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Agency of Human Services

November 6, 2018

Daniel Collins, Director
Division of Materials Safety, Security, State and Tribal Programs
Office of Nuclear Material Safety and Safeguards
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Collins,

This document addresses the comments made in a letter of March 27, 2018 from Kevin Williams and its enclosure entitled *Comments on Section 4.5, 4.6 and 4.7 of the Draft Vermont Application for an Agreement Dated September 15, 2017 (ML18017A174)*. To facilitate an efficient review, it addresses each general and specific comment as numbered in that enclosure.

This is the second of two letters that address the Nuclear Regulatory Commission (NRC) comments on the Draft Application for an Agreement Dated September 15, 2017. A first letter addressed NRC comments on Sections 4.3 and 4.4. Each of the letters is attached to the related revised sections of the Draft Application for an Agreement. NRC completed its review of Sections 4.1 and 4.2 of the Vermont Draft Application to Become an Agreement State with on August 7, 2018.

The revisions we made benefitted from the thorough review of NRC staff and multiple conference calls with NRC staff. The staff here in Vermont that addressed the NRC comments and prepared the revised sections of the Draft Application for an Agreement appreciate the extensive time, obvious effort and thorough attention of the NRC staff involved.

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

Thank you.



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Attachment: Address of NRC Comments on Sections 4.5, 4.6 and 4.7 of the Draft Vermont
Application for an Agreement

Address of NRC Comments on Sections 4.5, 4.6 and 4.7 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, Staff Attorney
David Englander, Senior Policy and Legal Advisor

The staff addressed four general comments and 103 specific comments. Note that considerable revision has occurred since the first draft and procedural citations may no longer be accurate. Comments have been inserted in the procedures to point to where the original NRC specific comment (in red and by Comment number) was addressed.

General Comments

1. In addition to responding to our comments on Section 4.5, we recommend the State also provide a summary of the overall enforcement process that the State will use. This summary is often a flow chart that describes the steps and roles of individuals or groups within the State involved in the routine and escalated enforcement processes.

Section 4.5 has been modified to reflect the overall enforcement process that the Vermont Department of Health (Department) will use implementing the Agreement State Program. This includes an Enforcement Flow Chart in Radioactive Materials Program Procedure (RMPP) 2.5 Enforcement, Escalated Enforcement and Administrative Actions.

2. In addition to responding to our comments on Section 4.7, we recommend that the State provide a summary of the overall allegation process that the State will use. This summary can also be of similar format as described above.

Section 4.7 has been modified with an in-depth description of how allegations are received, categorized and processed. This includes revision of RMPP 3.1 Management of Allegations with additional details from initial contact through allegation close out.

3. In Section 4.7, we noted that none of the three procedures reviewed included notifications to the licensing staff. The next revision of these procedures should include these notifications.

Section 4.7 has been modified to reflect the Vermont Department of Health's licensing and inspection staff roles. RMPP 3.1 Management of Allegations, RMPP 3.2 Incident Response, RMPP 3.3 Scrap Yard Incident Response and RMPP 3.4 Nuclear Materials Event Database Input have more detailed descriptions of staff notifications.

4. In several places in the application, the terms “Vermont,” “State,” “Department,” “Agency” and “RMP” are used interchangeably. In some cases, the use of the correct term is required depending on the particular circumstance or reference. For example, certain definitions referenced in a procedure may be used Statewide or only within the Department of Health. Please ensure that these terms are used consistently and as required depending on the particular circumstance or reference involved in the next revisions of these procedures.

Sections 4.5-4.7 and the associated RMPPs and Attachments have been revised to ensure consistency in terminology.

Specific Comments

Section 4.5 – Enforcement Program Elements

All comments in Section 4.5 reference the State’s Radioactive Materials Program Procedure Section 2.5, Revision 0, *Enforcement, Escalated Enforcement and Administrative Actions*

1. Section 1.2 states “Statutory authority for promulgation and implementation of enforcement procedures is contained in the Code of Vermont.” Please provide specific references to the Code that provide the statutory authority for enforcement in the Department of Health.

Statutory authority for promulgation and implementation of enforcement procedures is contained in Vermont law at 18 V.S.A. Chapter 3, in §§ 123-131. The language in Section 1.3 of RMPP 2.5 Enforcement, Escalated Enforcement and Administrative Actions in the draft application has been updated to include this statutory reference.

2. Sections 1.4.4 and 3.4.3.1 cites 18 V.S.A. § 125 as a reference for a written agreement between the violator/respondent and the Agency regarding an Assurance of Discontinuance (AOD). 18 VSA 125 states that the Commissioner has the authority to do this, not the Agency. Please clarify if this authority needs delegation from the Commissioner to the appropriate level within the Agency. In addition, please clarify section 3.4.3.1 where these type of orders are discussed.

18 V.S.A. §125 authorizes the Commissioner to enter into a written agreement with the violator, an Assurance of Discontinuance. 18 V.S.A. §104 authorizes the Commissioner to delegate any of his duties to members of the Department; however, in practice, the Commissioner does not delegate AOD authority.

3. Section 1.4.5 states that civil enforcement is “an action brought by the Agency in superior court pursuant to 18 V.S.A. § 130 due to a violation of Title 18 or any rules, permits, or orders issued by the health department or due to a public health hazard or public health risk.” It is not clear whether this also includes AODs. Please clarify in your application if violations of AODs can serve as the basis for bringing an action pursuant to 18 V.S.A. § 130.

Yes, violations of an AOD can serve as the basis for bringing a civil enforcement action pursuant to 18 V.S.A §130. 18 V.S.A. §130 reads “The Commissioner... may bring an action in Superior Court... to enforce the provisions of this title... including the terms of an assurance of discontinuance entered into under Section 125 of this title.”

4. Section 1.4.6 states that, “the agency’s authority to either escalate or mitigate enforcement sanctions to ensure that the resultant enforcement action appropriately reflects the level of Vermont’s concern regarding the violation at issue and conveys the appropriate message to the licensee and the public.” Please clarify if this authority reflects the State’s level of concern or the agency’s. It appears from the language at the beginning of the sentence that “Vermont” should be replaced by “agency”.

Section 1.5.6 has been modified to change “Vermont” to “Department.”

5. Sections 1.4.8 and 1.4.14 define “enforcement action” and “Notice of Violation.” Since the definition of “enforcement action” depends on the definition of “Notice of Violation”, used together. These definitions are not clear and problematic when applied. For example, the definition of “enforcement action” should also include orders, civil penalties, or potentially in the case of Vermont, a civil enforcement action. Please revise the definition of “enforcement action” in Section 1.4.8 to broaden the definition of enforcement action to include appropriate additional actions.

The definition of “enforcement action” in 1.5.8 has been clarified to be independent of a Notice of Violation.

6. In Section 1.4.9, the definition of “escalated enforcement action” is dependent upon the definition of “Notice of Violation” as noted in the previous comment. As also noted above, the use of these definitions together is problematic since “escalated enforcement action” is narrowly defined. Please revise the definition of “escalated enforcement action” in Section 1.4.9 to broaden its scope to include additional appropriate actions.

The definition of “escalated enforcement action” in 1.5.9 has been revised to be independent of a Notice of Violation.

7. Section 1.4.10 defines “hearing and judicial review” and describes the topics to be governed by such a proceeding. The review of exemptions is not included. Please indicate if exemptions are subject to such proceedings and if so, please revise the definition.

“Hearing and judicial review” in Section 1.5.10 has been defined to include “determining compliance with or granting exemptions from rules and regulations.”

8. Section 1.4.15 defines “pre-decisional enforcement conference” and describes what occurs at the conference. Please clarify the following items in this Section:

- a. This definition uses “RMP” whereas other definitions in this procedure use “Agency”. Please use only one term to ensure consistency and avoid confusion.
- b. The timing of the pre-decisional enforcement conference is not clear. It is not clear whether the conference takes place before or after the licensee has been notified that the Agency/RMP has identified a potential violation.
- c. The phrase “necessary for determination of enforcement action” is not clear. Please revise to clarify in terms of how violations are disposed by the enforcement actions described in Section 3.0 of this procedure.

The definition of Pre-decisional Enforcement Conference in 1.5.15 has been clarified, using the term Department for RMP, specifying when they occur and for what purposes.

9. In Section 1.4.17, please clarify if the term “legally binding obligation” is the same or different from the term “legally binding requirement.”

Yes, these terms having the same meaning. To clarify, all references to “legally binding requirement” have been changed to “requirement,” which is defined in 1.5.17. as “a legally binding obligation such as a statute, regulation, license condition, or order.”

10. Section 1.4.19 includes two types of willfulness. The NRC also includes two types of willfulness in their evaluations: deliberate misconduct and careless disregard. However, both “deliberate misconduct” and “careless disregard” have unique definitions and are separate concepts. We recommend including a definition for each in your procedure.

*The definition of willfulness has been taken from:
<https://www.nrc.gov/docs/ML1627/ML16271A446.pdf> and included in the definitions of section 1.5 of RMPP 2.5. The definition includes these two parts:*

Deliberate misconduct means an intentional act or omission that the person knows (1) Would cause a violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Department; or (2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

Careless disregard refers to situations in which an individual acts with reckless indifference to at least one of three things: (1) the existence of a requirement, (2) the meaning of a requirement, or (3) the applicability of a requirement. Careless disregard occurs when an individual is unsure of the existence of a requirement, the meaning of a requirement, or the applicability of the requirement to the situation, but nevertheless proceeds to engage in conduct that the individual knows may cause a violation. Although aware that the action might cause a violation, the individual proceeds without first ascertaining whether a violation would occur.

11. In Section 1.4.20, the definition of wrongdoing appears to be redundant when compared to the definition of willfulness. Please revise this definition to make it distinct from the definition of willfulness.

The definition of “Willfulness” has been included as definition 1.5.21 and distinguishes between “Deliberate Misconduct” and “Careless Disregard”. The definition of wrongdoing has been deleted.

12. Section 2.1.1 defines neither “routine inspections” nor “special inspections.” Please include definitions for both types of inspections in this procedure. In addition, please ensure these definitions are consistent with the application’s inspection procedures.

Section 2.1.1 has been revised to include a reference to the definitions of “routine inspections” and special inspections” in section 1.5. This is also reflected in the remainder of the Application’s inspection and allegation procedures.

13. In Section 2.2.4, please revise and clarify this subsection to align with the revision of “pre-decisional enforcement conference” as noted in Comment 8b above.

Section 2.2.4 has been revised to reflect the timing of a pre-decisional enforcement conference.

14. In Section 2.3.3, please revise and clarify based on the following:

- a. 10 V.S.A § 1657 does not address assistance; this section of the statute specifies the penalties that can be applied upon conviction.
- b. The request for assistance appears inconsistent with the rest of Section 3.3. It is not clear whether this request contemplates seeking assistance from the Commissioner or a local board of health.
- c. The civil penalties in the two statutes cited in this section are very different. It appears that the statutory references are not appropriate.

We have removed the incorrect citations and clarified this section.

15. Section 3.1.1 provides a high-level description of a notice of violation (NOV). Please revise this section to provide additional detail on the content to be included in the NOV beyond what is described in section 1.4.14. Section 2.3.3 of NRC’s Enforcement Policy may be useful in responding to this comment.

The description of a Notice of Violation in Section 3.1 of RMPP 2.5 has been clarified and expanded.

16. In Section 3.1.4, the timing for issuing the revised NOV is not clear. It appears that the Agency is issuing “apparent” violations to the licensee first and then issuing the “final” or “revised” violations after the Agency determines whether escalated enforcement action is warranted or not. Please revise this section to clarify the process.

The description of an NOV in 3.1 clarifies the timing and includes allowance for revision if the determination is later made that the violations were Severity Level I, II, or III, necessitating an escalated enforcement action.

17. In Section 3.2.1, it is not clear from the description regarding the timing of the NOV being issued or the pre-decisional enforcement conference. In addition, and as noted in Comment 8a above, “VDH” is indicated as one of the groups that participates in determining the appropriate enforcement action. Please revise this section to clarify the steps and the roles of various groups within the State in the process surrounding the pre-decisional enforcement process.

Section 3.2 of RMPP 2.5 has been revised to clarify the timing of pre-decisional enforcement conferences and the Department role and purposes.

18. Section 3.2.4 describes an immediate effectiveness order as a type of escalated enforcement action. These are two different things. Escalated enforcement action relates to the severity of the violation while an immediate effectiveness order depends on other circumstances described later in the procedure. For example, the State could use immediately effective orders to protect public health and safety or in response to a willful violation. Please revise the section to clarify the differences between immediately effective orders and escalated enforcement actions.

Section 3.2.4 has been edited to clarify that an escalated enforcement action may come in the form of an emergency order if the violation requires immediate action to protect public health and safety. There is no longer any reference to an immediately effective order.

19. Section 3.3.2 provides criteria that can be used to determine a civil penalty. Please provide any additional guidance that specifies when civil penalties would be appropriate and for what severity levels or provide reference to the appropriate regulations or statutes.

Section 3.3.2 has been revised to include that Civil penalties may be levied pursuant to 18 V.S.A. §130 for any violation of title 18, or rules, permits or orders issued pursuant to the title.

20. Section 3.3.3 provides guidance on licensee management involvement in a violation being considered for civil penalty. Since this section describes enforcement discretion as a general matter, it would be more appropriate to include this discussion in Section 3.7 (Enforcement Discretion) of the procedure. In addition we offer the following revision to clarify the statement:

“If licensee management is directly or indirectly involved in the violation, an increase in the amount of the penalty may be imposed. However, if licensee management is not involved in the violation, that information alone shall not be used to mitigate the penalty sought by the Agency.”

Discussion of enforcement discretion has been removed from section 3.3.3 and section 3.7 has been revised as recommended and the above language incorporated accordingly.

21. For Section 3.3.4, we offer the following revision to the statement to narrow the scope to penalties to maintain it in this part of the procedure. In addition, if this section relates to discretion, then this information should be included in Section 3.7 of this procedure.

“The RMP exercises enforcement discretion to mitigate the penalty, but only if the RMP is satisfied that such discretion will not adversely affect health and safety.”

This section has been revised as recommended and incorporated in Section 3.7.

22. Section 3.4.3.2 describes license condition orders. Please clarify whether this order would also amend the license condition.

Section 3.4.3.2 has been revised accordingly.

23. Section 3.4.3.2 (should be 3.4.3.3) describes suspension orders. The following comments are provided:

- a. Please clarify whether a suspension order is meant to be temporary, as opposed to a revocation order, which is permanent.

Section 3.4.3.3 has been revised, “a suspension order is temporary. A revocation order is permanent.”

- b. The following sentence contains a number of negatives: “Normally, a licensed activity is not suspended nor is suspension prolonged for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken or planned.” We recommend that the sentence be phrased in a positive manner to improve its clarity.

Section 3.4.3.3 has been revised to improve clarity..

- c. The fourth bullet that describes the use of suspension orders states: “for any reason not addressed above for which suspension of license activity is legally authorized.” Please clarify this statement to specify what is authorized.

This statement has been removed and replaced with language from the Department’s statutory authority and incorporated into Section 3.4.3.3.

24. Sections 3.4.3.2, 3.4.3.3, 3.4.3.4 (should be 3.4.3.3, 3.4.3.4 and 3.4.3.5) provide descriptions for using suspension, revocation, and cease and desist orders. It is not clear

when a suspension order is more appropriate than a revocation order or a cease and desist order since it difficult to follow the differences between them. For example, similar circumstances are used for both suspension and revocation orders. Please revise the description of these orders to clarifying the circumstances under which each is used.

18 V.S.A. §123 does not delineate when suspension vs. revocation is appropriate; the determination is made on a case-by-case basis.

25. Section 3.4.3.5 (should be 3.4.3.6) describes an “emergency order.” Please revise the description of this order to clarify the difference between an emergency order and an immediately effective order.

Section 3.4.2.4 has been edited to clarify that an escalated enforcement action may come in the form of an emergency order if the violation requires immediate action to protect public health and safety. There is no longer any reference to an immediately effective order.

26. Section 3.4.3.6 (should be 3.4.3.7) describes orders to unlicensed persons. The following comments are provided:

- a. Please revise the section to cite the appropriate State regulations that give authority to issue unlicensed person orders.

Section 3.3.3.7 has been revised to reflect that Health Orders can be issued to any party creating a public health hazard or to correct a violation of Title 18 or any rules promulgated thereunder, regardless of whether the party is licensed.

- b. The term “deliberate misconduct” is included. The term was not defined in Section 1.4. Please include a definition of “deliberate misconduct” in Section 1.4 of this procedure. As noted in Comment 10 above, we recommend including a definition for deliberate misconduct.

Section 1.5 has been revised to include a definition of “deliberate misconduct” (1.5.5).

27. Section 3.5.3 describes notices of nonconformance. The following comments are provided:

- a. The section initially states it applies to “contractors” but later, the section describes the notice as a request to “non-licensees”. It appears that the notices can apply to any non-licensee, not just contractors. Please revise to clarify whether the notices apply to any non-licensee.
- b. The section describes “...commitments which have not been made legally binding requirements by VDH.” Please describe what is meant by “commitments”.
- c. Nonconformance can be used in context of Part 21 requirements for defects of components used for licensed activities, including devices with agreement

materials. Since the State of Vermont would not have any manufacturers under the Agreement, please clarify the circumstances wherein the State would use this enforcement mechanism.

Notices of Non-conformance have been deleted.

28. In Section 3.5.5, please revise this section to define and provide a reference for the “clear inspection” form used by inspectors.

Reference to the Form 591M has been deleted. The form is described in the inspection procedures.

29. Section 3.6.1 describes enforcement actions against non-licensees. The following comments are provided:

- a. Please revise this section to specify the regulations or statutes that provide the State the authority to enforce against non-licensees.

The statutory citations have been added to section 3.6.1

- b. Please revise this section to remove all reactor licensing terms and include only those licensing terms that apply to agreement materials.

Section 3.6.1 has been revised to remove references to certificates of compliance, early site permits, and standard design certificates.

- c. The term “deliberate misconduct” is used in this section and it is not defined in Section 1.4. Also see Comments 10 and 26b.

Section 1.5 has been revised to add the definition of “deliberate misconduct”.

30. Section 3.6.3 describes enforcement actions against non-licensees. The following comments are provided:

- a. The term “contactors” is used in this section whereas it appears this section applies to any non-licensee (also see Comment 27a above). Please revise the section to clarify whether the section also applies to non-licensees.
- b. In Section 3.1.1, it appears as though an NOV only applies to a licensee. Please revise 3.1 to include non-licensees in addition to licensees.
- c. A broad range of statutes is provided at the end of this section making it difficult to identify the authority to issue NOVs to non-licensees. Please revise the section to provide specific citations.

Revised to clarify that the Department’s enforcement authority extends to all individuals violating title 18 statutes or rules, whether licensed or not.

31. Section 4.1 uses the terms “willful” and “willfully.” As discussed in comment 10 to this letter, “willfulness” can encompass both deliberate misconduct and careless disregard. As written, the section is confusing with regard to the use of willful. For example, it would appear that an individual is being willful by refusing to correct a minor violation. It is not clear if the State actually means careless disregard in this case. Please revise and clarify this section by appropriately applying the concepts of deliberate misconduct and careless disregard.

More information provided to clarify the roles of careless disregard, repeated violations and deliberate misconduct in the disposition of inspection findings.

32. Section 4.1.1.2 states, “If inspection findings result in any Severity Level IV violations (willful or both willful and repetitive), then inspection personnel shall refer the finding to the RMPM for review and determine the need for prompt escalated enforcement action.” Please revise the section to clarify that escalated enforcement will consider these violations at a Severity Level III.

Language added relative to elevating willful and both willful and repetitive Level IV violations to Severity Level III.

Section 4.6 – Technical Staffing and Training

33. Section 4.6.1 states that “staff devoting the most time to the Radioactive Materials Program are the Radiological and Toxicological Sciences Chief, the Senior Radiological Health Specialist and the Radiological and Toxicological Scientist.” This sentence suggests that others might devote time to the agreement program as well. Please revise this sentence to clarify whether only the three listed position are assigned to the agreement program. If there are other individuals who will routinely work on the agreement program, please revise Section 4.6 to include those individuals.

Language has been added to specify Health Department staff who support the Radioactive Materials Program administratively, for public communications, compliance and enforcement, legal counsel and emergency response.

34. Table 3 (staff needs analysis) of Section 4.6.1a, breakdown on the estimated number of licensing actions and amount of time it would take to complete these actions, is provided. Based on NRC staff experience with other Agreement States with similar number of licenses, the amount of time you estimated to complete certain licensing actions appears low. Please review the assumptions made for licensing and inspections to ensure that the estimates have allowed for sufficient time for the review of a variety of licensing actions and inspections.

The staff needs analysis was reconducted using historical averages of licensees, provision of sixteen hours per licensing activity and estimated inspection numbers based on frequencies required by priority codes assigned to program codes. Tables 3, 4 and 5 have been revised for this re-analysis.

35. Section 3.1.3.1 of Radioactive Materials Program Procedure Section 5.1, Qualifications and Training states that the trainee prepares for, conducts, and records findings for assigned parts of the inspection twice under the supervision of two different qualified inspectors. Given the small staff in Vermont, this may not be feasible. This section also indicates that a trainee will prepare and conduct an inspection under the observation of the Radiation Control Program Director (RCPD) or designee. We suggest that only the RCPD perform this activity given the small size of the program. We recommend that this section be revised to address these two comments.

Section 3.1.3.1 has been revised accordingly.

36. Section 3.2 of Radioactive Materials Program Procedure Section 5.1, Qualifications and Training the qualification process to become an inspector and license reviewer is described. Inspection Manual Chapter (IMC) 2800 requires inspectors going through qualification to perform licensing actions and for license reviewers going through qualification to go on applicable inspections. Vermont is missing equivalent requirements. Please revise this section of the procedure to include those requirements.

NRC Inspection Manual Chapter 1248 and its Appendices A, B and F (as referenced) are used as the model for Vermont Radioactive Materials Program staff qualifying as a license reviewer and inspector.

37. Attachment 5.1-1 of RMPP 5.1 provides a worksheet on continuing education and training. It is not clear if this worksheet is meant to satisfy the requirement for 24 hours of refresher training required every two years by IMC 1248. Additional information can be found in the State and Tribal Communication “Refresher Training for Agreement States (STC-15-069).” The requirement for refresher training should be included in the qualification and training procedure. Please revise the procedure to specify the requirement for refresher training and revise the worksheet to include additional opportunities for meeting the refresher training requirements.

RMPP 5.1 and Attachment 5.1-1 have been revised to include procedural guidance on Refresher Training in accordance with State and Tribal Communication “Refresher Training for Agreement States (STC-15-069).”

38. Section 4.6.2 states that “the Vermont Radioactive Materials Program will be an on-going concern, so planning for staff replacement is essential.” There appears to be a missing word in this sentence. It appears that the sentence should say “the Vermont Radioactive Materials Program *staffing* will be an on-going concern, so planning for staff replacement is essential.” Please revise this sentence to clarify its intent.

This statement is no longer in Section 4.6.1.

Section 4.7 – Event and Allegation Response Program Elements

Allegations (RMPP 3.1 – Management of Allegations)

39. Section 1.1 states that "at any time, the need for criminal investigatory capacity is required, contact the Local Law Enforcement Agency (LLEA) and/or the Vermont State Police and/or other state and federal agencies such as the Federal Bureau of Investigation (FBI), as appropriate." According to the SA-700, the Agreement State applicant "should have procedures for contacting appropriate authorities when needed." The procedure does not provide criteria for determining when "criminal investigatory capacity" is required. Please revise the procedure to include criteria for determining when criminal investigatory capacity is needed and provide a process to contact the appropriate law enforcement agency.

Sections 1.1 and 3.1.2 have been revised to provide criteria for "criminal investigatory capacity" requirements.

40. Sections 1.3 and 4.1 include a section on "hardcopy files." The purpose of this section is not clear. It appears to indicate that allegations files will only be stored as hard copies. Since reports and documents will be processed on computers, it is not clear how the will State protect those electronic documents while they are under development. Please revise these sections to either incorporate them elsewhere in the procedure or revise this section to provide a clear purpose. The revision should be clear on the appropriate handling of hard copy and electronic versions of allegations records.

Section 1.3 has been revised to clarify the handling of allegation files. All documents are maintained only electronically where only Radioactive Materials Program staff have access. Section 4 no longer exists.

41. Section 1.4.6 states that confidentiality is granted in accordance with state procedures. Please revise this section to identify the state procedures for granting confidentiality.

Since Vermont is incorporating 10 CFR 30.7 by reference, the Radioactive Materials Program will provide confidentiality via 1 V.S.A. § 317 (c)1.

42. Section 1.4.7 states that an investigation is a "special activity" used by the program to evaluate and resolve an allegation. It is unclear as to whether a "special activity" means that the State will gather testimonial, documentary and physical evidence. Please revise this procedure to provide more detail on what is meant by "special activity" to clarify this definition.

Section 1.4.7 has been revised to eliminate the term special activity in defining investigation.

43. In Section 1.4.8, the definition of an overriding safety issue implies that the allegation has already been evaluated and determined to be an immediate threat. It is unclear whether this definition includes allegations that could be an immediate threat, but have not been thoroughly vetted. We recommend using the definition of "overriding safety issue" in Management Directive 8.8: "An issue that may represent an actual or potential immediate threat to public health, safety, or security..." Please revise the definition to include both allegations that have been evaluated and those that have been not fully vetted.

Section 1.4.8 has been revised to address allegations and overriding safety issues and allegations not fully vetted.

44. Section 1.4.10 states that allegation files should be “locked” when not in use and controlled on a need-to-know basis. The definition should indicate an expectation regarding the type or nature of the “lock” to be used. It is not clear if the State expects these files to be kept in a pad locked file cabinet? Please revise the definition to provide an expectation on how allegation files should be secured when not in use.

Section 1.4.10 and 3.2 have been modified to clarify the methods in which allegation files are secured.

45. Sections 1.4.11 and 1.4.12 provide definitions of willfulness and wrongdoing. Please revise the definitions as described in Comments 10 and 11 above to be consistent with the application’s enforcement procedures.

Section 1.4.11 has been revised to define willfulness and wrongdoing consistent with RMPP 2.5 Enforcement, Escalated Enforcement and Administrative Actions.

46. Section 2.1.1 states that any member of the RMP staff is responsible for recording an initial allegation. The procedure does not specify how an allegation may be received. Allegations can be received by telephone, email, in-person, through the news, etc. Please revise the procedure to define how an allegation may be received and recorded from the various forms of communication modes. The revision should be reconciled with the hard copy restrictions in this procedure and with appropriate attachments to this procedure.

Section 2.1.1 has been revised to describe the various methods in which allegations may be received by the department.

47. Section 2.2.1 states that the Lead Investigator (LI) “performs the investigation of the allegation and upon finding of an incident through an investigation of the allegation, the LI would be responsible to respond immediately, take actions to mitigate the incident, and notify the RMPM immediately of the incident and request assistance.” Please revise this section to:

- a. Define the term “incident” and reference the term with your application’s inspection procedures; and
- b. The LI’s response will be based on its significance since not all incidents require an immediate response.

Section 2.2.1 has been modified to better relate to allegation response, and not incident response which is guided elsewhere in the procedure. Varying response times commensurate with the allegation is also addressed.

48. Section 2.3.1 references “the Allegation Management Program (AMP)”. The AMP is not defined or mentioned elsewhere in this procedure. Please revise your procedure to include the AMP or revise this section to delete this reference.

References to an allegation management program have been deleted.

49. Section 2.4.1 states that the RCPD “approves actions to be taken in response to allegations.” However, Section 2.2.1 states that the LI has the authority to take immediate action to mitigate an incident discovered as the result of an allegation. Please revise Section 2.4.1 to clarify the responsibilities of the RCPD.

Section 2.4.1 has been revised to clarify the role of the RCPD as related to allegations.

50. Section 2.4.2 authorizes RCPD to release the identity of allegeders or confidential sources. Please revise this section to reference Section 3.2.2 of this procedure, which provides conditions for the releasing the identity of allegeders or confidential sources.

Section 2.4.2 has been revised to reference section 3.2.

51. In Section 3.1.1, the description appears to indicate that the allegation can only come via the telephone. As noted in Comment 46 above, allegations can be received in a variety of communication modes. Please revise this section to be consistent with Comment 46.

Section 3.1.1 has been revised to address the various methods in which allegations may be received by the department.

52. Section 3.1.2 states “Allegations regarding suspected improper conduct by a RMP employee do not fall within the scope of this procedure and shall be promptly reported to the employee’s immediate supervisor.” Since this type of conduct is not an “allegation” as defined in Section 1.4.2 of this procedure, the word “allegation” should not be used here. Also, this information would be more appropriately placed in the definition of “allegation” above. Please revise this sentence to state “Reports of suspected improper conduct...”

This language was deleted. Reports of suspected improper conduct by RMP employees do not fall within the scope of this procedure and shall be reported to the employee’s immediate supervisor.

53. Section 3.1.5 states that “all documentation pertaining to an allegation shall be securely stored.” As noted in Comment 44, the definition of secure files should indicate an expectation regarding the type or nature of the lock to be used. Please revise Section 3.1.5 to align with the revised definition in Section 1.4.10 to provide an expectation on how allegation files should be secured when not in use.

Section 3.1.5 and 1.4.10 have been revised to address the security of allegation files.

54. Section 3.1.6 indicates that any staff member can terminate the allegation process if the allegation is determined not to be credible. Although the NRC does not have a comparable section in Management Directive 8.8, the State should consider if such a determination should be left to one staff member. If the State determines this section is needed, please revise this section to include a process and the criteria for determining an individual's credibility.

Section 3.1.6 has been revised to clarify the disposition of an allegation's credibility.

55. Section 3.2 includes the procedures for protecting and disclosing an alleged's identity and other sensitive information. The procedure does not define "other sensitive information." Please revise the allegation procedure to include a definition of sensitive information and any additional measures needed, if any, to protect it.

Section 3.2 has been modified to clarify sensitive and confidential information.

56. Section 3.2.1 describes the process for maintaining confidentiality. Please revise this section to address the following items:

- a. This section states "Indicate all information deemed sensitive as confidential." Since confidential is not defined elsewhere in the procedure, the meaning of this statement is unclear. Please revise the procedure to include a definition of "confidential."

Section 3.2.1 has been modified to clarify sensitive and confidential information.

- b. This section states "Prior to terminating initial contact (see 3.1) with an alleged..." This appears to presume that State staff is communicating with the alleged in the initial contact. As noted in Comment 46 above, allegations can be received in a variety of communication modes. Please revise this section to address the possibility that an allegation can be received in a number of ways. As noted under the second General Comment, we recommend that the State include an overview of their allegation process as part of response to this letter.

The various means in which allegations are received has been expanded elsewhere in this procedure, and the notion of required contact with alleged has been deleted.

- c. In the third bullet for this section, the beginning of the sentence should be revised to state "Inspection reports and correspondence *with...*" to indicate that any correspondence going back and forth should not contain sensitive information.

Changed as recommended.

57. Section 3.2.2 provides criteria for disclosing the identity of an alleged or of other sensitive information. Please revise this section to address the following items:

- a. It appears that the statement before the bulleted criteria is missing the following phrase: “any of the below criteria are met:” Any one of the criteria can be used as a basis to disclose the identity or sensitive information.

Section 3.2.2 has been revised to refer to criteria in Attachment 3.1-2 which clarifies the disclosure criteria.

- b. The citation of statute 1 VSA § 315 in the last bullet of this section is a statement of policy and does not mandate the circumstances for disclosure. Please provide the appropriate statute or regulation that provides the authority for disclosure of alleged or for other sensitive information.

Section 3.2.2 has been revised to refer to criteria in Attachment 3.1-2 which clarifies the disclosure criteria and provides citation to 1 V.S.A. § 315.

58. Section 3.2.3 states that approval to disclose an alleged’s identity or other sensitive information is made by the RCPD. Please indicate if the RCPD is the appropriate level of management to approve the disclosure and is consistent with Department policy or State law. If not, please revise to indicate the appropriate approval level of staff or management.

This paragraph has been revised to include consultation with the Environmental Health Division Director and Department Legal Division.

59. Section 3.2.4 states that information on the protection of an alleged’s identity will be provided in writing if the allegation is received by other means than by telephone. Please revise this section to be consistent with Comment 46 and the various modes that an allegation can be received.

Revised for clarity.

60. Section 3.3.2.5 addresses handling multiple allegations from the same alleged. This section does not provide sufficient details on how the State would handle multiple allegations. Please revise this section to include additional details on how to handle this situation. We recommend that the response include the identification of all allegations in order to ensure the allegation review addresses all the alleged’s concerns.

3.3.2.5 has been revised to address these comments.

61. Section 3.4 discusses the process to refer allegations. Please revise this section to address the following items:

- a. This section states that “If an allegation raises an overriding safety issue, the substance of the allegation will be released to the licensee, regardless of the need to protect the identity of the alleged or the sensitive information, if release of the information is necessary to protect public health, safety, or security.” There are two standards for release in this sentence. It appears that the State intended to

state: “If an allegation raises an overriding safety issue, the substance of the allegation will be released to the licensee, regardless of the need to protect the identity of the alleged or the sensitive information.”

Revised 3.4 to address these comments.

- b. If an overriding safety concern is raised, it would appear that the 30-day waiting period would be automatically waived regardless of whether the alleged or confidential source could be contacted or not.

Revised 3.4 to address these comments.

- 62. In Section 3.4.1, the discussion on the prohibition on referrals does not address 1) conflicts with public release criteria (i.e., overriding safety issue); and 2) allegations involving willfulness. Please revise this section to address these issues.

Revised 3.4.1 to address these comments.

- 63. Section 3.4.3.4 references factors in Sections 3.3.1, and 3.3.2. It is not clear how these sections are relevant to the decision making process. Please revise this section to correct the references or provide more information on why these sections are relevant.

Revised to refer to appropriate sections of the procedure.

- 64. In Attachment 3.1-2 to RMPP 3.1, the list provided in the nondisclosure statement does not match the list provided in Section 3.2 of the procedure. Please revise the list in the Attachment 3.1-2 with Section 3.2 of the procedure to reconcile their contents.

Revised to refer to Attachment 3.1-2 only, not another list in the procedure Section 3.2.

- 65. In Attachment 3.1-4 to RMPP 3.1, the first paragraph states, in part, “the alleged may request and reasonably expect that his/her identity will be protected as confidential information as long as an overriding safety issue has not been determined to exist.” This statement is not consistent with the Section 3.2 of the procedure. Please revise this sentence to reconcile with the procedure. For example, the procedure could be revised to state “the alleged may request and reasonably expect that his or her identity will be protected as confidential information as long as the criteria in section 3.2 of this procedure have been met.”

Attachment 3.1-4 has been revised in accordance with this comment.

- 66. Attachment 3.1-4 to RMPP 3.1, item 2 states that the allegation files will be maintained in a locked filing cabinet. This section may require revision based on the response to Comment 44.

Attachment 3.1-4 has been revised in accordance with this comment.

67. Attachment 3.1-4 to RMPP 3.1, item 4 states that if email must be used, consider discussing the issue(s) without including identifying information. If the State receives an allegation by email, that email may include identifying information. Please revise this item to be consistent with the revisions requested by Comment 46.

Attachment 3.1-4 has been revised in accordance with this comment.

68. The Acknowledgement Letter to Alleger states, in part, “During this investigation, it was able to be determined that you...” We recommend the use of “RMP staff” or “we” instead of “it was able to be” to add clarity to the sentence.

Attachment 3.1-5 Acknowledgement Letter to Alleger has been revised in whole for better clarity.

Incident Response (RMPP 3.2 – Incident Response)

69. Section 1.1 states that the procedure applies to “non-nuclear power plant” incidents involving radioactive materials. This statement requires clarity given the State’s broad responsibilities with regard to emergency response. Since the intent of this procedure is to address responsibilities under the Agreement, it is recommended that the sentence be revised to remove the phrase “non-nuclear power plant.”

Deleted reference to nuclear power plants.

70. Section 1.1.6 states that the procedure “establishes guidelines for managing, including impounding, radioactive material that is, or could be, a threat to public health and safety.” Since all radioactive materials fall into the category of “could be a threat to public health and safety,” depending on how the materials are stored, handled, or transported, the type of circumstances that would apply to this procedure need to be provided. Please revise this section to clarify the type of circumstance that would apply.

Section 1.1.6 has been revised to include voluntary report on lost and stolen radioactive material, as well as situations that cannot be specifically tied to a reporting requirement (such as “found” sources that were not reported as lost, materials contaminated with radioactive material and landfill alarm trips).

71. Section 1.1.7 states that the procedure describes management options for handling radioactive material. This statement appears to be redundant with Section 1.1.6. Recommend that the section be deleted or revised to specify management options for handling radioactive materials incidents.

Sections 1.1.6 and 1.1.7 have been deleted as the remaining content is sufficient.

72. Sections 1.3 “Hardcopy Files” and 4.0 “Records” have no apparent purpose. A similar comment for the allegation procedure was provided above (see Comment 40). Please revise these sections to clarify their purpose.

Sections 1.3 and 4.0 have been defined better.

73. Section 1.4.5 defines the term “incident” as an event that may have caused, or threatens to cause conditions in certain NRC regulations. The list of events is not complete. Please revise this definition to reference the list of regulations in NMSS Procedure SA-300, Appendix A.

Section 1.4.5 and Attachment 3.2-4 provide better examples of incidents and their reporting requirements and are modeled after SA-300 Appendix A.

74. Section 1.4.6 defines the term “immediate notification.” The definition does not list the circumstances in which the immediate notification is required nor does it provide a time period required for the immediate notification. Please revise this definition to clarify the circumstances that are required and the time period required for immediate notification.

Immediate notification is defined as within 4 hours or less.

75. Section 1.4.8 does not have a complete definition of notice of violation. Please revise to provide a complete definition of notice of violation that is consistent with Comment 5.

*Definition revised to be consistent with definitions used elsewhere, as in RMPP 2.6 **Materials Inspection Checklists and Definitions.***

76. In Section 1.4.12, the definition of “significant event” requires “prompt notification” of the incident. It is not clear the difference between “prompt notification” and “immediate notification” and what the time period is involved for a prompt notification. Please revise this section to clarify between “immediate” and “prompt” notifications and provide a time period required for prompt notification.

Revised to define as immediate notification (4 hours or less) or within 24 hours, eliminating the term “prompt”.

77. Sections 1.4.16 and 1.4.17 provide the definitions of willfulness and wrongdoing. Please revise the definitions as described in Comments 10 and 11 above to be consistent with the application’s enforcement and allegation procedures.

*Definitions revised to be consistent with definitions used elsewhere as in RMPP 2.6 **Materials Inspection Checklists and Definitions.***

78. Section 2.3.6 does not contain a complete list of reportable events. As noted in Comment 73 above, a complete list of reportable events can be found in SA-300, Appendix A. Please revise this section to be consistent with the revised definition of incident.

Section 2.3.6 has been deleted. Attachment 3.2-4 as referenced in Section 1.4.5 provides better examples of incidents and their reporting requirements and are modeled after SA-300 Appendix A

79. Section 2.3.7 indicates that abnormal occurrences should be identified using the criteria listed in the SA-300. There is no definition of “abnormal occurrence” in Section 1.4 of

this procedure. Please revise Section 1.4 to include a definition of “abnormal occurrence” that is consistent to the definition used RMPP 3.4.

Definition of abnormal occurrence provided in Section 1.1.1.

80. Throughout Section 3.0, there is an assumption that the State would respond immediately to all events. If this is the State’s intent, please clarify how the State would handle two incidents simultaneously. If this is not the State’s intent, please revise this section of the procedure to incorporate a graded approach to responding to radioactive materials incidents.

Prioritization and coordination of response to multiple simultaneous incidents is described in Section 3.2.

81. In Section 3.1.1, there is an assumption that incidents will only be reported by telephone. Incidents may be reported via other communication modes. Please revise this section to provide a generic approach for the receipt of an incident. For example, posting the information listed in Section 3.1.1 on the Program’s webpage to facilitate reporting incidents electronically maybe useful.

Section 3.2 revised to include the variety of means by which incidents are reported.

82. Section 3.1.2 discusses the reporting of security event involving Category 1 and 2 quantities. This section does not specify the circumstances, the timing of such reports, or references to Part 37. The NRC should also be added to the list of contacts at the end. Please revise this section to provide sufficient information for the reporting of Part 37 security related events.

Section 3.2.2 has been revised to reference reporting requirements of 10 CFR 37.57.

83. Section 3.1.3 discusses notification of specific state personnel or organizations. The first sentence in the section suddenly ends and appears not to include all the intended information. Please revise this section to include all information and specify if the phone number provided is answered 24/7.

Section 3.2.3 has been revised to include missing information.

84. Section 3.1.4 provides the criteria to determine the level of immediate response for incidents is. Not all incidents will require immediate response. Please revise this section to provide a more graded approach to incidents and clarify what type of incidents would require immediate response and what types of incidents could be responded at some later time.

The procedure as a whole has been revised modeling after SA 300, differentiating responses based on risk and safety significance.

85. Section 3.1.5 specifies that there is an assumption that the incoming event would always be by telephone. Please revise the procedure as noted in Comment 81 to provide a more generic approach.

Section 3.2 has been revised to note the variety of means by which incidents may be reported.

86. Section 3.2.7 specifies that materials being transported for analysis or storage should be packaged to meet DOT requirements. Radioactive materials must be transported according to all DOT requirements or be transported in accordance with specific DOT exemptions. Please revise this section to change “should” to “must.”

“Should” changed to “must”.

87. Section 3.3.1 uses the term “investigator.” This term is not defined in the responsibilities section of this procedure. Please revise this procedure to include the term investigator or revise Section 3.3.1 to clarify who is responsible for the preparation of the report.

“Investigator” changed to “Radiological Health Specialist assigned to the incident”.

88. Section 3.3.3 specifies that the incident report must be forwarded to the Nuclear Materials Event Database (NMED) and to the NRC. The information provided to NMED must be done in accordance with SA-300. Please revise this section to specify the notification and follow-up requirements for events in accordance to the requirements in SA-300.

Revised per comment.

89. Attachment 3.2-2 to RMPP 3.2 provides questions and answers on radiological incident response. Please clarify how this attachment will be used and distributed.

Described in Section 3.2.5.

90. Attachment 3.2-4 to RMPP 3.2 appears to be guidance for VDH licensees to report incidents to the State. Please revise this attachment to address the following items:

- a. If this attachment is intended for licensees, please remove all references to NMED since that system is for use only by the NRC and the Agreement States. All licensee incidents must be reported to the State.

Deleted references to NMED.

- b. The subsequent sections in this attachment include numerous omissions of reporting requirements (see Comment 73). For example, there are no reporting requirements listed for Parts 34, 37, and 70. Please revise the entire attachment using Appendix A of SA-300 as guidance. In addition, the NUREG-1556 licensing guidance for specific licensed activities may be a useful guide since

each volume of the NUREG includes a comprehensive table on the type of incidents that require reporting.

Reporting requirements revised to be more inclusive of incidents, including those related to 10 CFR 34 and 37.

Incident Response (RMPP 3.3 – Scrap Yard Incident Response)

91. Section 3.2 provides a reference section that is not found in other procedures. Please revise this section to address the following items:

- a. The citation for the impoundment provision in statute is provided (18 VSA 1653(b)(7)(B)) in this procedure but not in other procedures where this is discussed. Please clarify why only the scrap yard incident response procedure includes this reference.

18 VSA 1653(b)(7)(B) is referenced in other procedures, as well as in statute and regulations.

- b. One of the references listed is 18 V.S.A. Chapter 6 Subchapter 5 “Vermont Radiation Protection Regulations.” On the State’s website, this is listed as “Chapter 5: Cancer Clinics.” Please clarify if this is a reference to a proposed chapter of VSA or revise to provide the correct citation.

Revised to reference Radioactive Materials Rule.

- c. Please revise to specify the US DOT Special Permit number.

SP 10656 added.

92. Sections 4.1 through 4.3 and 3.3 through 3.5 and the subsections to these sections are incorrectly numbered in the procedure. Please revise the numbering of the procedure.

Numbering throughout has been corrected.

93. Section 4.2.5 (incorrectly listed as 2.3.5) appears to be missing a word. It appears that this should read “advises the Radiation Control Program Director *that* legal assistance is required.” Please revise the statement to include the correct wording.

Section 2.2.5 revised per comment.

94. Sections 4.2.6 and 4.2.7 (incorrectly listed as 2.3.6 and 2.3.7), references Attachment 3.2-5 to RMPP 3.2, “Procedures for Reporting Events to the NRC.” This attachment was not included in the table of contents for RMPP 3.2 nor was it included in your application. Please provide this attachment and revise RMPP 3.2.

*Section 2.2.6 is revised to references RMPP 3.2 Incident Response and its Attachment 3.2-4 **Procedure for Reporting Events**.*

95. Section 4.2.8 (incorrectly listed as 2.3.8) states “Ensures a report documented the incident response.” There appears to be missing words. It would appear that the statement should say “ensure that a complete report is prepared documenting the incident response” or something similar. Please revise to clarify and correct the statement.

Revised Section 2.2.8 to complete the sentence.

96. Section 5.1.2 provides the contact of the RMP staff with the initial information from the report of scrap yard incident. It would appear that the initial information is collected by someone other than the RMP staff. Please revise Sections 5.1.1 through 5.1.4 to indicate who is responsible for completing the actions in each of these sections. For example, can the individual who collects information under 5.1.1 also determine the level of response required in 5.1.3?

Revised Section 3.1 to describe how information is collected by RMP staff.

97. Section 5.3.3 (incorrectly listed as 3.3.3) is titled “Approach.” It is not clear what this means. Please consider revising the title to clarify the intent of this particular section of the on scene response.

Revised Section 3.3.3 to describe on-scene response upon arrival.

98. Section 5.3.4 (incorrectly listed as 3.3.4) describes actions to taken by the RMP. Although these actions are appropriate if there is no immediate health and safety action required, the RMP should first ensure that the incident does not pose any immediate health and safety concerns. Please revise the procedure to clarify that the RMP will ensure that all immediate health and safety concerns are first addressed.

Section 3.1.3 has been included to determine the level of immediate response required.

99. Section 5.3.8 (incorrectly listed as 3.3.8) specifies that materials being transported for analysis or storage should be packages to meet DOT requirements. Radioactive materials must be transported according to all DOT requirements or be transported in accordance with specific DOT exemptions. Please revise this section to change “should” to “must” and delete the phrase “if practical.”

Section 3.3.8 has been revised so “should” is now “must” and the words “if practical” have been deleted.

100. Section 5.4.1 (incorrectly listed as 3.4.1) uses the term “investigator.” This term is not defined in the responsibilities section of this procedure. Please revise this procedure to include the term investigator or revise Section 4.0 to clarify who is responsible for the preparation of the report.

Section 3.4 has been revised to make reports the role of RMP staff.

101. Section 6.0 does not have a clear purpose. Similar comments have been provided for the incident response (see Comment 72) and allegation (see Comment 40) procedures. Please revise this section to clarify its purpose.

Section 4.0 has been revised to describe the purpose of records relevant to scrap yard incidents.

Incident Response (RMPP 3.4 – Nuclear Material Event Database (NMED) Input)

102. Section 3.6 describes the reporting of theft or terrorist activity involving Category 1 and Category 2 quantities of radioactive materials in accordance with 10 CFR 37.57. This section as written does not describe the appropriate action required by 37.57. Both suspicious activity involving the possible theft, sabotage, or diversion and the actual or attempted theft, sabotage or diversion of Category 1 and Category 2 licensed material must be reported to the NRC Operations Center with 4 hours after their discovery. Please revise this section to be consistent with the requirements in 37.57.

Section 3.6 has been revised to address this comment.

103. Section 6.0 states the abnormal occurrence (AO) guidelines and criteria are covered in more detail in Management Directive 8.1. For Agreement States, a better reference for AOs would be NMSS Procedure SA-300. Please revise this section to indicate that the State will follow the requirements in SA-300 with regards to the processing of AOs.

Section 6.0 has been revised to address this comment.