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Agency of Human Services

June 18, 2018

Andrea L. Kock, Acting Director
Division of Material Safety, State, Tribal and Rulemaking Programs
Office of Nuclear Material Safety and Safeguard
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Ms. Kock,

This document addresses the comments made in your letter of December 18, 2017 and its enclosure entitled Comments on Section 4.1 and 4.2 of the Draft Vermont Application for an Agreement Dated September 2017. To facilitate an efficient review, it addresses each general comment and specific comment as numbered in the enclosure. Our response to the majority of NRC comments are in this document and they are italicized. Also enclosed with this letter are tracked changes and clean versions of Sections 4.1 and 4.2 of the Draft application.

This is the first of three letters that address the Nuclear Regulatory Commission (NRC) comments on the Draft Application for an Agreement Dated September 2017. A second letter will address NRC comments on Sections 4.3 and 4.4 of the Draft Application for an Agreement Dated September 2017, and a third will address NRC comments on Sections 4.5, 4.6 and 4.7 of the Draft Application for an Agreement Dated September 2017. Each of the three letters is attached to the related revised sections of the Draft Application for an Agreement Dated September 2017.

Please contact me if I can be of further assistance with this.

Thank you.



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Address of NRC Comments on Sections 4.1 and 4.2 of the Draft Vermont Application for an Agreement.

The NRC comments of December 18, 2017 were addressed by the following team of Vermont Department of Health staff:

William Irwin, Radiation Control Program Director
Francis O'Neill, Radioactive Materials Program Manager
Littia Mann, X-Ray and Mammography Program Manager
Lillian Colasurdo, Public Health Policy Advisor
Bessie Weiss, Staff Attorney
David Englander, Senior Policy and Legal Advisor

The staff addressed four general comments and 29 specific comments.

General Comments

1. Please ensure that your application is spell checked and proofread prior to its resubmission. We note that in several sections the descriptions, procedures, and guidance documents are missing words, bullets, sentences, and paragraphs. You may also insert an abbreviations page in the beginning of your submission to identify all the acronyms used. Otherwise, please define each acronym at its first use.

Section 4.1 and 4.2 of the Draft Application to Become an Agreement State have been spell checked and proofread, verifying there are no missing words, bullets, sentences and paragraphs. We have also inserted an abbreviations page to identify acronyms used.

2. Throughout your submission you reference a specific citation in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30 but fail to provide the appropriate counterpart in Parts 40 and 70. Since the Agreement will also include authority over source material and less-than-critical-mass quantities of special nuclear material, it is important to make the correct references for all types of material pertinent to your request (i.e., byproduct, source, and special nuclear material). Please verify that you are citing the correct citations for the appropriate type of material.

We have verified that we reference 10 CFR Parts 40 and 70 for source material and less than critical mass special nuclear material commensurate with our purposes of the Agreement.

3. Throughout your submission, we found errors with the units of measurements. For example, we found a leak test threshold was listed as "0.005 Ci." The correct threshold is 0.005 microcuries. Please review your submission to ensure the correct units are listed.

We have reviewed for errors with units of measurement, including the leak test threshold of 0.005 microcuries and made appropriate corrections.

4. Since Vermont is not assuming authority to evaluate sealed source and devices (SS&D), please remove any references for the review of SS&D for commercial distribution. Any Agreement State can approve the custom use of a single device that is otherwise not approved under 10 CFR 32.210 or a compatible Agreement State regulation. A broad scope licensee can also use SS&D that is not approved under 32.210 or a compatible Agreement State regulation. Additional guidance on custom SS&D reviews can be found in NUREG-1556, Volume 3, Revision 2, Section 5.1.3.

We have removed any references that Vermont would assume authority to evaluate sealed sources and devices for commercial distribution.

Specific Comments

Section 4.1 – Legal Elements

1. In Section 4.1.1.1.b.1., you cite 18 VSA § 1653(b)(1) as the appropriate statute to impose additional license requirements. We believe that 18 VSA § 1653(b)(2)(A) is the more appropriate citation. Please revise your application to reflect the appropriate citation.

Replaced citation of 18 VSA § 1653(b)(1) with citation of 18 VSA § 1653(b)(2)(A) in Section 4.1.1.1.b.1.

2. In Sections 4.1.1.1.b.1., 4.1.1.1.c., 4.1.1.2.a., 4.1.1.2.c., and 4.1.1.2.f., you cite 18 VSA § 1653(b)(1), which states, in part, “except as the Commissioner determines is necessary to protect public health.” As currently written, this authority appears overly broad. The State could, in theory, attempt to use this authority to override an NRC requirement with a compatibility category B designation. Please provide a response from the Vermont Attorney General’s Office (AG) that the Commissioner’s authority is not so broad as to override an NRC requirement with a compatibility category B designation.

A separate letter from the Vermont Attorney General’s Office is attached to address this comment.

3. In Section 4.1.1.1.b.5., you cite 18 VSA § 1653(b)(5), which indicates that an Agreement State license will be transferred to the State as part of this Agreement. The transfer of licenses under a Section 274b. Agreement is limited between the NRC and the signatory Agreement State. The section should read

“Any person having a license immediately before the effective date of an agreement under subsection (a) of this section from the federal government relating to by-product material, source material, or special nuclear material and which on the effective date of this agreement is subject to the control of this State shall be considered to have a like license with the State of Vermont until the expiration date specified in the license from the federal government or until the end of the 90th day after the person receives notice from the Department that the license will be considered expired.”

Please provide a response to address this deficiency or amend the statute as noted above.

The Department and the NRC conducted a teleconference on 10 January 2018 to discuss all of the comments in the 18 December 2017 NRC letter commenting on Sections 4.1 and 4.2. As discussed in the 10 January 2018 phone call, Vermont will not be assuming licenses issued by other states. The specific requirements for obtaining either a Vermont license or a reciprocity license can be found in the proposed Radiological Health Rule.

4. In Section 4.1.1.1.c. of your application, your response should reference the relevant sections in the VT Administrative Procedure Act for the adoption of rules (see e.g., 3 VSA §§ 836-848) and 3 VSA § 340, which applies to public participation. Please include this reference in your response.

In Section 4.1.1.1.c.1., we now cite 3 VSA §§ 836 – 848 on administrative procedures for rulemaking, not just 3 VSA § 840 which applies specifically to public participation in rulemaking.

5. Section 4.1.1.1.c. should reference 18 VSA §1652(c). Please include this reference in your response.

Citation of 18 VSA §1652 (c) and a quote of 18 VSA §1652 (c) has been added to Section 4.1.1.1.c.1.

6. Sections 4.1.1.1.c. and 4.1.1.2.a. reference the term “consistent.” We believe the more correct term is “compatibility.” Please provide a response from the AG that the term “consistency” can be used in instead of the term “compatible” or amend these statutes to correct the language.

A separate letter from the Vermont Attorney General’s Office is attached to address this comment.

7. In Section 4.1.1.1.c.2, the cited references to 18 VSA § 1653(b)(7)(B) and 18 VSA § 1656 appear inappropriate to this section. These statutes should be included in the references for enforcement. In your response, please move these statutes to the enforcement section.

Citations of 18 VSA §1653 (b)(7)(B) and 18 VSA §1656 have been removed from Section 4.1.1.1.c.2.

8. Section 4.1.1.1.c.2 states that the Department has the authority to issue orders to protect public health and safety in accordance with 18 VSA § 1655 (b); however, this statute appears to only apply in an emergency situation. This limitation on the authority of the statute should be noted when presented in this section. Please provide additional statutory citations to impose requirements in the form of other generic legally binding requirements, such as license conditions or orders, since the cited statutes only provide

limited authority. If there are no other applicable citations, additional legislative changes may be required.

Citations to 18 VSA §§ 130, 125, 126 and Sections 9 and 10 of the Radiological Health Rule are provided.

9. In Section 4.1.1.1.f, the references to 18 VSA § 1655 (a) and (b), 18 V.S.A. § 1656, and Vermont Regulation Section 10 appear not to provide sufficient authority for a compatible enforcement program. 18 VSA § 1655(a) and (b) do not allow the program to impose sanctions for violations. Those sections relate to hearings and judicial review. Paragraph (a) is related to the rulemaking proceedings for the program; paragraph (b) relates to immediate actions to protect public health and safety and could, in certain limited circumstances, apply to violations. Please provide additional citations to demonstrate the program has authority to impose sanctions for violations of the regulations, orders, or license conditions. If there are no other applicable citations, additional legislative changes may be required.

Citations to 18 VSA §§ 130, 125 and 126, Sections 9 and 10 of the Radiological Health Rule and 18 VSA § 1653(b)(2)(A) are provided.

10. In Section 4.1.1.1.f, the following quote is attributed to 18 VSA § 1655(a) and (b): “The Department shall have the authority in the event of an emergency to impound or order the impounding of by-product, source, and special nuclear materials in the possession of any person who is not equipped to observe or fails to observe the provisions of this chapter or any rules adopted under this chapter.” This statute language is found in 18 VSA § 1653(b)(7)(A), not 18 VSA § 1655(a) and (b). Please correct the citation for this section in your response.

In Section 4.1.1.1.f. the first citation of 18 VSA § 1655 (a) and (b) has been deleted, and the citation of 18 VSA § 1655 (b)(7)(B) has been revised to 18 VSA § 1653 (b)(7)(B).

11. In Section 4.1.1.1.g, while there are no inconsistencies between Vermont’s ethics rules for non-appointees and the federal ethics rules as they relate to conflicts of interest, it is not clear what ethics rules apply to non-appointees. We further note that Vermont’s Executive Code contains conflict-of-interest provisions that are equivalent to the federal rules, but the code does not appear to apply to non-appointees. Please indicate in your response if Vermont’s Executive Code applies to non-appointees. If Vermont’s Executive Code does not apply to non-appointees, please indicate which Vermont ethics rules apply to non-appointees and what differences, if any, exist for the ethics rules for non-appointees and appointees.

In 4.1.1.1.g., language has been inserted stating that the two cited personnel policies for conflict of interest among all State employees are equivalent to the cited Executive Code of Ethics that applies to appointed officials.

12. Section 4.1.1.2.a. references 18 VSA Section § 1652(b), which states “the Department shall, for the protection of the occupational and public health and safety, develop

programs for the control of ionizing and nonionizing radiation compatible with federal programs for regulation of by-product, source and special nuclear materials.” The reference to “nonionizing radiation” is not compatible with NRC legislative and regulatory requirements. Please revise the statute to remove the reference to “nonionizing radiation” in this section.

The Vermont General Assembly vested in the Vermont Department of Health authority to address issues related to nonionizing radiation decades ago. That authority is used to evaluate health issues related to laser radiation, ultraviolet radiation, radiofrequency radiation, extremely low frequency electromagnetic fields and other nonionizing radiations and the Department must maintain that authority.

13. Section 4.1.1.2.b. references 18 VSA § 1653(c), which states that “this section does not confer authority to regulate materials or activities reserved to the NRC under 42 U.S.C. § 2021 (c) and 10 CFR Part 150.” There are other NRC regulations in other Parts of Title 10 of the Code of Federal Regulations that are reserved to the NRC. It appears that 18 VSA § 1653(c) does not take into account other sections of Title 10 applicable to the Agreement. Please revise the statute or provide a response from the AG that the statute will address all sections of Title 10 reserved to the NRC.

A separate letter from the Vermont Attorney General’s Office is attached to address this comment.

14. Section 4.1.1.2.e. should indicate that Vermont will adopt the relevant sections for Title 10 of the CFR with respect to specific exemptions and prime contractors. The citations should be 10 CFR Parts 30.12, 40.11, and 70.11. Please revise your application to include these changes.

Section 4.1.1.2.e. revised to change 10 CFR 30.11 to 30.12, and to add 40.11 and 70.11.

15. Section 4.1.1.2.f. references 18 VSA § 1656, which appears to grant the Department the broadest enforcement authority. The other statutes were specific to certain situations (e.g., emergencies) or particular enforcement capabilities (e.g., impoundment), and therefore would more appropriately be placed in section 4.1.1.2.h. The following statutes do not appear to be responsive to this section and should be moved to a more appropriate section:

3 VSA § 800–849, Vermont’s Administrative Procedure.
18 VSA § 101–131
18 VSA § 1653(b)(7)(B)
18 VSA § 1655

Please revise this section of the application to address our comment.

Eliminated references to 3 VSA § 800 – 849, 18 VSA § 101 – 131, 18 VSA § 1653(b)(7)(B) and 18 VSA § 1655.

16. Section 4.1.1.2.i is supposed to reference statutes that authorize the Agreement program to “seek injunctive relief, and refer licensees for criminal prosecution. The program should also consider authority to impose civil or administrative monetary penalties.” The statutes and explanations provided do not provide sufficient detail to support their applicability to this part of the application. You should clearly explain how the laws listed accomplish what this section of the application requests. For example, replace “18 VS § 1656 adds:” with “18 VS § 1656 authorizes the Department to seek injunctive relief.” Please revise your application to explain why each section of the cited statutes accomplishes what the section requires.

Added language regarding civil penalties in accordance with 18 VSA § 130, criminal penalties in accordance with 18 VSA § 131 and use of the assurance of discontinuation (AOD) in accordance with 18 VSA 125. Deleted references to statutes (18 VSA 1657 that did not specifically describe the authority of the Department to seek injunctive relief or to suspend or revoke a license for noncompliance to regulations. Placed emphasis on how 18 VSA § 1656 provides for injunctive relief and 18 VSA § 1653(b)(1) provides for suspension or revocation of licenses.

17. Section 4.1.2.1.b. states that “All required elements of the Radioactive Materials Program are carried out by the staff within the Radiological and Toxicological Sciences Program in the Department of Health; none are carried out by other agencies in the State of Vermont.” We note that the AG would be responsible for some enforcement activities involving agreement materials. Please revise your application to include the roles and responsibilities of the AG.

4.1.2.1.b has been revised to add the role of the Attorney General’s Office in supporting the Radiological and Toxicological Sciences Program in regulatory elements of the Radioactive Materials Program.

18. Section 4.1.2.1.c. states that “In accordance with 3 VSA § 800 – 849, Vermont’s Administrative Procedure, the Department makes rules to describe this authority for radioactive materials licensees.” This is an incorrect statement. The sentence should read “In accordance with 3 VSA § 800 – 849, Vermont’s Administrative Procedure, the Department makes rules to regulate radioactive materials licensees.” Please revise your application with the revised sentence.

Sentence in 4.1.2.1.c, was revised in accordance with the comment.

19. Section 4.1.2.1.c. states that “The subsections here incorporate the Suggested State Regulations (SSRs) as published by the Conference of Radiation Control Program Directors.” Some sections of the SSRs are applicable to agreement materials while others are not. Please revise your application to include those specific sections of the SSRs that the State plans to adopt.

4.1.2.1.c. was revised to state the specific Suggested State Regulations of the Conference of Radiation Control Program Directors being incorporated by reference for the regulation of radiation generating devices. These are SSRs Part B, Registration of Radiation Machine Facilities, Services and Associated Healthcare Professionals; Part F, Medical Diagnostic and Interventional X-Ray Systems; Part H, Radiation Safety Requirements for Non-Healing Arts Radiation Generating Devices; Part I, Radiation Safety Requirements for Particle Accelerators; and Part X, Therapeutic Radiation Machines.

20. Section 4.1.2.1.c. states that “Section IV is specific to Vermont Yankee Nuclear Power Station. It incorporates content directly from the Radiological Health Rule as amended January 1, 2010.” Please delete this sentence and any other sentences or sections in your application involving the Vermont Yankee Nuclear Station. A Section 274b. Agreement between the NRC and an Agreement State specifically excludes any oversight activities associated with production and utilization facilities since that authority is reserved to the NRC.

Deleted all references to Vermont Yankee decommissioning and regulation. Maintained references to Vermont Yankee as part of Vermont responsibilities as an offsite response organization in radiological emergency response.

21. In Section 4.1.2.1.d., the “Regulatory Requirements Program Elements of the Cross Reference of Program Elements” (Table 2) did not include the appropriate NRC reference for each of the Vermont references provided. We also note multiple incorrect citations listed in this section. Please revise this table to include the correct citations and the appropriate NRC reference for each Vermont legal element.

Table has been revised.

22. In Section 4.1.3, we have made some edits to the proposed Agreement to make it consist with our model Agreement. We will transmit these edits to you separately. Please incorporate these changes to the proposed Agreement.

Incorporated the model Agreement sent to us by NRC staff on April 5, 2018.

23. In Article II, No. 1, the proposed Agreement states, “The regulation of the construction, and operation of any production or utilization facility or any uranium enrichment facility.” Given that Vermont Yankee will soon be undergoing decommissioning, the NRC recommends that decommissioning be added to the standard language of the Agreement. The revised sentence would read “The regulation of the construction, operation, and decommissioning of any production or utilization facility or any uranium enrichment facility.” Please confirm that you agree with the revised sentence and incorporate this change into the revised Agreement.

Revised Article II to include the decommissioning of Vermont Yankee as regulatory authority retained by the Commission.

24. In Article III, the proposed Agreement states, in part, "... to include the additional areas specified in Article II, paragraphs six, seven, and eight," The NRC cannot relinquish authority over the items described in paragraph 6 of Article II. Please delete "six" from the draft Agreement.

Deleted "six" from paragraph numbers in Article II which the State can exert authority over should it apply for and obtain an Agreement with the Commission for such.

Section 4.2 – Regulatory Requirements

25. Section 4.2 states that “A complete copy of the Radiological Health Rule is attached as Appendix G. Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70, 71, 150.1, 150.2, 150.3, 150.11, 150.20, 170, and 171 of the CFR are incorporated by reference” and “Vermont’s regulatory requirements with significant transboundary implications are those of the incorporated Parts of the CFR.” These statements are not correct. The statements should indicate that 1) some sections in the first statement are reserved to the NRC; 2) the first statement should also include Part 61 and 3) many of the provisions referenced in the second statement are Compatibility Categories C, D, H&S or reserved to the NRC. Please revise your application to address these exceptions. We suggest the first statement be revised to state “A complete copy of the Radiological Health Rule is attached as Appendix G. Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61, 70, 71, 150.1, 150.2, 150.3, 150.11, 150.20, 170, and 171 of the CFR are incorporated by reference with the exception of those sections reserved to the NRC” and the second statement be revised to state “Vermont has adopted those regulatory requirements designated by the NRC with significant transboundary implications.”

Revised two statements in 4.2 as recommended. Did not add Part 61 to list of Parts of 10 CFR being incorporated because Vermont is not applying for an Agreement that includes licensure of low level radioactive waste land disposal.

26. In Section 4.2.1, the first paragraph should be revised to recognize that not all of the regulations noted are Compatibility Category A. The revised paragraph should state: “Vermont has adopted those NRC requirements designated as Compatibility Category A as defined in the Handbook to Management Directive 5.9. The NRC program elements in Category A are those that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. The program elements adopted by the State of Vermont are identical to those of the NRC and provide uniformity in the regulation of agreement material.” Please revise your application as noted.

Revised statement in 4.2.1 as recommended.

27. Section 4.2.2 does not provide sufficient information on Compatibility Category B regulations. We suggest that only the first three sentences be maintained and modified, and the balance of the section deleted. The revised section should state “Vermont has adopted those regulatory requirements that satisfy the criteria for Compatibility Category B as defined in the Handbook to Management Directive 5.9. The NRC program elements in Category B are those that apply to activities that have direct and significant transboundary implications. The program elements adopted by the State of Vermont are identical to those of the NRC and provide uniformity in the regulation of agreement material.” Please revise your application to incorporate the suggested changes.

Three sentences in 4.2.2 were revised as recommended, and the balance of the content was deleted.

28. Section 4.2.3 does not provide sufficient information on Compatibility Category C regulations. We suggest that the first paragraph be revised to state “Vermont has adopted those regulatory requirements that satisfy the criteria for Compatibility Category C as defined in the Handbook to Management Directive 5.9. The NRC program elements in Category C are those that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis.” Please revise your application to incorporate the suggested changes.

Revised two sentences in 4.2.3 as recommended.

29. Section 4.2.3 does not provide sufficient information on Category Health and Safety in your regulations. We suggest that paragraph be revised to state “Vermont has adopted those regulations that satisfy the criteria for the health and safety category as defined in the Handbook to Management Directive 5.9. These are NRC program elements that are not required for compatibility (i.e., Category D), but that have been identified as having a health and safety role (i.e., adequacy) in the regulation of agreement material within the State. Failures could lead to an exposure to an individual in excess of the basic radiation protection standards in Category A if its essential objectives were not adopted. Although not required for compatibility, the State adopts program elements in this category, based on those of NRC, because of particular health and safety considerations.” Please revise your application to incorporate the suggested changes.

Revised two sentences of 4.2.4 as recommended.

