

March 27, 2018

William Irwin, Sc.D., CHP  
Chief, Office of Radiological Health  
Department of Health  
108 Cherry Street  
P.O. Box 70  
Burlington, VT 05402

Dear Dr. Irwin:

We have finished our review of Vermont's draft application to become an Agreement State in accordance with Section 274b of the Atomic Energy Act. A U.S. Nuclear Regulatory Commission (NRC) interoffice review team conducted the review following the guidance in NRC Commission Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" that provides criteria for new agreements, and the NRC Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-700, "Processing an Agreement" and its Handbook. The review was conducted to determine whether the proposed Vermont Agreement State Program (hereafter, the Program) met the evaluation criteria for an Agreement Program that is adequate to protect public health and safety and compatible with NRC requirements. The review team found that the request provided information on all major program elements. However, as commented in Enclosure 1, the review team identified a number of areas where additional information is needed in order for NRC to complete its review. We request a response to the comments.

For your reference, the comments are correlated to the pertinent sections of your request and the pertinent sections of the SA-700 Handbook. As previously discussed with Duncan White of my staff and you, our comments on the draft application are provided to the State in multiple letters. This is the third and last of our comment letters and provides our comments to Sections 4.5, 4.6 and 4.7 of the draft application.

We would welcome an opportunity to meet with you in person to discuss our comments and answer any questions concerning our review, the additional information needed, or the steps involved in processing the Agreement. Duncan White, team leader for the Vermont Agreement Review Team, can be reached at (301) 415-2598 or [Duncan.White@nrc.gov](mailto:Duncan.White@nrc.gov), and will work with you to set up a meeting.

Sincerely,

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Kevin Williams, Acting Director  
Division of Materials Safety, Security, State,  
and Tribal Programs  
Office of Nuclear Material Safety  
and Safeguards

Enclosure:  
NRC Comments

SUBJECT: RESPONSE LETTER WITH COMMENTS ON SECTION 4.5, 4.6 AND 4.7  
VERMONT DRAFT AGREEMENT APPLICATION. DATE: MARCH 27, 2018.

Distribution:

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**ML18017A124**

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<b>NAME</b>	DWhite	PMichalak	LShrum	KWilliams
<b>DATE</b>	1/18/18	1/29/18	1/29/18	3/27/18

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## **Comments on Sections 4.5, 4.6 and 4.7 of the Draft Vermont Application for an Agreement Dated September 15, 2017**

The draft application was reviewed by a team of NRC staff:

Duncan White, Team Leader and Technical Reviewer, NMSS  
Tison Campbell, Legal Reviewer, OGC  
Monica Ford, Technical Reviewer, Region I  
Robert Gallagher, Technical Reviewer, Region I  
Kathleen Modes, Technical Reviewer, NMSS  
Lizette Roldan-Otero, Technical Reviewer, NMSS  
Laura Shrum, Legal Reviewer, OGC  
Duane White, Technical Reviewer, NSIR

This letter contains the review team's 103 specific comments in three areas: Enforcement, Technical Staffing and Training, and Event and Allegation Response Program Elements. We are requesting responses to those comments. The team also identified a number of general comments, which are also provided. We are not requesting a specific response to our general comments, but we ask that these comments are addressed in subsequent versions of the application.

### 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.
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.
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.
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.

### 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*

Enclosure

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.
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.
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.
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”.
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.
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.
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.
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.
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.”
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.
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.
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.
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.
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.
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.
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.
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.

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.
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.
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.”

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.”

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

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.
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.
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.
  - 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.
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.
28. In Section 3.5.5, please revise this section to define and provide a reference for the “clear inspection” form used by inspectors.
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.
  - b. Please revise this section to remove all reactor licensing terms and include only those licensing terms that apply to agreement materials.
  - 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.

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

#### 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.
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.
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.

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.
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.
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.

#### 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.
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 State will 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.
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.

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.
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.
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.
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.
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.
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.
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.
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.

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.
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.
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..."
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.
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.
55. Section 3.2 includes the procedures for protecting and disclosing an allegeder'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.
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."
  - b. This section states "Prior to terminating initial contact (see 3.1) with an allegeder..." This appears to presume that State staff is communicating with the allegeder 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.

- 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.
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.
  - 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.
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.
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.
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.
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."
  - 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.

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.
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.
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.
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.”
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.
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.
68. The Acknowledgement Letter to Allegor 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.

#### 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.”
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.

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.
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.
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.
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.
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.
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.
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.
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.
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.
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.
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.

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.
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.
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.
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.
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."
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.
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.
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.
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.
  - 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.

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

98. Section 5.3.4 (incorrectly listed as 3.3.4) describes actions to be 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.
99. Section 5.3.8 (incorrectly listed as 3.3.8) 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" and delete the phrase "if practical."
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.
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.

#### 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.
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.