

The NRC staff had the following comments on the final Vermont application received on April 11, 2019. We request that Vermont Department of Health (VDH) provide us a revision to each section as indicated.

1. Section 4.1 Legal Elements

Section 4.1.1.1.f of the application states:

4.1.1.1.f Authorizes the program to impose sanctions for violations of the regulations, orders, or license conditions.

The Commissioner has the authority to enforce all the provisions of Title 18, or the rules, permits, or orders issued pursuant to the title. 18 V.S.A. §130. The Commissioner can issue health orders and, in lieu of instituting an action or proceeding against a person, may enter into an assurance of discontinuance with the party which is filed with the Superior Court and becomes an order of the court. *See* 18 V.S.A. §§125 and 126.

The Department's Radioactive Materials Rule provides for amendment, suspension, or revocation of licenses. *See* section 10 of the Radioactive Materials Rule; 18 V.S.A. §1653(b)(1) (directing the Department to provide by rule for the "amendment, suspension, or revocation of licenses"). In addition, section 10.1.1 of the Radioactive Materials Rule permits the Department to impose sanctions for violation of the regulations:

Whenever the Department has reasonable grounds to believe that there has been a violation of any of the provisions of this rule, the Department may take appropriate action as provided in this subsection or otherwise provided in law at 18 V.S.A. Ch. 32, to protect the public health and safety.

In turn, §1657 of 18 V.S.A. Ch. 32 provides for fines and criminal penalties for those in violations of the rules under Ch. 32:

Any person who violates this chapter or rules in effect pursuant thereto shall, upon conviction thereof, be imprisoned not more than six months or fined not more than \$500.00 or less than \$100.00, or be both imprisoned and fined. 18 V.S.A. §1657.

18 V.S.A. §1653(b)(2)(A) provides that the Department shall have authority to "impose conditions that are individual to a license when necessary to protect public health and safety."

18 V.S.A. §1653(b)(7)(B) authorizes the Department to impound certain material in the event of an emergency:

"The Department shall have the authority in the event of an emergency to impound or order the impounding of by-product, source, and special nuclear materials in the possession of any person who is not equipped to observe the provisions of this chapter or any rules adopted under this chapter."

In 18 V.S.A. §1655(a) and (b), further provisions exist to impose sanctions for violations of regulations, orders, or license conditions:

(a) In any proceeding under this chapter for the issuance or modification of rules relating to control of by-products, source, and special nuclear materials; or for granting, suspending, revoking, or amending any license; or for determining compliance with or granting exemptions from rules and regulations of the Department, the Department shall hold a public hearing upon the request of any person whose interest may be affected by the proceeding, and shall admit any such person as a party to the proceeding, subject to the emergency provisions in subsection (b) of this section.

(b) Whenever the Department finds that an emergency exists requiring immediate action to protect the public health and safety, the Department may, without notice or hearing, issue an order reciting the existence of the emergency and requiring that such action be taken as necessary to meet it. Notwithstanding any contrary provision of this chapter, the order shall be effective immediately. Any person to whom the order is directed shall comply with the order immediately, but on application to the Department shall be afforded a hearing within ten days. On the basis of the hearing, the emergency order shall be continued, modified, or revoked within ten days after the hearing.

Further, the Attorney General's office shall, at the request of the Department, seek injunctive relief, 18 V.S.A. §1656:

Whenever, in the judgment of the Department, any person has engaged in or is about to engage in any acts or practices which constitute or will constitute a violation of any provision of this chapter, or any rule issued thereunder, the Attorney General shall make application to the appropriate court for an order enjoining such acts or practices, or for an order directing compliance, and upon a showing by the Department that such person has engaged or is about to engage in any such acts or practices, a permanent or temporary injunction, restraining order, or other order may be granted.

NRC staff previously indicated that 1655(a) and (b) (highlighted) have nothing to do with sanctions for violations. VDH legal staff agreed and VDH indicated that this citation would be deleted. Please resubmit Section 4.1.1.1.f. without the reference to 1655(a) and (b).

2. Section 4.3 Licensing Program Elements

Section 4.3.5 discusses the review process for licensing actions and states:

"The elements include primary review, secondary review by two different qualified license reviewers, and a supervisory review".

This sentence appears to indicate that the secondary review requires two separate reviews. Based on the rest of the procedure, it is clear that the secondary review is done by only one individual who is not the primary reviewer. Please resubmit this sentence to clarify that the secondary reviewer is done by only one individual who is not the primary reviewer.

3. Section 4.3 Licensing Program Elements

In Procedure 1.3 "License Termination/Revocation", the definitions in Section 1.4.7, 1.4.8 and 1.4.14 reference NRC and not the State or VDH. In addition, Section 1.4.7 does not reference 10 CFR Part 20 subpart E requirements. Please resubmit these three sections with the correct agency and citation.

4. Section 4.4 Inspection Program Elements

Table 4.4-1 appears to missing following audit checklists and reference:

Volume 11, Appendix F: Sample Audit Program—Non-Medical
Volume 14, Appendix E: Suggested Well Logging and Subsurface Tracer Studies Audit Checklist
Volume 18, Appendix L - Suggested Service Provider Audit Checklist
Volume 21, Appendix E Sample Audit Program
NRC Enforcement Policy

Please revise and resubmit Table 4.4-1 to include these five references.

5. Inspection Program Elements

Section 3.12.1 of Radioactive Materials Program Procedure 2.3 “Performance-Based Inspection” states:

“The requirements of 10 CFR Part 37 apply only to licensees in possession of aggregated category 1 and 2 quantities of radioactive materials, including sealed and unsealed sources.”

The requirements of Part 37 apply either category 1 or category 2 quantities. Please change “category 1 and 2” to “category 1 or 2” and resubmit section 3.12.1 of this procedure.

6. Inspection Program Elements

Section 2.4 of Radioactive Materials Program Procedure 2.6 “Materials Inspection Checklists and Definitions” does include references to Part 37 requirements, particularly 37.57 and 37.81. Please add 37.57 and 37.81 to section 2.4 and resubmit this section of the procedure.

7. Inspection Program Elements

Section 2.20 of Radioactive Materials Program Procedure 2.6 “Materials Inspection Checklists and Definitions”, the definition of Notice of Violation (NOV) is different and much longer than the definition for NOV in your RMPP 2.5 and 4.5 procedures. Please revise the definition of NOV in section 2.20 of this procedure to be consistent with RMP 2.5 and 4.5 procedures and resubmit.

8. Inspection Program Elements

Section 2.44a of Radioactive Materials Program Procedure 2.6 “Materials Inspection Checklists and Definitions”, the definition of deliberate misconduct is different than the definition of deliberate misconduct in your RMPP 2.5 and 4.5 procedures. Please revise the definition of deliberate misconduct in section 2.44a of this procedure to be consistent with RMP 2.5 and 4.5 procedures and resubmit.

9. Inspection Program Elements

Section 3.1 of Radioactive Materials Program Procedure 4.2 "Tracking Inspection Reports & Correspondence" does not indicate that the inspector needs to be qualified to be assigned a particular inspection. Please include "inspector qualifications" in section 3.1 of this procedure and resubmit.

10. Section 4.7 Event and Allegation Response Program Elements

Section 3.4.3.3. of RMPP 3.1 states:

If the allegor or confidential source objects to the referral or does not respond to the letter within 30 calendar days, and the factors described in section 3.4.1 and 3.4.2 concerning the referral prohibitions and allowances and 3.3.2.5 concerning an overriding safety issue **have been considered**, then refer the allegation to the licensee.

The highlighted phrase "have been considered" is not clear. VDH should determine (rather than simply consider) that an allegation is an overriding safety issue to refer the allegation over the allegor's objection. Please replace the phrase "have been considered" with "was determined" or a similar phrase and resubmit section 3.4.3.3. of this procedure.