

To Duncan White

United States Nuclear Regulatory Commission

The following is supplemental information requested for Vermont's Application to Become an NRC Agreement State. There were ten specific changes requested, and the revised application content is provided in this document.

1. Section 4.1 Legal Elements, Section 4.1.1.1.f is changed to:

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.”

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.

2. Section 4.3 Licensing Program Elements, Section 4.3.5 is changed to:

4.3.5 Procedures for Assuring the Technical Quality of Licenses

Vermont Department of Health Radioactive Materials Program staff will use RMPP 1.1 Review of Initial Application for License or an Amendment Request to provide means by which the technical quality of licenses is assured. The elements include primary review, secondary review by a different qualified license reviewer, and a supervisory review. The primary and secondary review are documented using the RMPP 1.1 Attachment 1.1-4 License Review Job Aid and the supervisory review is documented using the RMPP 1.1 Attachment 1.1-5 Administrative Qualitative Checklist. These three reviews are used for all new licenses, license amendments, license renewals, and license terminations to help assure the quality of licensing actions. All licensing procedures and their attachments are found Application Section 4.3.6 Administrative Licensing Procedures.

3. Section 4.3 Licensing Program Elements, Sections 1.4.7, 1.4.8 and 1.4.14 of Radioactive Materials Program Procedure (RMPP) 1.3 License Termination/Revocation is changed to:

- 1.4.7 Closeout Inspection. An inspection performed by the Department, or its contractor, to determine if a licensee has adequately decommissioned its facility. Typically, a closeout inspection is performed after the licensee has demonstrated that its facility is suitable for release in accordance with 10 CFR Part 20 subpart E requirements.
- 1.4.8 Confirmatory Survey. A survey conducted by the Department, or its contractor, to verify the results of the licensee’s final status survey. Typically, confirmatory surveys consist of measurements at a fraction of the locations previously surveyed by the licensee, to determine whether the licensee’s results are valid and reproducible.
- 1.4.14 Decommissioning Plan (DP). A detailed description of the activities that the licensee intends to use to assess the radiological status of its facility, to remove radioactivity attributable to licensed operations at its facility to levels that permit

release of the site in accordance with Department regulations and termination of the license, and to demonstrate that the facility meets 10 CFR Part 20 subpart E requirements for release. A DP typically consists of several interrelated components, including (1) site characterization information; (2) a remediation plan that has several components, including a description of remediation tasks, a health and safety plan, and a quality assurance plan; (3) site-specific cost estimates for the decommissioning; and (4) a final status survey plan (see 10 CFR 30.36(g)(4)).

4. Section 4.4 Inspection Program Elements, Table 4.4-1 is changed to:

Table 4.4-1

NRC Documents Serving as Model Guidance for Vermont

Inspection Manual Chapters and Titles	
0610	Nuclear Material Safety and Safeguards Inspection Reports
0620	Inspection Documents and Records
1220	Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20
1248 App A	Materials Health Physics License Review Qualification Journal
1248 App B	Materials Health Physics Inspector Qualification Journal
1301	Response to Radioactive Material Incidents That Do Not Require Activation of the NRC Incident Response Plan
1302	Follow-up Actions and Action Levels for Radiation Exposures Associated with Materials Incidents Involving Members of the Public
1303	Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE)
1330	Response to Transportation Accidents Involving Radioactive Materials
2602	Decommissioning Oversight and Inspection Program for Fuel Cycle Facilities and Materials Licensees
2800	Materials Inspection Program
Inspection Procedures and Titles	
83822	Radiation Protection
83890	Closeout Inspection and Survey
84850	Radioactive Waste Management - Inspection of Waste Generator Requirements of 10 CFR Part 20 and 10 CFR Part 61.
84900	Low-Level Radioactive Waste Storage
86730	Transportation of Radioactive Materials
86740	Inspection of Transportation Activities
87102	Maintaining Effluents from Materials Facilities As Low As Is Reasonably Achievable (ALARA)
87103	Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
87104	Decommissioning Inspection Procedure for Materials Licensees
87121	Industrial Radiography Programs
87122	Irradiator Programs

87123	Well Logging Programs
87124	Fixed and Portable Gauge Programs
87125	Materials Processor/Manufacturer Programs
87126	Industrial/Academic/Research Programs
87127	Radiopharmacy Programs
87130	Nuclear Medicine Programs Written Directive Not Required
87131	Nuclear Medicine Programs Written Directive Required
87132	Brachytherapy Programs
87133	Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs
87134	Medical Broad-Scope Programs
87137	10 CFR Part 37 Materials Security Programs
87250	Locating Missing Materials Licensees
NUREG 1757	Consolidated Decommissioning Guidance
NUREG 1556	<p>Volume 1, Appendix E- Portable Gauge Audit Checklist</p> <p>Volume 2, Appendix G- Industrial Radiography Radiation Safety Audit Checklist</p> <p>Volume 4, Appendix E- Fixed Gauge Audit Checklist</p> <p>Volume 5, Appendix I- Self-Shielded Irradiator Audit Checklist</p> <p>Volume 6, Appendix G-10 CFR Part 36 Irradiators Suggested Audit Checklist</p> <p>Volume 7, Appendix H-Academic, Research and Development, and Other Licenses of Limited Scope Sample Audit Program Checklist</p> <p>Volume 9, Appendix L-Medical Licenses Model Medical License Audit Checklist</p> <p>Volume 11, Appendix F-Broad Scope Sample Audit Program-Non-Medical</p> <p>Volume 12, Appendix G- Sample Audit Program Possession Licenses for Manufacturing and Distribution Checklist</p> <p>Volume 13, Appendix I-Suggested Commercial Radiopharmacy Licenses Audit Checklist</p> <p>Volume 14, Appendix E-Suggested Well Logging and Subsurface Tracer Studies Audit Checklist</p> <p>Volume 17, Appendix E-Suggested Audit Checklist Special Nuclear Material of Less than Critical Mass</p> <p>Volume 18, Appendix L-Suggested Service Provider Audit Checklist</p> <p>Volume 21, Appendix E-Production of Radioactive Material Using an Accelerator Sample Audit Program</p>
10 CFR Part 37 Checklist	
RMPP 1.1 Attachment 1.1-1 Pre-Licensing Checklist	
RMPP 1.1 Attachment 1.1-2 Risk Significant Radioactive Materials Checklist	
NRC Enforcement Manual	
STP SA-102 “Reviewing the Common Performance Indicator, Technical Quality of Inspections”).	
NRC Enforcement Policy	

5. Section 4.4 Inspection Program Elements, Section 3.12.1 of RMPP 2.3 Performance-Based Inspections is changed to:

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

6. Section 4.4 Inspection Program Elements, Section 2.4 of RMPP 2.6 Materials Inspection Checklists and Definitions is changed to:

2.4 Incident: An event that may have caused, or threatens to cause, conditions described in Title 10 Code of Federal Regulations (CFR) 20.1906, 20.2201 through 20.2203, 10 CFR 30.50, 10 CFR 31.5, 10 CFR 34.27, 10 CFR 34.101, 10 CFR 35.3045, 10 CFR 35.3047, 10 CFR 35.3067, 10 CFR 36.83, 10 CFR 37.57, 10 CFR 37.81, 10 CFR 39.35, 10 CFR 39.77, 10 CFR 40.60, 10 CFR 70.50, 10 CFR 71.95, or other regulatory reporting requirements imposed by order or license condition.

7. Section 4.4 Inspection Program Elements, Section 2.20 of RMPP 2.6 Materials Inspection Checklists and Definitions is changed to:

2.20 Notice of Violation (NOV): A formal written notice that sets forth one or more apparent violations of a requirement following an inspection. An NOV formally documents violations and is typically the only enforcement action taken unless the criteria for escalated enforcement are met.

8. Section 4.4 Inspection Program Elements, Section 2.44.a of RMPP 2.6 Materials Inspection Checklists and Definitions is changed to:

2.44 Willfulness: There are two types of willfulness:

a. Deliberate misconduct occurs when an individual voluntarily and intentionally (1) engages in conduct that the individual knows to be contrary to a requirement, procedure, instruction, contract, purchase order, or policy of a license, applicant for a license, or a contractor or subcontractor of a licensee or applicant for a license; or (2) provides materially inaccurate or incomplete information to a licensee, applicant for a license, or a contractor or subcontractor of a licensee or applicant for a license;

b. 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 ascertaining whether a violation would occur.

9. Section 4.4 Inspection Program Elements, Section 3.1 of RMPP 4.2 Tracking Inspection Reports and Correspondence is changed to:

3.1 Assignment of Inspection

Inspections will be performed by Radiological Health Specialists based on inspector qualifications, workloads, experience levels, and the priority assigned to the inspection. Radiological Health Specialists should review the *Inspections Due for the Next 6 Months-By Priority Report* and RMPP 2.1 *Scheduling of Inspections* to determine inspection options.

10. Section 4.7 Event and Allegation Response Program Elements, Section 3.4.4.3 of RMPP 3.1 Management of Allegations is changed to:

3.4.3.3 If the allegation raises an overriding safety issue, the RMPM or designated staff may refer the allegation to the licensee, regardless of any factor in Sections 3.4.1 and 3.4.2. If the allegation raises an overriding safety issue and the allegor or confidential source objects to the referral or does not respond to the letter within 30 calendar days, the RMPM or designated staff may refer the allegation to the licensee despite the allegor's objection or lack of response when (1) an effort has been made to contact the allegor, (2) sufficient effort is made to evaluate any feedback provided by the allegor, and (3) the RMPM or designated staff continues to believe the referral is warranted.

11. Section 4.2 Licensing Program Elements, Attachment 1.1-3 to RMPP 1.1 Review of Initial Application for License or an Amendment Request is changed to:

Vermont Department of Health Radioactive Materials Program

ATTACHMENT 1.1-3 TO RMPP 1.1

CHECKLIST FOR REQUESTS TO WITHHOLD INFORMATION FROM PUBLIC DISCLOSURE



Name:		License Number:	
<p>To request that the Department withhold information contained in an application from public disclosure, the applicant must submit the information, the application, and a justification affidavit. The affidavit must detail what exemptions to the public records law under 1 V.S.A. § 317 apply and the justification for claiming such exemptions, so that the Department may comply with any records requests in accordance with 1 V.S.A. § 318. The applicant should submit all the following:</p>			
<input type="checkbox"/>	<p>A proprietary copy of the information. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.</p>		
<input type="checkbox"/>	<p>A non-proprietary copy of the information. Applicants should white out or black out the proprietary portions (i.e. those in the brackets), leaving the non-proprietary portions intact. This copy should not be marked as proprietary.</p>		
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<p>An affidavit that:</p> <p>Is notarized.</p> <p>Clearly identifies (such as by name or title and date) the document to be withheld.</p> <p>Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information sought to be withheld and authorized to apply for withholding on behalf of the company.</p>		
<input type="checkbox"/>	<p>States that the company submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.</p>		
<input type="checkbox"/>	<p>Provides a rational basis for holding the information in confidence.</p>		
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<p>A letter that fully addresses the following issues:</p> <ul style="list-style-type: none"> Is the information submitted to, and received by, the Department in confidence? Provide details. Does the applicant customarily treat this information, or this type of information, as confidential? Explain why. Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of the information to your company, amount of effort or money expended in developing the information, and the ease or difficulty of others to acquire the information. 		