

Burgos, Alexander N

Subject: FW: Submission of Technical Changes - NC Radiation Protection Commission - 10A NCAC 15
Attachments: 10A NCAC 15 .1301.docx; Req for Tech Changes Ch15 RRC response.docx; NC-NRC Agreement original.pdf; NC-NRC Agreement Gov recent.pdf; CompatCategories H&SID NRC Regs 8-27-20.pdf

From: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Sent: Tuesday, September 6, 2022 4:58 PM
To: Rules, Oah <oah.rules@oah.nc.gov>
Cc: Liebman, Brian R <brian.liebman@oah.nc.gov>
Subject: Submission of Technical Changes - NC Radiation Protection Commission - 10A NCAC 15

We have been notified of the technical changes requested by Mr. Brian Liebman on August 29, 2022 pursuant to G.S. 150B-21.10 for Rule 10A NCAC 15 .1301. In preparation for the September 15, 2022 RRC meeting, attached to this email you will find the amended text for that rule as requested in the Request for Technical Change document received, as well as the Agency's responses to the concerns raised in the "Request for Changes" document as seen in bold black font on the document. In addition, to accompany the Agency's responses to the "Request for Changes" attached are these additional documents: the Nuclear Regulatory Commission Agreement with NC (original), the most recently governor signed Nuclear Regulatory Commission Agreement with NC, and the Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements issued 8/27/20.

Should you have any questions regarding the attachments, please feel free to contact me.

Thank you,

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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: “~~a~~Association”
 - 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: Radiation Protection Commission

RULE CITATION: 10A NCAC 15 .1301

DEADLINE FOR RECEIPT: Friday, September 9, 2022.

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:

In general, where is your statutory authority to state which provisions of the CFR will not apply within the State of North Carolina?

State Policy Regarding Radiation

N.C. Gen. Stat. § 104E-3 establishes the State's policy regarding radiation. The statute states as follows:

[I]n furtherance of its responsibility to protect the public health and safety:

(1) To institute and maintain a program to permit development and utilization of sources of radiation for purposes consistent with the health and safety of the public; and

(2) To prevent any associated harmful effects of radiation upon the public through the institution and maintenance of a regulatory program for all sources of radiation, providing for:

a. A single, effective system of regulation within the State;

b. A system consonant insofar as possible with those of other states; and

c. Compatibility with the standards and regulatory programs of the federal government for by-product, source and special nuclear materials.

N.C. Gen. Stat. § 104E-3.

Authority to Promulgate Rules Governing Radioactive Materials and Machines

Several statutes grant the North Carolina Department of Health and Human Services authority to create, adopt, and repeal necessary rules and regulations governing radioactive materials in the State of North Carolina. Specifically, N.C. Gen. Stat. § 104E-7(a) creates the Department's Radiation Protection Commission, and N.C. Gen. Stat. § 104E-7(a)(2) provides the Commission with authority to:

(2) To adopt, promulgate, amend and repeal such rules, regulations and standards relating to the manufacture, production, transportation, use, handling, servicing, installation, storage, sale, lease, or other disposition of radioactive material and radiation machines as may be necessary to carry

Brian Liebman

Commission Counsel

Date submitted to agency: August 29, 2022

out the policy, purpose and provisions of this Chapter. To this end, the Commission is authorized to require licensing or registration of all persons who manufacture, produce, transport, use, handle, service, install, store, sell, lease, or otherwise dispose of radioactive material and radiation machines, as the Commission deems necessary to provide an adequate protection and supervisory program. . . .

N.C. Gen. Stat. § 104E-7(a)(2).

The Atomic Energy Act of 1954 and North Carolina's 1964 Agreement

This particular rule area also implicates federal authority. The Atomic Energy Act of 1954 states that the United States Nuclear Regulatory Commission may enter into an agreement with any state in order to discontinue the Nuclear Regulatory Commission's regulatory authority over certain types of radioactive materials and activities within that state. In exchange, a state assumes regulatory authority over the radioactive materials and activities identified in such an agreement.

Specifically, Section 274(b) of the Act, codified at 42 U.S.C. § 2021(b), provides that the Nuclear Regulatory Commission is authorized to enter into agreements with the "Governor of any State providing for the discontinuance of the regulatory authority of the Commission . . . with respect to any one or more of the following materials within the State: (1) Byproduct materials; (2) Source materials; (3) Special nuclear materials in quantities not sufficient to form a critical mass." It further provides that "[d]uring the duration of such an agreement it is recognized that the State shall have authority to regulate the materials covered by the agreement for the protection of the public health and safety from radiation hazards." 42 U.S.C. 2021(b).

The North Carolina Radiation Protection Act grants the Governor authority to enter into such an agreement. N.C. Gen. Stat. § 104E-10(a). On July 21, 1964, the Governor of North Carolina executed an agreement with the Nuclear Regulatory Commission in accordance with 42 U.S.C. 2021(b). The Agreement became effective on August 1, 1964. As a result, North Carolina is known as an "Agreement State." The Agreement provides that the State of North Carolina maintains a "program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory responsibility for such materials." Taken together, the applicable federal statutes and the 1964 Agreement provide that the State of North Carolina maintains authority to regulate the certain radioactive materials and activities.

Section 274(g) of the Atomic Energy Act, codified at 42 U.S.C. § 2021(g), requires each Agreement State's program to be both: (1) adequate to protect the public and (2) compatible with the Nuclear Regulatory Commission's programs. In order to evaluate compatibility, the Nuclear Regulatory Commission publishes a set of Compatibility Categories for Agreement

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Commission Counsel

Date submitted to agency: August 29, 2022

States to use in determining what is subject to exclusive federal jurisdiction and what is subject to state jurisdiction and regulation. A copy of the most recent Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements, issued on August 27, 2020, is attached. The Compatibility Categories are defined in greater detail in Agreement State Policy Statement, 82 Fed. Reg. 48535 (Oct. 18, 2017).

To comply with the compatibility requirement, an Agreement State is required to “adopt program elements assigned Compatibility Categories A, B, and C.” Agreement State Policy Statement, 82 Fed. Reg. 48535 (Oct. 18, 2017). Category A requires “basic radiation protection standards.” Category B requires “cross-jurisdictional program requirements,” and Category C requires other program elements that are necessary “in order to avoid conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis.” Agreement State Policy Statement, 82 Fed. Reg. 48535 (Oct. 18, 2017). In contrast, Category D elements are “not required to be adopted for purposes of compatibility,” and Category NRC includes “program elements over which the NRC cannot discontinue its regulatory authority pursuant to the AEA or provisions of 10 CFR.”

Accordingly, the federal regulations that are specifically excluded from incorporation by reference in in the North Carolina rules are those that are either: (1) under exclusive federal jurisdiction (and included in Compatibility Category NRC) or (2) are not required to be adopted (and included in Category D). If a federal regulation falls into Category D or Category NRC, it may be excluded from a state rule. Finally, federal regulations that apply to activities not conducted in the State of North Carolina also are excluded from incorporation by reference.

North Carolina General Statutes Regarding Federal Compatibility

N.C. Gen. Stat. § 104E-3 also addresses the above-listed federal compatibility requirements. N.C. Gen. Stat. § 104E-3(2)(c) states that it is the policy of the State of North Carolina to provide for “compatibility with the standards and regulatory programs of the federal government for by-product, source and special nuclear materials.” Pursuant to N.C. Gen. Stat. § 104E-7(a)(2), the Commission has authority to “adopt, promulgate, amend and repeal such rules, regulations and standards” regarding radioactive materials “as may be necessary to carry out the policy, purpose and provisions of [Chapter 104E].” The proposed rule comports with the State’s policy to ensure compatibility “with the standards and regulatory programs of the federal government” as set forth in N.C. Gen. Stat. § 104E-3. As applied to this particular rule, 10 CFR §§ 39.5, 39.8, 39.101, and 39.103 are categorized as federal Compatibility Category D. As a result, the State of North Carolina may exclude them from its proposed rule in accordance with the federal statutes, N.C. Gen. Stat. §§ 104E-3 and 104E-7(a)(2), and the 1964 Agreement.

Brian Liebman
Commission Counsel

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In (a), line 17, it is unclear whether “mineral logging” and the terms that come after are types of wireline-service operations, or are independent operations. Please clarify. Mineral logging is most often associated with wireline operations but is not dependent upon wireline operations. The original wording was intended to include mineral logging as an activity separate from well logging. Revised the Rule for clarity.

Is the final sentence in (a) unnecessary, since the requirement for subsurface tracer studies is listed in paragraph (d)?

We had a lot of discussion about the addition of this sentence in (a), lines 19 and 20. It’s there to point out that the additional requirements are there, and to help our regulated community comply with the rules. It can also be regarded as extraneous because the additional requirements are stated in the Rule. Thank you for your comment, and this sentence has been removed from the rule accordingly.

In (c), are the “forms provided by the agency” the same as the ones set forth in this Rule? Yes.

In (c)(1) and (2), what are the “instructions” being required? To the extent you’re requiring compliance with them, I think they may need to be stated in the Rule.

The instructions on the form are to complete items 1 – 5 of the form if the application is for a new license or the renewal of an existing license, and to complete items 1 – 7 of the form if it is an amendment of an existing license. Subparagraphs (c)(1) and (2) contain instructions that take the applicant step-by-step through either form. The emphasis on the forms about item 5 and item 7 (depending on the form used) is because we often get unsigned forms, and we do not take action to review the form and any supplemental information without the certifying official’s signature to avoid unintended license amendments. The instructions also provide the applicant an email address to send the forms to the agency and specifies that only one copy of the form and supporting information is required.

The Rule has been revised to include the instructions that the applicant must follow as opposed to stating that the applicant must follow the instructions printed on the form. I also revised the address information in (c) to include the email address that appears on the forms and to clearly give the applicant the option to email or to deliver the form to the agency at the address in Rule .0111

Under (c)(1)(B), what are “temporary jobsites” and how are they defined?

Temporary jobsites are defined in 10 CFR 39.4 for the purpose of this Rule.

*Under (c)(1)(E), consider removing the commas to clarify the requirement on both application and renewals. **Commas removed per suggestion***

*In (c)(3), include the language “free of charge” after “available.” **Language added***

Brian Liebman
Commission Counsel

Date submitted to agency: August 29, 2022

In (d), what does it mean to “obtain agency approval”? What exactly are you requiring the regulated public to do?

Revised this paragraph to clarify that the regulated public has to apply for a license, or to amend an existing license, to get agency approval to conduct subsurface studies using unsealed radioactive material in accordance with Paragraph (c).

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

Brian Liebman
Commission Counsel

Date submitted to agency: August 29, 2022

1 10A NCAC 15 .1301 is readopted with changes as published in 36:19 NCR 1527-1530 as follows:

2
3 **SECTION .1300 - REQUIREMENTS FOR WIRELINE-SERVICE OPERATORS AND**
4 **SUBSURFACE-TRACER STUDIES**

5
6 Codifier's Note: 10 NCAC 03G .3400 was transferred to 15A NCAC 11 .1300 effective January 4, 1990.
7 Recodification pursuant to G.S. 143B-279.3.

8
9 **10A NCAC 15 .1301 ~~PURPOSE AND SCOPE~~ WELL LOGGING, WIRELINE-SERVICE**
10 **OPERATIONS, AND SUBSURFACE TRACER STUDIES: REQUIREMENTS FOR**
11 **LICENSEES**

12
13 ~~(a) The rules in this Section apply to all licensees who use sources of radiation for wireline service operations~~
14 ~~including mineral logging, radioactive markers, or subsurface tracer studies.~~

15 ~~(b) The requirements of this Section are in addition to, and not in substitution for, the requirements of Sections .0100,~~
16 ~~.0300, .0900, .1000, .1100 and .1600 of this Chapter.~~

17 (a) Persons using sources of radiation for well logging, wireline-service ~~operations including~~ operations, mineral
18 logging, radioactive markers, or subsurface tracer studies shall comply with the provisions of 10 CFR Part 39, except
19 that 10 CFR 39.5, 39.8, 39.101, and 39.103 shall not apply. ~~Persons conducting subsurface tracer studies shall meet~~
20 the additional requirement listed in Paragraph (d) of this Rule.

21 (b) In addition to the terms defined in 10 CFR 39.2, the following definitions shall also apply to this Section:

22 (1) "Mineral logging" means any logging performed for the purpose of mineral exploration other than
23 oil or gas;

24 (2) "Well-bore" means a drilled hole in which wireline-service operations and subsurface-tracer studies
25 are performed;

26 (3) "Wireline" means a cable containing one or more electrical conductors that is used to lower and
27 raise logging tools in the well-bore; and

28 (4) "Wireline-service operations" means any evaluation or mechanical service that is performed in the
29 well-bore using devices on a wireline.

30 (c) Applications required by 10 CFR 39.11 shall be made on forms provided by the agency, and the payment of fees
31 required by 10 CFR Part 170 shall not apply. ~~Applications~~ One copy of the application and supporting material shall
32 be submitted to the agency ~~by e-mail at Licensing.RAM@dhhs.nc.gov, or~~ at the address shown in Rule .0111 of this
33 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 instructions~~
36 for completing the application printed on the application form shall be followed. Items one through

1 five on the application form shall be completed by the applicant, using additional sheets as
 2 necessary. The following 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,] license or for the
 11 renewal of an existing [license,] 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
 21 the application printed on the application form shall be followed.] Items one through seven on the
 22 application form shall be completed by the applicant, using additional sheets as necessary. The
 23 following information shall appear on the application:

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

1 (I) 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 to
3 sign license applications on behalf of the business or licensee.

4 (3) Applications specified in this Rule are available free of charge at:
5 [www.ncradiation.net/rms/rmsforms2.htm\(Rev01\).htm](http://www.ncradiation.net/rms/rmsforms2.htm(Rev01).htm).

6 (d) Persons conducting subsurface tracer studies using unsealed sources of radiation shall obtain agency approval
7 prior to injecting licensed material into the subsurface. Agency approval shall be obtained by submitting a license
8 application to the agency in accordance with Paragraph (c) of this Rule.

9 (e) Notifications, authorization requests, and reports required by 10 CFR 39.77 shall be made to the agency at the
10 address shown in Rule .0111 of this Chapter in lieu of the NRC.

11 (f) Applications for exemptions to this Rule shall be submitted to the agency at the address shown in Rule .0111 of
12 this Chapter in lieu of the NRC.

13 (g) The regulations cited in this Rule from 10 CFR Part 39 are hereby incorporated by reference, including subsequent
14 amendments and editions. Copies of these regulations are available free of charge at [https://www.nrc.gov/reading-](https://www.nrc.gov/reading-rm/doc-collections/cfr/part039/)
15 [rm/doc-collections/cfr/part039/](https://www.nrc.gov/reading-rm/doc-collections/cfr/part039/).

16
17 *History Note: Authority G.S. 104E-3; 104E-7;*

18 *Eff. June 1, 1989;*

19 *Amended Eff. January 1, 1994;*

20 *Transferred and Recodified from 15A NCAC 11 .1301 Eff. February 1, ~~2015~~. 2015;*

21 *Readopted Eff. October 1, 2022.*



Office of Nuclear Material Safety and Safeguards Procedure Approval

Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements, State Agreements (SA) Procedure SA-200

Issue Date: August 27, 2020

Review Date: August 27, 2025

Michael C. Layton

Director, NMSS/MSST

Michael C. Layton

Digitally signed by Michael C. Layton
Date: 2020.08.27 15:08:22 -04'00'

Date:

Lizette Roldan-Otero, Ph.D.

Acting Chief, NMSS/MSST/SALB

Lizette Roldan-Otero

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Michelle Beardsley

Procedure Contact, NMSS/MSST/SALB

Michelle A. Beardsley

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Beardsley
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Date:

ML20183A325

NOTE

***Any changes to the procedure will be the responsibility of the NMSS Procedure Contact.
Copies of NMSS procedures are available through the NRC Web site at <https://scp.nrc.gov>.***

I. INTRODUCTION

This procedure establishes the compatibility, and health and safety (H&S) components assigned to the U.S. Nuclear Regulatory Commission (NRC) regulations and program elements as determined in accordance with Management Directive (MD) and Handbook 5.9, *Adequacy and Compatibility of Program Elements for Agreement State Programs*.

II. OBJECTIVE

To provide guidance to the Agreement States, States pursuing Agreement State status, and the NRC staff on the adequacy, compatibility and H&S components assigned to NRC regulations and other program elements.

III. BACKGROUND

- A. On October 18, 2017, the NRC published a merged revision to the two 1997 Policy Statements (i.e., Policy Statement on the Adequacy and Compatibility of Agreement State Program and the Statement of Principles and Policy for the Agreement State Program). The resulting "Agreement State Program Policy Statement" set forth the approach that the Commission will use when determining which of its regulations and program elements should be adopted by an Agreement State to maintain an adequate and compatible program. The Agreement State Program Policy Statement also specifies that an Agreement State should have legally binding requirements to maintain adequate protection of public health and safety, including security of radioactive materials. The Policy Statement defines "program element" as any component or function of a radiation control regulatory program, including regulations or other legally binding requirements imposed on regulated persons, which contributes to implementation of that program. It identifies those NRC program elements required for adequacy and having a particular H&S component as those that are designated as compatibility categories A, B, C, D, NRC, and H&S: and those required for compatibility include those regulations and other legally binding requirements designated as compatibility categories A, B, and C (see Section V.B.1.d of this procedure for definitions of these compatibility categories).
- B. MD 5.9 describes the criteria and process the NRC staff should follow to determine which NRC regulations and other program elements should be adopted by an Agreement State for purposes of adequacy and compatibility. In accordance with MD 5.9, each regulation and program element are analyzed and classified with a specific compatibility category designation or H&S component.
- C. This procedure was developed for use by Agreement State and NRC staff. It identifies the assigned compatibility category or H&S component for each rule and program element, as determined in accordance with MD 5.9. The terms "rules" and "regulations" are used interchangeably in this procedure. The component classifications are set out in individual tables as described in Section V.A. of this procedure.

IV. ROLES AND RESPONSIBILITIES

- A. The Director, Division of Material Safety, Security, State, and Tribal Programs (MSST), is responsible for the implementation of MD 5.9.
- B. The Branch Chief for the State Agreement and Liaison Programs Branch, MSST is responsible for assigning a staff member to serve as the State Regulation Review Coordinator (SRRC), assisting in procedure updates, and determining rule and program element compatibility designations in accordance with MD 5.9.
- C. The SRRC is responsible for the review, evaluation, and resolution of adequacy and compatibility concerns that are identified during the review of Agreement State legislation, regulations, and other program elements, in collaboration and coordination with the Agreement State and NRC staff.
- D. The Standing Committee on Compatibility is responsible for:
 - 1. The independent review of regulations and other program elements (e.g., inspection procedures, licensing guidance, pre-licensing guidance checklist, etc.) required for Agreement State adequacy and compatibility with NRC requirements.
 - 2. Ensuring consistency during the rulemaking process by documenting the basis for decisions made regarding compatibility determinations while taking into consideration (a) program element implementation issues, (b) the NRC staff's review of State regulations, and (c) other program elements under the Integrated Materials Performance Evaluation Program (IMPEP).
 - 3. Evaluating and documenting compatibility designations as described in MD 5.9.

V. GUIDANCE

The NRC staff should follow the guidance presented in the Handbook of MD 5.9, which describes the criteria and the process that will be used to determine the adequacy and compatibility category designations and H&S components of NRC regulations and program elements that an Agreement State should adopt for an adequate and compatible program.

- A. Title 10 Code of Federal Regulations (CFR)

A current section-by-section summary of the compatibility and H&S categories of regulations in Title 10 of the CFR can be found on the Regulation Toolbox of the

state communications portal Web site at:
https://scp.nrc.gov/regsumsheets_newregs.html.¹

The NRC staff should follow the guidance that an Agreement State need not adopt a specific regulation if the Agreement State has no licensees that would be subject to that regulation. In such cases, the Agreement State would need to commit to adopting the regulation, or to impose the regulation through license conditions or other legally binding means, if an application were to be received by the Agreement State for a license authorizing materials subject to that regulation.

The Handbook of MD 5.9 contains information regarding program elements that are applicable to the regulation of agreement materials. Management Directive 5.9 provides the process and the categorization criteria. In accordance with MD 5.9, program elements should be adopted within 6 months unless otherwise specified. The Parts of 10 CFR on the state communications portal Web site for which tables are provided below have been analyzed section-by-section; those Parts that do not have a corresponding table have been determined to address areas in which Agreement States either do not have regulatory authority or that are applicable specifically to NRC's regulatory program and need not be addressed by an Agreement State. For completeness, those Parts that address areas of exclusive NRC authority are listed in Table 1. Those Parts that generally are applicable specifically to NRC's regulatory program, but are not areas of exclusive NRC authority, are listed in Table 2. Any future changes to these determinations will be reflected in revisions to Tables 1 and 2 and to the program element and 10 CFR tables on the Web site, as appropriate.

¹ The Statements of Consideration for NRC regulations developed prior to September 3, 1997, do not contain the compatibility designations and associated rationale for compatibility designation. For NRC rules developed after September 3, 1997, the Statements of Consideration contain a section entitled, "Agreement State Compatibility," which includes information on NRC rule compatibility designation and rationale.

Table 1

Specific Parts of Title 10 of the Code of Federal Regulations That Address Areas of Exclusive NRC Authority

Parts 10, 11, 25, 26, 50, 51, 52, 53, 54, 55, 60, 62, 72, 73², 74, 75³, 76, 81, 95, 100, 110⁴, 140, and 160.

Table 2

Specific Parts of Title 10 of the Code of Federal Regulations That Address Areas That Generally Are Applicable Only to NRC's Regulatory Program

Parts 1, 2, 4, 7, 8, 9, 12, 13, 14, 15, 16, 21⁵, 170, and 171

B. Regulations and Program Element Review Summary Sheets (RSS)

1. The RSS, also known as the Regulation Amendment Tracking System (RATS) sheet, is based on the "Summary of Change" document which is created when the NRC revises its regulations. The Summary of Change document contains all regulation changes that were included in the rulemaking. This document is included as an enclosure to the State and Tribal Communication (STC) letter announcing the rulemaking.

The RSS or RATS sheet is also used to document the NRC staffs' review of the Agreement State's equivalent rule provisions; these sheets can be found

² Section 73.67 (Physical Protection of Special Nuclear Material of Moderate and Low Strategic Significance) of 10 CFR Part 73 is applicable to certain Agreement State licensees pursuant to 10 CFR 150.14. The Agreement States, therefore, may wish to inform their licensees of the provisions of this part through a mechanism that is appropriate under the State's administrative procedure laws, but does not grant regulatory authority on the State in this area of exclusive NRC jurisdiction.

³ Part 75 (Safeguards on Nuclear Material - Implementation of US/IAEA Agreement) may be applicable to certain Agreement State licensees as delineated in Section 75.2 - Scope. The Agreement States, therefore, may wish to inform their licensees of the provisions of this part through a mechanism that is appropriate under the State's administrative procedure laws, but does not grant regulatory authority on the State in this area of exclusive NRC jurisdiction.

⁴Section 110.54(a) (Reporting Requirements) may be applicable to certain Agreement State licensees as delineated in Section 110.1, Purpose and Scope. The Agreement States, therefore, may wish to inform their licensees of the provisions of this section through a mechanism that is appropriate under the State's administrative procedure laws, but does not grant regulatory authority on the State in this area of exclusive NRC jurisdiction.

⁵ The provisions in Part 21 derive from statutory authority in the Energy Reorganization Act, not the Atomic Energy Act, which does not apply to Agreement States. Therefore, this Part cannot be addressed under either compatibility or adequacy. While it may be argued that there are health and safety reasons to require States to adopt the certain provisions of Part 21, States may not have the statutory authority to do so.

on the Regulation Toolbox of the state communications portal Web site at: https://scp.nrc.gov/rss_regamendents.html. The sheet is divided into eight columns: NRC Regulation Section; Section Title; State Section; Compatibility Category; Summary of Change to the CFR; Difference Yes/No; Significant Yes/No; and If Difference Why or Why Not was a Comment Generated.

- a. The “NRC Regulation Section” column contains the numbering of the regulation section as it appears in the 10 CFR.
- b. The “Section Title” column contains the section title as it appears in 10 CFR.
- c. The “State Section” will be used by NRC staff during a review of Agreement State regulations to list that State’s corresponding regulation section.
- d. The “Compatibility Category” column contains the compatibility or H&S category for the regulation section that has been determined in accordance with the categorization criteria in MD 5.9.

Compatibility Categories and H&S Identification:

- A = Basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. The program elements adopted by an Agreement State should be essentially identical to those of the NRC to provide uniformity in the regulation of agreement material on a nationwide basis.;
- B = These limited number of program elements apply to activities that cross jurisdictional boundaries. These program elements have a particular impact on public health and safety and need to be adopted in an essentially identical manner in order to ensure uniformity of regulation on a nationwide basis.;
- C = These program elements are important for an Agreement State to have in order to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis. The Agreement State program elements may be more restrictive than the NRC program elements provided that the essential objective is met, and the State requirements do not jeopardize an orderly pattern of regulation of agreement material on a nationwide basis.
- D = Not required for purposes of compatibility;

NRC = These are NRC program elements that address areas of regulation that cannot be discontinued when a State enters into an Agreement with the NRC pursuant to the Atomic Energy Act or provisions of 10 CFR regulations. The State should not adopt these program elements;

H&S⁶ = Program elements identified by H&S in the Comment column are not required for purposes of compatibility; however, they do have particular H&S significance. Although not required for compatibility, the State must adopt program elements in this category, that embody the basic H&S aspects of the NRC's program elements because of particular H&S considerations; and

[] = A bracket around a category means that the Section may have been adopted elsewhere and it is not necessary to adopt it again.

- e. The "Summary of Change to the CFR" Section contains the revised rule text for those sections of the 10 CFR included in the rulemaking.
- f. The "Difference Yes/No" column will be used by NRC staff during a review of Agreement State regulations to indicate whether the corresponding Agreement State regulation differs from the NRC's regulation.
- g. The "Significant Yes/No" column will be used by NRC staff during a review of Agreement State regulations to indicate whether an identified difference found in the Agreement State regulation, is in accordance with the compatibility category or H&S designation assigned to the regulation.
- h. The "If Difference Why or Why Not was a Comment Generated" column will state what the difference is, and whether or not that difference is in accordance with the regulation's compatibility category designation. If the difference makes the regulation non-compatible, NRC staff will also list what changes are needed to make the Agreement State regulation compatible and address H&S issues.

⁶ The program elements in this category are not required for compatibility. These program elements are considered to have particular health and safety significance based on the "two or fewer failures criteria." If the essential objectives of the program element were not adopted by the Agreement State, an individual could receive an exposure in excess of the basic radiation protection standards in Compatibility Category A resulting from the higher probability of failure occurring with, at most, one other failure event(Management Directive 5.9., Handbook, Part II, Section F).

2. Staff should be aware of the following:
 - a. The following sections are found in multiple Parts of 10 CFR: *Purpose, Scope, Interpretations, Communications, OMB Approval, Violations, Criminal Penalties* and *Inspections*. These sections are all essentially identical from Part to Part. These requirements are not required for adequacy, compatibility or H&S reasons. The Agreement State may elect to adopt similar sections based on their requirements;
 - b. When using the Review Summary Sheets for Regulation Adoption for New Agreement State Programs (i.e., 10 CFR sheets: https://scp.nrc.gov/regsumsheets_newregs.html), unless otherwise indicated in the tables, the compatibility category or identification of H&S significance applies to the entire section of the Part. See, for example, the 10 CFR table for 10 CFR Part 20, Section 20.2003, where individual paragraphs are assigned different components.
3. A *Program Element Table and Associated Compatibility Categories as Noted in SA-200* can be found on the Regulation Toolbox of the state communications portal Web site at: <https://scp.nrc.gov/regtoolbox.html> for both regulation and non-regulation program elements. The table is in alignment with the program elements outlined in the Agreement State Program Policy Statement and includes: The Program Element, State Requirement, Adequacy/Compatibility Category, and References. Staff should use SA-107, *Reviewing the Non-Common Performance Indicator, Legislation, Regulations, and Other Program Elements*; SA-201, *Review of State Regulatory Requirements*; and MD 5.6, *Integrated Materials Performance Evaluation Program* along with other IMPEP guidance documents in the review of these program elements.

C. Approvals

1. Approvals of compatibility category designations of final regulations and program elements will be done in accordance with MD 5.9 and MD 6.3, *The Rulemaking Process*.
2. Approvals of revisions to compatibility category designations of rules will be submitted to the Commission for approval. The rules developed after September 1997, are in accordance with MD 5.9, and MD 6.3, which included Commission review and approval and public notice in the *Federal Register*; thus, it is essential to obtain Commission approval of any revisions.

D. Compatibility Resolution

Section III in MD 5.9, Organizational Responsibilities and Delegations of Authority, provides that the Office of Nuclear Material Safety and Safeguards (NMSS) will implement the program to evaluate adequacy and compatibility of Agreement State programs and in coordination with other NRC offices will

review, evaluate, and determine those NRC regulations that an Agreement State should adopt as legally binding requirements for the purpose of adequacy, compatibility or H&S. In accordance with this provision, the "Compatibility Resolution (CR)" process was initiated. This CR process is used to clarify or resolve minor differences that are considered acceptable between the language used in the NRC's regulation as compared to the regulation of an Agreement State. Significant compatibility issues will require Commission approval and will be handled outside of the CR process (see Section V.C.2. of this procedure).

The NRC staff will document these clarifications in a "CR document." The CR document will identify the issue, provide a discussion of the issue, and provide observations and/or conclusions of the staff's resolution of the issue. The CR document will be reviewed by the Standing Committee on Compatibility for consistency with MD 5.9 and will require concurrence by all relevant offices. The CR document will be distributed to the Agreement States and States pursuing Agreement State status, the Organization of Agreement States, the Conference of Radiation Control Program Directors, Inc., and all relevant NRC staff. A list of all CR documents will be maintained on the state communications portal Web site at: <https://scp.nrc.gov/regtoolbox.html>.

VII. REFERENCES

Management Directives (MD) available at <https://scp.nrc.gov>

NMSS SA Procedures available at <https://scp.nrc.gov>

Title 10, Code of Federal Regulations available at: <https://www.nrc.gov/reading-rm/doc-collections/cfr/>

Program Element Table and Associated Compatibility Categories as noted in SA-200; <https://scp.nrc.gov/regtoolbox.html>

Program Elements: Regulation and Non-Regulation: <https://scp.nrc.gov/regtoolbox.html>

VIII. ADAMS Reference Documents

For knowledge management purposes, listed below are all previous revisions of this procedure, as well as associated correspondence with stakeholders, that have been entered into the NRC's Agencywide Document Access Management System (ADAMS).

No.	Date	Document Title/Description	Accession Number
1	02/06/01	Final STP Procedure SA-200	ML010580517
2	10/25/02	STP-02-075, Opportunity to Comment on Draft Revisions to STP Procedure SA-200	ML022980631
3	10/08/04	Final STP Procedure SA-200	ML042820600
4	10/08/04	Resolution of Comments	ML042820609
5	03/22/05	Final STP Procedure SA-200	ML050770486 (pkg. ML51030417)
6	06/05/09	Final FSME Procedure SA-200	ML091190055
7	11/19/19	Interim NMSS Procedure SA-200	ML19311C784
8	07/02/20	Comment Resolution	ML20184A179
9	08/27/20	Final NMSS Procedure SA-200	ML20183A325

OFFICE OF THE SECRETARY
CORRESPONDENCE CONTROL TICKET

Date Printed: Mar 15, 2007 14:42

PAPER NUMBER: LTR-07-0173
ACTION OFFICE: EDO

LOGGING DATE: 03/08/2007

To: Miller, FSME

AUTHOR: Michael Easley
AFFILIATION: NC-GOV
ADDRESSEE: CHRM Dale Klein
SUBJECT: Concerns program for licensing byproduct material

CYS:
EDO
DEDMRS
DEDR
DEDIA
AO
R11

ACTION: Appropriate
DISTRIBUTION:

LETTER DATE: 02/08/2007

ACKNOWLEDGED Yes

SPECIAL HANDLING: Immediate release to the public via SECY/EDO/DPC

NOTES:

FILE LOCATION: ADAMS

DATE DUE:

DATE SIGNED:



STATE OF NORTH CAROLINA
OFFICE OF THE GOVERNOR
20301 MAIL SERVICE CENTER • RALEIGH, NC 27699-0301

MICHAEL F. EASLEY
GOVERNOR

February 8, 2007

The Honorable Dale E. Klein, Ph.D., Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Dr. Klein:

The purpose of this letter is to comply with the provisions of Section 651(e) of the Energy Policy Act of 2005, regarding the licensing of certain naturally occurring and accelerator produced radioactive materials now defined as byproduct material in Sections 11e.(3) and 11e.(4) of the Atomic Energy Act of 1954 as amended.

In 1964, the State of North Carolina entered into an Agreement with the Commission under Section 274b. of the Atomic Energy Act of 1954 as amended. Under that Agreement, the State licenses byproduct material as defined in Section 11e.(1) of the Atomic Energy Act. In addition, the State licenses the naturally occurring and accelerator produced radioactive materials now defined as byproduct material.

Our program for licensing the new byproduct material is not separate and distinct from the program for licensing 11e.(1) byproduct material, and no changes have been made to the licensing program that would impact the previous IMPEP finding of adequacy. Further, we intend to continue to license the new byproduct material under this same program.

Accordingly, I certify to the Commission that the State of North Carolina has a program for licensing byproduct material, as defined in paragraph (3) or (4) of Section 11e. of the Atomic Energy Act of 1954, as amended, that is adequate to protect the public health and safety, and that the State intends to continue to implement our regulatory responsibility with respect to the byproduct material.

This certification is effective on the date of publication of the NRC's "Plan for the Transition of Regulatory Authority Resulting from the Expanded Definition of Byproduct Material."

With kindest regards, I remain

Very truly yours,

A handwritten signature in black ink that reads "Mike Easley".

Michael F. Easley

MFE:lj1

CC: Terry L. Pierce, DEH
Beverly Hall, DEH – Radiation Protection

AGREEMENT
BETWEEN THE
UNITED STATES ATOMIC ENERGY COMMISSION
AND THE
STATE OF NORTH CAROLINA
FOR
DISCONTINUANCE OF CERTAIN COMMISSION REGULATORY
AUTHORITY AND RESPONSIBILITY WITHIN THE STATE PURSUANT TO
SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

WHEREAS, The United States Atomic Energy Commission (hereinafter referred to as the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended, (hereinafter referred to as the Act) to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and

WHEREAS, The Governor of the State of North Carolina is authorized under North Carolina General Statutes (G.S. 104C-5; 1963, c. 1211) to enter into this Agreement with the Commission; and

WHEREAS, The Governor of the State of North Carolina certified on May 15, 1964, that the State of North Carolina (hereinafter referred to as the State) has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory responsibility for such materials; and

WHEREAS, The Commission found on July 8, 1964, that the program of the State for the regulation of the materials covered by this Agreement is compatible

with the Commission's program for the regulation of such materials and is adequate to protect the public health and safety; and

WHEREAS, The State recognizes the desirability and importance of maintaining continuing compatibility between its program and the program of the Commission for the control of radiation hazards in the interest of public health and safety; and

WHEREAS, The Commission and the State recognize the desirability of reciprocal recognition of licenses and exemption from licensing of those materials subject to this Agreement; and

WHEREAS, This Agreement is entered into pursuant to the provisions of the Atomic Energy Act of 1954, as amended;

NOW, THEREFORE, It is hereby agreed between the Commission and Governor of the State, acting in behalf of the State, as follows:

ARTICLE I

Subject to the exceptions provided in Articles II, III, and IV, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following materials:

- A. Byproduct materials;
- B. Source materials; and
- C. Special nuclear materials in quantities not sufficient to form a critical mass.

ARTICLE II

This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to regulation of:

- A. The construction and operation of any production or utilization facility;
- B. The export from or import into the United States of byproduct, source, or special nuclear material, of any production or utilization facility;
- C. The disposal into the ocean or sea of byproduct, source, or special nuclear waste materials as defined in regulations or orders of the Commission;
- D. The disposal of such other byproduct, source, or special nuclear material as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed of without a license from the Commission.

ARTICLE III

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

ARTICLE IV

This Agreement shall not affect the authority of the Commission under subsection 161 b. or i. of the Act to issue rules, regulations, or orders to protect the

common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material.

ARTICLE V

The Commission will use its best efforts to cooperate with the State and other agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible. The State will use its best efforts to cooperate with the Commission and other agreement States in the formulation of standards and regulatory program of the State and the Commission for protection against hazards of radiation and to assure that the State's program will continue to be compatible with the program of the Commission for the regulation of like materials. The State and the Commission will use their best efforts to keep each other informed of proposed changes in their respective rules and regulations and licensing, inspection and enforcement policies and criteria, and to obtain the comments and assistance of the other party thereon.

ARTICLE VI

The Commission and the State agree that it is desirable to provide for reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any agreement State. Accordingly, the Commission and the State agree to use their best effort to develop appropriate rules, regulations, and procedures by which such reciprocity will be accorded.

ARTICLE VII

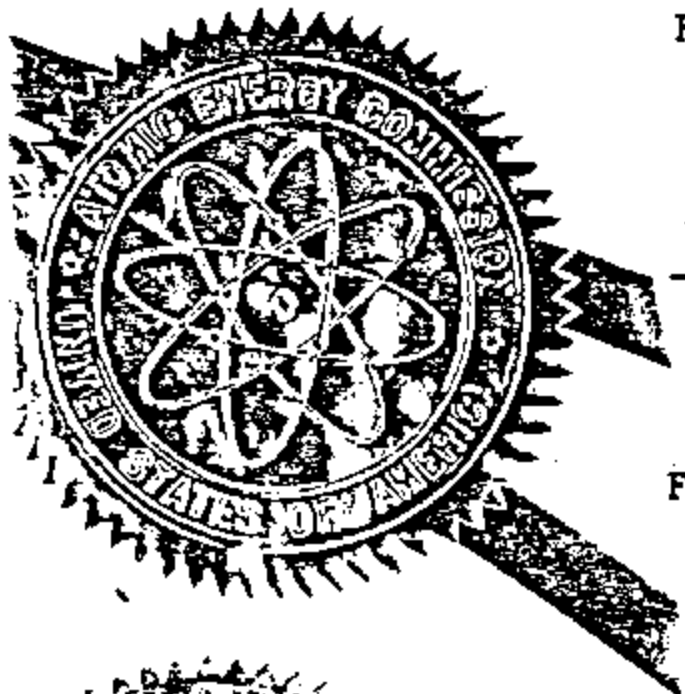
The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State, or upon request of the Governor of the State, may terminate or suspend this Agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that such termination or suspension is required to protect the public health and safety.

ARTICLE VIII

This Agreement shall become effective on August 1, 1964, and shall remain in effect unless, and until such time as it is terminated pursuant to Article VII.

Done at Raleigh, State of North Carolina, in triplicate, this 21st day of July, 1964.

FOR THE UNITED STATES ATOMIC ENERGY COMMISSION



[Handwritten signature]
James T. Ramey, Commissioner

FOR THE STATE OF NORTH CAROLINA

[Handwritten signature]
Terry Sanford, Governor



Burgos, Alexander N

Subject: FW: 10A NCAC 15 .1301 Requests for Changes - September 2022 RRC

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

Sent: Monday, August 29, 2022 2:51 PM

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

Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>

Subject: RE: 10A NCAC 15 .1301 Requests for Changes - September 2022 RRC

Great! Thanks, Nadine.

Brian Liebman
Counsel to the North Carolina Rules Review Commission
Office of Administrative Hearings
(984)236-1948
brian.liebman@oah.nc.gov

E-mail correspondence to and from this address may be subject to the North Carolina Public Records Law N.C.G.S. Chapter 132 and may be disclosed to third parties.

Burgos, Alexander N

From: Pfeiffer, Nadine
Sent: Monday, August 29, 2022 12:12 PM
To: Liebman, Brian R
Cc: Burgos, Alexander N
Subject: RE: 10A NCAC 15 .1301 Requests for Changes - September 2022 RRC

Thanks Brian,
We'll get on it and respond to you as quickly as we can!

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 <brian.liebman@oah.nc.gov>
Sent: Monday, August 29, 2022 11:35 AM
To: Pfeiffer, Nadine <nadine.pfeiffer@dhhs.nc.gov>
Cc: Burgos, Alexander N <alexander.burgos@oah.nc.gov>
Subject: 10A NCAC 15 .1301 Requests for Changes - September 2022 RRC

Hi Nadine,

I'm the attorney who reviewed the Rules submitted by the RPC for the September 2022 RRC meeting. The RRC will formally review these Rules at its meeting on Thursday, September 15, 2022, 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 Friday, September 9, 2022.

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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