointed to .0111(a) in the revised Rule, except in Subparagraph (a)(4), found on line 2 of page 2, where the word "address" is used as a verb on line 1. Also, since telephone reporting of incidents is important, the agency wants to be clear that the instructions in Rule .0111 are to be followed in this Subparagraph.

Subparagraphs (a)(10) and (11) have been revised to make the requirements easier to understand for workers by specifying "mailed or delivered" and 'as instructed by Rule .0111(a).'

In (a)(3), the list is out of order, with (D) out of place. Corrected the list order. Thank you very much.

In (a)(3), items (B), (D), and (E), are used in 10 CFR 19.3 but are not defined there. Thank you for this observation. The intent is to provide substitute definitions for these terms as they are used in 10 CFR 19, not just 10 CFR 19.3, for registrants registered under 10A NCAC 15 Section .0200. Revised the second sentence in Subparagraph (a)(3) for clarification.

In (a)(3), item F, "NRC-licensed", is not used or defined in 10 CFR 19.3.

Revised the second sentence in (a)(3) to clarify that this substitute term applies to 10 CFR 19 for the same reason cited for Parts (B), (D), and (E) of Subparagraph (a)(3) in the comment above this one.

In (a)(5)(A), p.2, line 2, is the "Notice to Employees" a form, as defined in 150B-2(8)? If so, are its contents or substantive requirements described in another Rule or statute? The "notice to employees" explains employer and employee rights and responsibilities while working with radioactive materials and sources of radiation. It includes instructions for employees about how to request inspections and how to address radiation safety concerns to the agency. In "NRC regulated space" the notice to employees is called "NRC Form 3." The agency believes that it is not a "Rule" or a "form" as defined by 150B-2(8a) because it contains nonbinding interpretive statements that explain the rules and appears to fall under the G.S. 150B-2(8a)c. exemption.

In (a)(5)(B), lines 5 and 6, capitalize "notice to employees" to be consistent with (a)(5)(A).

Done. Thank you for your recommendations.

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

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

AGENCY: North Carolina Radiation Protection Commission

RULE CITATION: 10A NCAC 15.1601

DEADLINE FOR RECEIPT: Wednesday, September 6, 2023.

<u>PLEASE NOTE:</u> 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:

Throughout the Rule, there are many instances where licensees and registrants are directed to address communications and report to the agency "at the address shown in Rule .0111 of this Chapter...." In Rule .0111, there is both a street and a mailing address. Please consider specifying how you want to receive these communications, and/or specifying "addresses" in this Rule.

The agency gave this recommendation considerable thought and revised the Rule language to provide clarity to licensees and registrants. Thus, for licensees and registrants, the agency specified "addresses" as suggested and pointed to .0111(a) in the revised Rule, except in Subparagraph (a)(6), found on lines 8 and 9 of page 2, where the word "address" is used as a verb on line 1. Also, since telephone reporting of incidents is important, the agency wants to be clear that the instructions in Rule .0111 are to be followed in this Subparagraph.

In (a)(3), item (B), is used in 10 CFR 20.1003 but is not defined there.

The intent of this Paragraph is to provide substitute definitions for some of the terms used in 10 CFR 20 for registrants registered under 10A NCAC 15 Section .0200. Revised subparagraph (a)(3) accordingly. Thank you for your comments, they make this a better Rule.

In (a)(3), item F, "NRC-licensed", is not used or defined in 10 CFR 19.3.

I think this is a typo, the term "NRC-licensed" does not appear in Subparagraph (a)(3).

In (b), p.4, line 23, the Rule prohibits exposing a monitoring device to deceptively indicate a dose. Is there a penalty associated with this prohibition?

The agency would conduct an escalated enforcement investigation to determine a cause for the deceptive exposure and the responsible party or parties. Any penalty assessed to the licensee is based on that investigation. In all cases, the licensee is required to resolve the cause of the deceptive exposure and to submit written procedures, policy changes, and

documentation of any other actions the licensee takes to prevent a recurrence of the deceptive exposure. The Department may also opt to issue an administrative penalty as authorized by G.S. 104E-24. That said, administrative penalties are usually reserved for cases of willful and repetitive violations, violations or multiple violations that indicate that the health and safety of the public or occupationally exposed workers are genuinely at risk, or if the licensee or registrant fails repeated attempts to collect annual license or registration fees.

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

From: Pfeiffer, Nadine

Sent: Wednesday, August 23, 2023 5:01 PM

To: Liebman, Brian R

Cc: Albright, James; Burgos, Alexander N

Subject: RE: 10A NCAC 15 Requests for Changes - September 2023 RRC

Thank you, Brian.

Nadine Pfeiffer

Rules Review Manager
Division of Health Service Regulation
NC Department of Health and Human Services

Office: 919-855-3811 Fax: 919-733-2757

nadine.pfeiffer@dhhs.nc.gov

809 Ruggles Drive, Edgerton Building 2701 Mail Service Center Raleigh, NC 27699-2701

From: Liebman, Brian R <bri> Sprian.liebman@oah.nc.gov>

Sent: Wednesday, August 23, 2023 4:50 PM

To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>

Cc: Albright, James <james.albright@dhhs.nc.gov>; Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: 10A NCAC 15 Requests for Changes - September 2023 RRC

Good afternoon,

I'm the attorney who reviewed the Rules submitted by the RPC for the September 2023 RRC meeting. The RRC will formally review these Rules at its meeting on Thursday, September 21, 2023, at 9:00 a.m. The meeting will be a hybrid of in-person and WebEx attendance, and an evite should be sent to you as we get closer to the meeting. If there are any other representatives from your agency who will want to attend virtually, let me know prior to the meeting, and we will get evites out to them as well.

Please submit the revised Rules and forms to me via email, no later than 5 p.m. on Wednesday, September 6, 2023.

In the meantime, please do not hesitate to reach out via email with any questions or concerns.

Thanks,

Brian

Brian Liebman Counsel to the North Carolina Rules Review Commission Office of Administrative Hearings

(984)236-1948

brian.liebman@oah.nc.gov

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