# 4.4 Inspection Program Elements

The State of Vermont, through the Vermont Department of Health (Department) Radioactive Materials Program (RMP) (*hereafter* "RMP" or "the program") will conduct inspections of radioactive materials licensees following the guidance in the NRC's specific Inspection Procedures, NUREG 1556 Safety Audits and relevant related documents for the various license types in Vermont. The program will also use the broader inspection guidance found in the NRC's Inspection Manual Chapters and relevant related documents. For the administration of the inspection program, Vermont has written administrative procedures, the Radioactive Material Program Procedures (RMPPs). The RMPPs apply broadly to all inspection activities. A table of inspection-related RMPPs is below.

| RMPP No. | Title |
|---|---|
| RMPP 2.1 | Scheduling of Inspections |
| RMPP 2.2 | Inspection Preparations |
| RMPP 2.3 | Performance-Based Inspections |
| RMPP 2.4 | Documentation of Inspection Results |
| RMPP 2.5 | Enforcement, Escalated Enforcement and Administrative Actions |
| RMPP 2.6 | Materials Inspection Checklists and Definitions |
| RMPP 2.7 | Assuring the Technical Quality of Inspections |
| RMPP 4.2 | Tracking Inspections |

In application section 4.4.1 Procedures for Inspecting Facilities Where Radioactive Material is Stored or Used, the RMP plans to use the NRC Inspection Manual Chapters, applicable NUREG 1556 Safety Audits, and Inspection Procedures. This section also briefly describes RMPP 2.1 through 2.6 which are written to guide the scheduling of inspections, preparations for an effective inspection for compliance and the methods to conduct, document and respond to the findings of radioactive materials licensee inspections.

RMPP 2.7 *Assuring the Technical Quality of Inspections* is described in application section 4.4.2. The key tenets of the process are checklist-guided initial inspections, secondary review of the inspection report by another qualified inspector and annual supervisory accompaniment of inspectors as they conduct performance-based inspections.

The administrative procedures appropriate for all inspections as required for Handbook Section 4.4.3 are copied into the concluding section of 4.4 with the exception of RMPP 2.5 *Enforcement, Escalated Enforcement and Administrative Actions*. While significantly related to inspection activities, it is described and found in application section 4.5 Enforcement Program Elements.

# *4.4.1 Procedures for Inspecting Facilities Where Radioactive Material Is Stored or Used*

This section describes the procedures and resources that will be used to inspect facilities where radioactive material is stored or used and specifically addresses:

- Scheduling of inspections and different kinds of inspections (including pre-licensing site visits);
- Inspection frequencies, including information on conducting pre-licensing site visits;
- The format and guidance for inspection reports;
- Performance of inspections, including performance-based criteria;
- Notifications to licensees of results and whether or not the licensee is in compliance; and
- State field instrumentation and laboratory analysis capabilities, including calibration and quality assurance.

**Scheduling of inspections and different kinds of inspections (including pre-licensing site visits.)**

The different types of inspections conducted and how they are scheduled are described in RMPP 2.1 *Scheduling of Inspections*. A copy is found with all other inspection-related administrative procedures in application section 4.4.3.

Pre-licensing site visits are described in application section 4.3 Licensing Program Elements of this application. The description is specifically in RMPP 1.1 *Review of an Initial Application for License or an Amendment Request*. A key component is the Pre-Licensing Checklist, Attachment 1.1-1 of that RMPP.

**Inspection frequencies, including information on conducting pre-licensing site visits.**

Vermont will use as a minimum inspection frequency as those documented in the NRC's Inspection Manual Chapter 2800 *Materials Inspection Program*. Specifically, inspections will be scheduled in accordance with Enclosure 1 – Inspection Priority Codes Assigned to Program Codes. The priority codes will be used as the maximum number of years between inspections. This correlates inspection frequency to the amount and kind of material and type of operation licensed. The inspection frequencies are based on the relative risk associated with material possessed by the individual licensee.

This table is copied into the licensing administrative procedure RMPP 1.1 *Review of an Initial Application for License or an Amendment Request*.

**The format and guidance for inspection reports; performance of inspections, including performance-based criteria; and notifications to licensees of results and whether or not the licensee is in compliance.**

The format and guidance for inspection reports, instructions for performing inspections and the documentation of inspections including notification of the licensee of the inspection results, especially as related to compliance, are found in RMPP 2.1 *Scheduling of Inspections*, RMPP 2.2 *Inspection Preparations*, RMPP 2.3 *Performance-Based Inspections*, RMPP 2.4 *Documentation of Inspection Results*, RMPP 2.6 *Materials Inspection Checklists and Definitions* and RMPP 4.2 *Tracking Inspections*. Each of these RMPPs is copied into Section 4.4.3 of this Application.

Rather than recreate inspection procedures and checklists for the specific types of licenses that will be issued in Vermont, the Vermont Department of Health will incorporate by reference certain Nuclear Regulatory Commission (NRC) Inspection Manual Chapters (IMC), NUREG 1556 Safety Audits and Inspection Procedures. The Department will use only those NUREGS, IMC chapters and inspection procedures relevant to Vermont's Radioactive Materials Program.

The Inspection Manual Chapters are found at https://www.nrc.gov/reading-rm/doc-collections/insp-manual/manual-chapter/. The NRC Inspection Procedures are found at https://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/. The NUREG 1556 "Consolidated Guidance About Materials Licenses" are found at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/. The specific NRC Inspection Manual Chapters, NUREG 1556 Audits, and Inspection Procedures to be used in Vermont at the time of this Application are listed in Table 4.4-1 below.

## 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 | Volume 1, Appendix E- Portable Gauge Audit Checklist<br>Volume 2, Appendix G- Industrial Radiography Radiation Safety Audit Checklist<br>Volume 4, Appendix E- Fixed Gauge Audit Checklist<br>Volume 5, Appendix I- Self-Shielded Irradiator Audit Checklist<br>Volume 6, Appendix G-10 CFR Part 36 Irradiators Suggested Audit Checklist<br>Volume 7, Appendix H-Academic, Research and Development, and Other Licenses of Limited Scope Sample Audit Program Checklist<br>Volume 9, Appendix L-Medical Licenses Model Medical License Audit Checklist<br>Volume 12, Appendix G- Sample Audit Program Possession Licenses for Manufacturing and Distribution Checklist<br>Volume 13, Appendix I-Suggested Commercial Radiopharmacy Licenses Audit Checklist<br>Volume 17, Appendix E-Suggested Audit Checklist Special Nuclear Material of Less than Critical Mass |
| 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 | |

**State field instrumentation and laboratory analysis capabilities, including calibration and quality assurance.**

To facilitate effective inspections, for radiation protection purposes and for emergency preparedness, the Vermont Department of Health possesses and maintains numerous radiological instruments, listed in Appendix I. These instruments are capable of measuring exposure rates from x- and gamma radiation, absorbed dose rates from beta radiation, and count rates from alpha, beta, beta-gamma, gamma and neutron radiation-emitting radioactive materials of a wide range of energies. Some field instruments are capable of isotopic identification. As we do now, the Radioactive Materials Program will maintain sufficient instruments for the above purposes in good working order. They will be calibrated annually by a facility licensed for such.

Most portable instrument calibrations are and will be conducted by Radiation Safety & Control Services of Stratham, New Hampshire. It is an ISO/IEC 17025 accredited instrument calibration service. Occasionally other licensed facilities are used, including those of our instrument manufacturers, especially if the instrument also needs repair or other service beyond calibration.

The services of the Vermont Department of Health Public Health Laboratory can be used for radiochemical analysis. Their instrumentation is also listed in Appendix I. The program has used private laboratories for radiochemical analysis in the past and could do so again should that be useful.

# *4.4.2 Procedures for Assuring the Technical Quality of Inspections and Inspection Reports*

RMPP 2.7 *Assuring the Technical Quality of Inspections* provides guidance on quality assurance for inspection reports. It describes secondary peer review and supervisory review, as well as the content of inspection reports. Significant detail is provided to help assure sound bases are documented for the findings of inspections. It is based upon guidance found in the NRC's SA-102 *Reviewing the Common Performance Indicator, Technical Quality of Inspections* and IMC 0610 *Nuclear Material Safety and Safeguards Inspection Reports*. RMPP 2.7 is copied below.

# Vermont Department of Health

# Radioactive Materials Program

## Radioactive Materials Program Procedure 2.7, Revision 0

## Procedures for Assuring the Technical Quality of Inspections and Inspection Reports

**Prepared By:**_____ **Date** _____

**Reviewed By:**_____**Date**_____

**Approved By:**_____**Date**_____

**Effective Date:**

| Revision | Date | Description of Changes |
|---|---|---|
| 0 | | |
| | | |

# Table of Contents

1.0 Purpose

2.0 Objectives

3.0 Responsibilities

4.0 Inspection Report Writing

5.0 Secondary Report Review And Concurrence

6.0 Inspection Report Content And Form

7.0 Notice Of Violation

8.0 Significance Of Observation

9.0 Minor Violations And Determining Whether To Document

10.0 Violations Identified As Part Of Licensee Self-Assessments

11.0 Thresholds Of Significance For Non-Enforcement-Related Issues

12.0 Determining The Significance Of Negative Findings

13.0 Determining The Significance Of Neutral Or Positive Findings

14.0 Findings Previously Covered In Licensee Self-Assessments

15.0 Documenting Noncompliance

16.0 Supervisory Accompaniments

17.0 Attachments

2.7-1 Inspection Report Quality Assurance (QA) Checklist

## 1.0 Purpose

The purpose of this Radioactive Materials Program Procedure (RMPP) is to provide guidance to ensure the technical quality of inspections and that inspection reports are consistent with the NRC's criteria for secondary reviews of inspections and inspection reports (See STP SA-102 "Reviewing the Common Performance Indicator, Technical Quality of Inspections").

## 2.0 Objectives

2.1. To ensure that inspections of licensed activities focus on health, safety, and security issues in accordance with NRC Inspection Manual Chapter 2800, "Materials Inspection Program".

2.2. To ensure that inspection findings are well-founded and well-documented in reports.

2.3. To verify that inspections are complete and reviewed by a second qualified inspector for technical quality.

2.4. To determine that procedures are in place and used to help identify incident root causes and poor licensee performance.

2.5. To confirm that follow-up inspections address previously identified open items and/or past violations.

2.6. To verify that inspection findings lead to appropriate and prompt regulatory action.

2.7. To confirm that supervisors conduct annual accompaniments of each inspector to assess performance and assure application of appropriate and consistent policies and guides.

2.8. To determine that inspection guides are consistent with NRC guidance, and that they are being used consistently by inspectors to assure uniform and complete inspection practices.

## 3.0 Responsibilities

3.1 All Department inspectors (Radiological Health Specialists) are required to prepare inspection reports in accordance with the guidance provided in this procedure. See Section 6.0.

3.2 Each inspection should be performed in accordance with IMC 2800, the NRC Inspection Procedure for that license type and applicable NUREG 1556 Appendix

audits and checklists. The checklists from the applicable NUREG Volumes provide for an objective evaluation of individual inspection tasks.

3.3 Each inspection of a license holder shall be documented. As a minimum a **Department Form 591M Safety Inspection and Compliance Inspection** (see Attachment 2.4-1 of RMPP 2.4. *Documentation of Inspection Reports*) may be used for inspections without issues. A narrative inspection report as described in Section 6.0 through 15.0 of this procedure is required for a notice of violation or other enforcement or escalated enforcement actions.

3.4 Each inspection report must be reviewed by a second qualified inspector for quality assurance purposes. The review is to assure compliance with this and other procedures of the Radioactive Materials Program and documented using Attachment 2.7-1 **Inspection Report Quality Assurance (QA) Checklist**.

3.5 The Radiation Control Program Director (RCPD) must annually complete an inspection accompaniment with each of the Radiological Health Specialists qualified as inspectors. These are documented using Appendix B of **NRC States Agreement Procedure SA-102 "Reviewing the Common Performance Indicator, Technical Quality of Inspections".** See Section 16.0 of this procedure.

3.6 The Radioactive Materials Program Manager (RMPM) must also review each inspection report in a timely manner before final filing.

## 4.0 Inspection Report Writing

4.1 Inspectors have the primary responsibility for ensuring that observations and findings are accurately reported, that referenced material is correctly characterized, and that the scope and depth of conclusions are adequately supported by documented observations and findings. Advice and recommendations are not to be included in inspection reports.

4.2 Inspectors are responsible for ensuring that the content and tone of the report, as issued, is consistent with the content and tone of the exit meeting presentation.

4.3 When the report differs significantly from the exit meeting, the individual conducting the inspection should discuss those differences with the licensee before the report is issued.

4.4 Inspectors must ensure that inspection reports follow the general format given in this procedure based on the type of inspection. Further guidance on inspection quality and performance is found in RMPP 2.1 *Scheduling of Inspections,* RMPP 2.2 *Inspection Preparations*, RMPP 2.3 *Performance-Based Inspections*. Audits to aid in the quality of inspection performance are found in in the applicable NUREG 1556 Safety Audit Appendices.

## 5.0 Secondary Report Review and Concurrence

5.1 Before issuance, each inspection report must be reviewed by a different member of the Radioactive Materials Program qualified to conduct similar inspections. This secondary report review is designed to better ensure the quality of all inspections and their reports. This secondary review is documented on Attachment 2.7-1 **Inspection Report Quality Assurance (QA) Checklist**.

5.2 The secondary report reviewer should establish that conclusions are logically drawn and sufficiently supported by observations and findings and that the observations, findings, and conclusions are consistent with Radioactive Materials Program and other Department policies and requirements.

5.3 The secondary report reviewer should ensure that assessments made in the inspection report represent the requirements of the Radioactive Materials Program and established Department policy rather than the personal views of an individual inspector. This is documented on Attachment 2.7-1..

5.4 The Department will maintain the Attachment 2.7-1 used for secondary report review with the original inspection report to provide a record of inspectors' and reviewers' concurrences. They should address how to ensure continued inspector concurrence when substantive changes are made to the report as originally submitted, and how to treat disagreements that occur during the review process. At a minimum, substantial changes should be discussed with the inspector or inspectors involved to ensure continued concurrence, and disagreements that cannot be adequately resolved should be documented.

## 6.0 Inspection Report Content and Form

6.1 Cover Letter.

6.1.1 The purpose of the cover letter is to transmit the inspection report results to licensee senior management representative and/or RSO.

6.1.2 Inspection reports are transmitted using a cover letter with Department of Health letterhead and summarizes the results of the inspection findings.

6.1.3 When the inspection findings reveal the licensee’s program is adequate to provide for the security of licensed radioactive materials and the protection of workers and the public, then a **Department Form 591M Safety Inspection and Compliance Inspection** (Attachment 2.4-1 of RMPP *Documentation of Inspection Results*) or Attachment 2.4-4 **Clean Inspection Report** follows the cover letter.

6.1.3.1 The Department Form 591M may also be left at the licensee site upon conclusion of the inspection.

6.1.3.2 The Clean Inspection Report is transmitted only with the cover letter and other elements of the inspection report.

6.1.4 When the inspection findings reveal a violation Attachment 2.4-3 **Notice of Violation Letter** of RMPP 2.4 *Documentation of Inspection Results* follows the cover letter.

6.1.5 The cover letter is written to transmit the inspection report to the licensee's management, and to deliver the "big picture" message regarding the inspection. Because it is the highest-level document, it does not need to (and normally will not) detail all the items inspected, and the inspection procedures used. It will note the areas covered by the inspection.

6.1.6 The tone of the cover letter must have a correct balance. The Department focuses on performance issues. If a licensee performed some activity 100 times, and succeeded 99 times, the inspector will be most interested in the single failure. But that does not mean that the cover letter will make it appear that the licensee rarely succeeded. The safety and regulatory significance of any licensee failure will be a primary consideration, above and beyond the numerical frequency of failure compared to success. When identifying problem(s) in a cover letter, the nexus to safety and security will also be provided.

6.1.7 The cover letter must always be consistent with the inspection report. In addition, it must be consistent with the information that the inspector conveyed to the licensee managers at the exit meeting. If the inspector's understanding of the facts, or the perspective on the nature or significance of the findings changes after the exit meeting, the Department shall call the licensee and re-exit. There should never be any surprises in a cover letter to anyone who was present at the exit meeting.

6.1.8 The cover letter should not contain recommendations. There should not be any statements to the effect: "the licensee should...." If the licensee is not meeting safety or regulatory requirements, the statements should clearly state those facts. If the Department believes that a licensee cannot ensure the safety of its activities, then an order or some similar official action may be appropriate.

6.1.9 **Cover Letter Content.** Cover letter content varies somewhat depending on whether the inspection resulted in findings or not. In general, every cover letter has the same basic structure, as follows:

6.1.9.1 **Addresses, Date, and Salutation.** At the top of the first page, the cover letter begins with the Department seal and address, followed by the date on which the report cover letter is signed and the report issued. In the upper left-hand corner above the principal's addressee's name, include the Nuclear Materials Events Database (NMED) number, if applicable.

6.1.9.2 **Subject Line.** The subject line of the letter should state the facility name (if it is not apparent from the Addressee line) and inspection subject. The words "NOTICE OF VIOLATION' should be included if such a notice accompanies the inspection report. The entire subject line should be capitalized.

6.1.9.3 **Introductory Paragraphs.** The first two paragraphs of the cover letter should give a brief introduction, including the type of inspection report.

6.1.9.4 **Body.** The body of the letter should discuss the most important topics first.

6.1.9.5 **Closing.** The final paragraph consists of standard legal language that varies depending on whether enforcement action is involved.

6.2 Inspection Report Details

6.2.1 The detailed discussion in the report provides the information which forms the bases upon which the other sections of an inspection report are developed.

6.2.1.1 In most cases, the detailed discussion will be organized into one or more sections, each addressing an area of inspection.

6.2.1.2 Each area will in turn be divided into three parts: scope, observations and findings, and conclusions.

6.2.1.3 Generic issues, if any, must be discussed in detail (see below).

6.2.1.4 Violations, if any, must be described in detail and with bases (see below).

6.2.2 **Scope.** Scope is the extent of, or the area dealt with, in the inspection. Elements documented in an inspection should cover all relevant areas of the inspection's scope. The "Scope" portion of each area inspected will describe what was inspected. In most cases, the approach that can be used in writing the scope should be

consistent with the Inspection Procedure (IP) which was used in performing that portion. Much of the writeup can be extracted from the "Purpose" section(s) of the applicable IP. When describing the Scope, it is acceptable to state either what the inspector(s) did, or what the inspection accomplished.

6.2.3 **Observations and Findings.** The observations and findings are the foundation of every inspection report. They derive out of performing inspections according to the applicable NRC inspection procedure(s).

6.2.3.1 There should always be a readily-identifiable connection between the stated Scope and the reported observations and findings. Thus, if the Scope was the review of personnel dosimetry records, the observations and findings will not be about packaging and shipping.

6.2.3.1 Observations and findings will be descriptive and will be relatively detailed compared to the other parts of the report documentation package. The amount of detail will be as much as is needed to make clear what was found, and whether it was significant. The inspector should say what was observed or found in an unequivocal manner. If an inspector was looking to see if contamination was well controlled - and it was - the report should state: "Contamination was well controlled" not "Contamination appeared to be well controlled." If too small a sample was examined to reach an unequivocal conclusion, the qualifier should state what specifically was inspected. For example, the report should state that, "Contamination was well controlled in the areas examined by the inspectors."

6.2.3.2 If the inspector identifies no findings during an inspection (other than minor findings), the report should state "No findings of significance were identified." A sample letter for an inspection with no items of nonconformance is found in RMPP 2.4 *Documentation of Inspection Results* as Attachment 2.4-4 **Clean Inspection Report.**

6.2.4 **Generic Issues.** Findings that are likely to have generic concerns e.g., product defects and software problems should include details such as the manufacturer's name and model number for components, specifications, and other names and technical data that identify the item of concern. A generic issue is a well-defined, discrete, radiological safety or environmental (with respect to

radiological health and safety) matter of which safety/risk significance has been adequately determined.

6.2.4.1 Generic issues have the potential to affect public health and safety, or the environment (with respect to radiological health and safety);

6.2.4.2 The generic issue applies to two or more facilities and/or licensees;

6.2.4.3 The issue is not being addressed using other regulatory programs and processes; existing regulations, policies or guidance;

6.2.4.4 The issue can be resolved by new or revised regulation, policy, or guidance;

6.2.4.5 Resolution of the issue may involve review, analysis, or action by the affected licensees or holders of other regulatory approvals.

6.2.4.6 Upon discovery of a generic concern during an inspection of a licensee's facility, the Department will notify affected Vermont licensees of the issue. The Department will notify the NRC of the discovery of the generic concern and resolution, if applicable.

6.2.5 **Violations.** In the case of a finding that results in a Notice of Violation, it is critical that enough detailed information be given so that the reader can understand what the requirement was, and how it was not met. See Sections 7.0 through 15.0 of this procedure for important information about violations and other findings. After the details of what occurred are provided, two specific concluding statements should be constructed.

6.2.5.1 The first statement will define what the requirement was, including any related regulation. For example, "10 CFR 20.1801 requires that licensees shall secure from unauthorized access or removal licensed materials that are stored in controlled or unrestricted areas."

6.2.5.2 The second statement will describe (or refer to a preceding description) how the requirement was violated. For example, "Specifically, failure by the licensee to secure the radiographic exposure device (manufacturer model and serial numbers.) that contained the sealed source of

iridium-192 (manufacturer model and serial numbers, activity, and date of activity) in storage, as described above, is considered a violation of 10 CFR 20.1801." Additional actions or responses by the licensee, if any, should be included to fully describe the violation.

6.2.6 **Conclusions.** The Conclusions are statements describing the quality of licensee performance in the area inspected. The report will discuss whether the licensee succeeded or failed, whether performance was good (or some other descriptor), and whether violations were identified. Every statement in a Conclusion section should have a basis (proof that it is correct) written in the observations and findings.

6.2.7 **Exit Meeting Summary.** The final section of each inspection report briefly summarizes the exit meeting, which is also described in the first paragraph of the cover letter and identifies the most senior licensee manager who attended the meeting, and includes the following information:

6.2.7.1 **Absence of Proprietary Information.** At the exit meeting, the inspectors should verify that information which the inspector reviews during the meeting and intends to include in the report is not proprietary. If the licensee does not identify any material as proprietary, the exit meeting summary or some other element of the inspection report should include a sentence to that effect.

6.2.7.2 **Subsequent Contacts or Changes in Department Position.** The inspector should briefly discuss any contact with the licensee management after the exit meeting to discuss new information relevant to an inspection finding. In addition, if the Department's position on an inspection finding changes after the exit meeting, that change should be discussed with the licensee before the report is issued.

6.2.7.3 **Characterization of Licensee Response.** Licensee responses should not be included in the summary except in cases where the licensee disagrees with the inspection findings. In that case, the summary should state that the licensee took exception to the findings.

6.2.7.4 **Oral Statements and Regulatory Commitments.** If at the exit meeting or at any other time during the inspection, the licensee makes an oral statement that it will take a specific action in response to a non-compliance, the statement may

be documented in the body of the report. Details of statements made at the exit meeting should not be included in the exit meeting summary. Such statements should only be characterized in the report if the statements represent licensee commitments in response to a non-compliance in order to eliminate the need for a subsequent licensee response. However, the report cover letter must include a provision for the licensee to respond if the commitment documented in the report does not accurately reflect the licensee's corrective actions or positions. Otherwise, licensee commitments are documented by licensee correspondence, after which the inspector may reference the correspondence in the inspection report. Because regulatory commitments are a sensitive area, the inspector should ensure that any reporting of licensee statements are paraphrased accurately, and contain appropriate reference to any applicable licensee document.

6.2.8 **Report Attachments.** The attachments discussed below are included at the end of the inspection report if applicable to the inspection. The attachments may be combined into a single attachment entitled "Supplementary Information."

6.2.9 **Key Points of Contact.** The inspector lists, by name and title, those individuals who furnished relevant information or were key points of contact during the inspection (except in cases where there is a need to protect the identity of an individual). The list need not be exhaustive; a list of 5–10 individuals is sufficient. The alphabetized list includes the most senior licensee manager present at the exit meeting and Department technical personnel who were involved in the inspection if they are not listed as inspectors on the cover page.

6.2.10 **List of Items Opened, Closed, and Discussed (Optional).** The report should include a quick-reference list of items opened and closed. Open items that were discussed (but not closed) should also be included in this list, along with a reference to the sections in the report in which the items are discussed.

6.2.11 **List of Documents Reviewed.** A list of the appropriate key documents and records reviewed during an inspection that are significant to any finding must be publicly available. Therefore, if a list is not otherwise made public, the report should include a listing of all the documents and records reviewed during the inspection that are not identified in the body of the report. (See IMC 0620, "Inspection Documents and Records.") "Reviewed" in

this context means to examine critically or deliberately. The list does not include records that were only superficially reviewed. Lists consisting of more than six condition reports, documents reviewed, procedures, etc., should normally be removed from the body of the report and included as an attachment to facilitate reading.

6.2.12 **List of Acronyms, as appropriate.** Reports whose details section exceeds 20 pages should include a list of acronyms. For reports in which a relatively small number of acronyms have been used, the list is optional. In all cases, however, acronyms should be spelled out when first used in inspection report text.

## 7.0 Notice of Violation.

7.1 Licensees are officially notified that they have failed to meet regulatory requirements when Department issues a Notice of Violation (NOV). NOV's may be sent with an inspection report or in a separate letter which refers to an inspection report that was distributed previously. An NOV should not be sent to the licensee in advance of the inspection report. An example of a **Notice of Violation Letter** is Attachment 2.4-3 of RMPP 2.4 *Documentation of Inspection Reports*.

7.2 Every NOV must be clear, so that there is little doubt that the licensee (or other reader) can understand the basis for the violation. The licensee may not agree with our basis, but they must understand our position.

7.3 Every NOV must clearly state what requirement was not met, including the date and revision number of any applicable documents related to the inspection. A clear statement of what happened (including when, if the timing is important) must be provided. The NOV should also provide the length of time the licensee was in non-compliance.

## 8.0 Significance of Observations

8.1 This section discusses the significance of observations including violations, noncompliances, and enforcement actions. The guidance provided in this section is for informational purposes.

8.2 **Thresholds of Significance.** When conducting inspections, the Department inspector reviews a selection of procedures, events, and operations; he or she cannot hope to monitor all the activities in progress, nor to document every minor discrepancy that occurs. As part of maintaining a focus on safety, inspectors continually use Department requirements, inspection procedures, industry standards, and their own training and insight to make judgments about which issues are worth pursuing and which are not.

8.3 To communicate effectively, inspection reports must give evidence of that judgment and prioritization, discussing significant safety issues in appropriate detail, treating less significant issues succinctly, and avoiding excess verbiage. To maintain some consistency in how minor issues are treated, report writers must recognize certain "thresholds of significance." They must use similar criteria in deciding whether an issue is significant and will need documentation, and if the issue is important enough to track or follow up, etc.

**9.0 Minor Violations and Determining Whether to Document**. Minor violations are those that are less significant than a Severity Level IV violation. Minor violations do not warrant enforcement actions and are not normally documented in inspection reports. However, minor violations must be corrected. While in general, minor violations should not be documented, certain exceptions apply. Documentation may be necessary as part of the resolution of an allegation. In other cases, while the violation itself is minor, the associated technical information may relate directly to an issue of broader concern. If, for these reasons or any other reason, the report writers and reviewers wish to document a minor violation, then it should be documented as a minor violation.

**10.0 Violations Identified as Part of Licensee Self-Assessments.** Under certain circumstances, even a violation that could be classified as Severity Level IV ("more-than-minor") need not be documented. This is generally justified when the violation has been identified and corrected as part of a licensee self-assessment effort. As a matter of policy, Department enforcement seeks to encourage licensee self-assessment efforts, and seeks to avoid the negative impact that can result from a redundant Department emphasis on problems which the licensee's responsible action has already identified and corrected.

10.1 For example, suppose that while evaluating the licensee's quality assurance efforts in the fire protection area, an inspector reviews relevant audits and surveillances conducted over the previous year. The review reveals that the audits have been probing and thorough; the findings are well-developed and technically sound, and include six noncompliance issues, four of which might be classified at Severity Level IV.

10.2 In such a case, the inspector should follow up on the non-compliances and other audit findings to ensure that root causes have been appropriately identified and assessed, that appropriate and comprehensive corrective actions have been taken, and that no new examples of the violations exist. Provided that no new problems are revealed by this follow-up, the inspector is normally not expected to cite the four violations individually, nor to report the details of those violations in the inspection report. Instead, the Department report findings and conclusions should assess the adequacy of the licensee's quality assurance efforts, including a clear reference to the name, dates, and general subject matter of the audit or self-assessment.

**NOTE**: This expectation only applies to Severity Level IV violations. Even when identified through a licensee self-assessment, violations that could be categorized at Severity Level III or above must be documented in the inspection report and given appropriate follow-up.

10.3 In some instances, reasons exist to document one or more of the violations found in a licensee audit or self-assessment. For example, if the report concludes that the licensee's self-assessment was especially negative, one or more examples should be given to support that conclusion.

10.4 In addition, the inspector may decide to document one or more of the violations found in a licensee self-assessment due to the technical significance or generic implications of the particular item. Technical details surrounding the violation may provide useful insight on equipment or system reliability, or on some aspect of human performance. In some cases, the inspector may decide to pursue additional follow-up of a particular licensee finding because of related licensee problems, previous Department observations or violations involving the same or a related topic, or emerging government or industry sensitivity in the given technical area.

10.5 If, for any of these reasons, the inspector decides to discuss in the inspection report a particular licensee self-assessment finding or audit finding, and that finding involves a violation, then the violation must be clearly dispositioned in the report. The violation may be dispositioned as a non-cited violation (NCV) unless any one of the following circumstances results in an NOV requiring a formal written response from the licensee:

10.5.1 The licensee or nonlicensee identified the violation.

10.5.2 The licensee or nonlicensee corrected or committed to correcting the violation within a reasonable period of time by specific corrective action committed to by the end of the inspection, including immediate corrective action and comprehensive action to prevent recurrence.

10.5.3 The violation is not repetitive as a result of inadequate corrective action.

10.5.4 The violation is not willful.

10.6 If the issue represents a minor violation, it should be documented on the relevant inspection Checklist or other record outside the inspection report as follows: “This failure is considered a minor violation and should not be documented in a Department inspection report.”

**11.0 Thresholds of Significance for Non-Enforcement-Related Issues**. Inspectors must also make judgments about the relative significance of non-enforcement-related findings. As with enforcement issues, the judgment of individual inspectors will differ; questions on the relative significance of an issue should be discussed with other inspectors and with Department managers.

**12.0 Determining the Significance of Negative Findings**. The following questions should be used to determine whether or not a finding should be documented in the inspection report. If the answer to any one of these questions is "yes," the finding should be documented in the inspection report. If the answers to all questions are "no," the finding normally should not be documented.

12.1 Does the finding have any actual impact (or any significant potential for impact) on safety?

12.2 Is this finding illustrative of a programmatic licensee problem that could have a safety or regulatory impact?

12.3 Does this finding provide insights on an equipment, system, or human performance problem?

12.4 Could the finding be viewed as the possible precursor to a significant event?

12.5 If the licensee takes no action on this matter, will the condition worsen (i.e., will the safety significance increase)?

12.6 If this finding recurs, will its recurrence result in more significant or additional safety concerns?

12.7 Will this information be useful in assessing the long-term performance of this licensee program or functional area?

12.8 Does this finding have generic significance?

13.0 **Determining the Significance of Neutral or Positive Findings**. For neutral or positive findings or for licensee improvements, similar thresholds of significance should apply. The inspector should ask questions similar to those below. If the answer to any one of these questions is "yes," the finding should be documented in the inspection report. If the answers to all questions are "no," the finding normally should not be documented.

13.1 Does the licensee improvement have an actual positive impact (or a significant potential for positive impact) on safety?

13.2 Will the licensee’s efforts to impact change in this area be likely to result in programmatic improvements to safety or regulatory performance?

13.3 Will this upgrade be likely to result in improved equipment or system reliability or improved human performance? Does this information provide useful equipment, system, or human performance insights?

13.4 Does this licensee action significantly reduce the probability of a particular event?

13.5 Will this information be useful in assessing the long-term performance of this licensee program or functional area?

13.6 Does this finding have a generic significance?

14.0 **Findings Previously Covered in Licensee Self-Assessments**.

14.1 This decision should be treated similarly to the corresponding decision for enforcement issues. In general, little benefit exists in the Department's re-emphasis of issues already covered in licensee self-assessments, unless there is some problem with the licensee's actions.

14.2 In some instances, however, the technical significance or generic implications of an issue merit ensuring that it is discussed and preserved as a matter of public record.

14.3 If the licensee self-assessment that initially discussed the issue is already in the licensee files, the inspection report may simply refer to the discussion in the licensee self-assessment. If more detail is needed, or if the licensee self-assessment is not in the licensee files, the inspector may wish to discuss the issue in the inspection report narrative.

**15.0 Documenting Noncompliance**

15.1 **Types of Noncompliance.** The manner of documenting a noncompliance in the inspection report depends on how that noncompliance will be dispositioned. A noncompliance may be addressed as a non-escalated enforcement action (i.e., a Severity Level IV violation, a deviation, or a nonconformance); as an escalated enforcement action (i.e., an apparent Severity Level I, II, or III violation); or as a Non-Cited Violation (NCV).

15.2 Note that a noncompliance may not be documented simply as a "weakness," "licensee failure," or a similar informal characterization. If the report narrative describes a condition or event in a manner that suggests to the reader that a violation may have occurred, then the finding must be clearly dispositioned as a violation, an apparent violation, or an NCV. If a violation does not exist (e.g., no requirement exists in this area), it may be appropriate to clarify the finding by stating that "this condition [or event] does not constitute a violation of Department requirements."

15.3 **Non-Escalated Enforcement Actions.** Most violations of moderate significance (i.e., more than minor concerns) fall into this category. If at the time of issuing the inspection report a violation has been identified, the inspection report will cite it as a "non-escalated" enforcement action.

15.4 **Potential Escalated Enforcement Actions.** When an issue is being considered for escalated enforcement action, the inspection report narrative should refer to the potential noncompliance as an "apparent violation." The report details should not include any speculation on the severity level of such violations nor on expected Department enforcement sanctions. Potential escalated actions, by their nature, require further Department deliberation (and, usually, additional licensee input) to determine the appropriate severity level and Department action.

15.5 Similarly, report narratives that discuss apparent violations should be carefully constructed to avoid making explicit conclusions (i.e., final judgments) about the safety significance of the issue. The report should include any available details that demonstrate safety significance, or that would help in making such a decision and should also describe any corrective actions taken or planned by the licensee. However, since a potential escalated enforcement action automatically entails further evaluative steps, neither the inspection report details nor the accompanying cover letter should present a final judgment on the issue.

15.6 **Minor Violations.** Minor violations should not normally be documented in inspection reports. However, to the extent that documentation is necessary, the standard language should be used: “This failure constitutes a violation of minor significance and is not subject to formal enforcement action.”

15.7 **Supporting Details and Discussions of Safety Significance.** The discussion of noncompliance issues must be sufficiently detailed to substantiate any Department safety and regulatory concerns and to support any enforcement sanction the Department may choose to issue. At a minimum, for a violation, the report should state:

15.7.1 What requirement was violated;

15.7.2 How the violation occurred;

15.7.3 When the violation occurred, and how long it existed;

15.7.4 Who identified it, and when;

15.7.5 Any actual or potential safety consequence;

15.7.6 The root cause (if identified);

15.7.7 Whether the violation appears isolated or programmatic;

15.7.8 What corrective actions have been taken or planned; and

15.7.9 Who was involved with the violation (i.e., management involvement or low-level individual).

15.8 The degree of detail necessary to support an enforcement action is a function of the significance and complexity of the noncompliance. Although supporting details clearly assist in determining the safety significance of the noncompliance, inspectors should be cautious in making direct statements regarding safety significance in the inspection report details.

15.9 Violation severity levels are based on the degree of safety significance involved. In assessing the significance of a noncompliance, the Department considers four specific issues: (1) actual safety consequences; (2) potential safety consequences, including the consideration of risk information; (3) potential for impacting the Department's ability to perform its regulatory function; and (4) any willful aspects of the violation.

15.10 As a result, if an inspection report refers to a noncompliance as being "of low safety significance" (meaning, in a general sense, that the noncompliance did not result in any actual adverse impact on equipment or personnel), the writer may have inadvertently made it difficult for the Department to subsequently decide that the potential for an adverse impact or the regulatory significance of the noncompliance warrants issuance of a Severity Level III violation. Therefore, before characterizing a violation as being of “low safety significance,” the inspector should also address the potential consequences and regulatory consequences of the violation in addition to the absence of an actual adverse consequence.

15.11 **Noncompliance Involving Willfulness.** Inspection reports should neither speculate nor reach conclusions about the intent behind a violation, such as whether it was deliberate, willful, or due to careless disregard. As with any observation, the report discussion should include relevant details on the circumstances of the violation without making a conclusion about the intent of the violator. EXAMPLE: "The radiographer failed to activate his alarming ratemeter, although he had informed the inspectors earlier that he had been properly trained on the use of the device;" not, "The radiographer deliberately failed to activate his alarming ratemeter.”

## 16.0 Supervisory Accompaniments

16.1 At least annually, the Radiation Control Program Director (RCPD) will accompany each Department materials license inspector on at least one inspection. This will allow the RCPD to determine whether the inspector is

following Department guidelines and good practices as established in Inspection Manual Chapter 2800 “Materials Inspection Program.”

16.2 In order to ensure the inspection meets Department criteria, the RCPD will use SA-102 Appendix B, “Inspector Accompaniment Summary Sheet” to document the inspection.

16.3 The review of the inspection will be discussed with the inspector. This will ensure that any deficiencies may be identified in a timely manner.

16.4 The inspection reports for the accompaniment inspection along with any associated correspondence will be placed in a file at the RCPD’s office.

16.5 Additionally, the RCPD will utilize SA-102 Attachment B-1 along with the relevant inspection checklist from the applicable NUREG 1556 Safety Audits when reviewing inspections and inspection reports to determine the adequacy of the inspection. The checklist provides for an objective evaluation of individual inspection tasks. Performance of each individual inspection task i.e., inspector instrumentation, inspection procedure used, effective licensee communication etc., are evaluated to determine the completeness of inspection preparation, performance and inspection report generation.

## 17.0 ATTACHMENTS

2.7-1 Inspection Report Quality Assurance (QA) Checklist

**ATTACHMENT 2.7-1 INSPECTION REPORT QUALITY ASSURANCE (QA) CHECKLIST**

| | | |
|---|---|---|
| License Number: | | |
| License type: | | |
| Inspector: | | |
| Inspections Date(s): | | |
| Inspection Type: ☐ Initial ☐ Routine ☐ Reactive ☐ Special ☐ Reduced | | |
| Inspection Area | Evaluation | Comments |
| Inspection report issued within 30 days (RMPP 2.4 section) | ☐ Satisfactory<br>☐ Unsatisfactory | |
| Department Form 591M issued | ☐ Satisfactory<br>☐ Unsatisfactory<br>☐ N/A | |
| Report Details | ☐ Satisfactory<br>☐ Unsatisfactory | |
| Observations and Findings | ☐ Satisfactory<br>☐ Unsatisfactory | |
| Conclusions | ☐ Satisfactory<br>☐ Unsatisfactory | |
| Documenting Noncompliance | ☐ Satisfactory<br>☐ Unsatisfactory<br>☐ N/A | |

| | |
|---|---|
| Report Review and Concurrence | List all items reviewed (note any non-concurrences) |
| Inspector: | Signature: |
| Secondary Reviewer | Signature: |

## *4.4.3 Administrative Procedures for Inspections*

There are five RMPPs that guide the administration of the inspection program. RMPP 2.1 is for the scheduling of inspections, RMPP 2.2 helps inspectors prepare for inspections, RMPP 2.3 provides specific guidance so they are performance-based inspections, RMPP 2.4 describes how inspection results are to be documented and RMPP 4.2 describes how inspections are tracked.

# Vermont Department of Health

# Radioactive Materials Program

## Radioactive Materials Program Procedure 2.1, Revision 0

## Scheduling of Inspections

**Prepared By:**_____ **Date**_____

**Reviewed By:**_____**Date**_____

**Approved By:**_____**Date**_____

**Effective Date:**

| Revision | Date | Description of Changes |
|---|---|---|
| 0 | | |
| | | |

# Table of Contents


**1.0 PURPOSE**

- **1.1 Applicability**
- **1.2 References**
- **1.3 Files**

**2.0 RESPONSIBILITIES**

- **2.1 Radiological Health Specialist (RHS)**
- **2.2 Radioactive Materials Program Manager (RMPM)**
- **2.3 Radiation Control Program Director (RCPD)**

**3.0 PROCEDURE**

- **3.1 License Priorities**
- **3.2 Inspection Priorities**
- **3.3 Routine Inspections**
- **3.4 Initial Inspections**
- **3.5 Reactive Inspections**
- **3.6 Special Inspections**
- **3.7 Significantly Expanded Programs**
- **3.8 Abandonment of Licensed Activities**
- **3.9 Reduction of Inspection Frequency**
- **3.10 Pre-Licensing Visits**
- **3.11 Change of Control**

**4.0 RECORDS**

- **4.1 Files**

**5.0 ATTACHMENTS TO RMPP 2.1**

**None**

## 1.0 PURPOSE

### 1.1 Applicability

1.1.1 This procedure applies to the scheduling of inspections based on the priorities assigned to the various licensed activities.

1.1.2 This procedure delineates core and non-core inspection priorities and establishes a program of special inspection activities for all licensees.

1.1.3 The Performance-Based Inspection program requires that poor performers be inspected more frequently.

### 1.2 References

1.2.1 NRC Inspection Manual, Chapter 1220, "Processing of NRC Form 241, 'Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters', and Inspection of Agreement State Licensees Operating under 10 CFR 150.20"

1.2.2 NRC Inspection Manual, Chapter 2800, "Materials Inspection Program"

1.2.3 Vermont Radiological Health Rule

### 1.3 Files

Records are primarily filed electronically and Web-based Licensing (WBL) is the primary residence of these records.

## 2.0 RESPONSIBILITIES

### 2.1 Radiological Health Specialist

2.1.1 Provides a list on a monthly basis, using Web-Based Licensing (WBL), for the Radioactive Materials Program Manager (RMPM) of inspections due for the next six months by priority code. This is documented on the *Inspections Due for the Next 6 Months-By Priority Report.*

2.1.2 Maintains the files and the computer-based letters, forms and report files.

2.1.3 Conducts inspections and recommends reduction of intervals in inspection frequency.

2.1.4 Reviews licenses and recommends inspection priorities.

2.1.5 Shares appropriate information about inspections to other qualified members of the inspection and licensing staff.

### 2.2 Radioactive Materials Program Manager (RMPM)

2.2.1 Prepares inspection schedules and assigns inspectors, approves reduction of inspection frequency, and approves the assignment of license priorities. Schedules are documented on the *Inspections Due for the Next 6 Months-By Priority Report* which the RMPM maintains.

2.2.2 Determines if a reduced, reactive or special inspection is warranted, should be performed promptly or can be included in the next routine inspection; and initiates an inspection, if appropriate.

2.2.3 Reports inspection and licensing statistics to the Radiation Control Program Director on a quarterly basis.

2.2.4 Reviews and approves inspection plans and reports.

2.2.5 Debriefs all inspectors upon completion of the inspection and all of its documentation.

## 3.0 PROCEDURE

Scheduling of inspections should be in accordance with this procedure and Attachment 1.1-6 **Inspection Priority Codes Assigned to Program Codes** in RMPP 1.1 *Review of Initial Application for License or an Amendment Request*. All inspections, except initial inspections, certain special inspections and inspections determined by the RMPM, will be unannounced. To achieve the goals of cost saving and efficient use of staff time and travel, inspections (other than initial inspections) may be scheduled and performed within a window around their inspection due date as defined in IMC 2800. Inspections will not be considered "overdue" until they exceed the inspection due date plus or minus window defined in IMC 2800. Inspections may be scheduled before their window if the inspector receives information that warrants an earlier inspection.

### 3.1 License Priorities

3.1.1 Each license Program Code is assigned a Priority Code, which is the inspection frequency expressed in years. Priority Code 1 is to be inspected annually, Priority Code 2 is inspected every two years, Priority Code 3 is inspected every three years and Priority Code 5 is inspected every five years.

3.1.2 Attachment 1.1-6 **Inspection Priority Codes Assigned to Program Codes** is a listing of materials programs and their associated inspection

priorities.

3.1.3 The RMPM, or designee, shall assign a primary program code which sets the inspection priority for each new license.

3.1.4 Some licenses authorize activities that can be classified under more than one program code.

3.1.4.1 If a license involves more than one type of use, each part of the program shall be inspected in accordance with its assigned priority.

3.1.4.2 For example, a license for a medical institution (Program Code 02121, Priority Code 5) may be amended to authorize use of a high dose rate (HDR) remote afterloader unit (Program Code 02230, Priority Code 2).

3.1.4.3 The licensee's primary program code would be Program Code 02230. However, both activities should be inspected simultaneously during the HDR inspection.

## 3.2 Inspection Priorities

3.2.1 An inspection priority code is assigned to each radioactive material license.

3.2.2 The priority code (i.e., 1, 2, 3 or 5) is the interval between routine inspections, expressed in years, i.e., priority code 1 is inspected annually, priority code 2 is inspected every two years.

3.2.3 The same priority code is assigned to all licenses that authorize that particular type of use.

3.2.4 Enclosure 1 of NRC Inspection Manual Chapter 2800 lists the program codes (types of use) along with the assigned priority codes. This is reproduced as Attachment 1.1-6 **Inspection Priority Codes Assigned to Program Codes** in RMPP 1.1 *Review of Initial License Application or an Amendment Request*.

3.2.5 The priority represents the relative risk of radiation hazard. Priority Code 1 represents the greatest risk to the health and safety of workers, members of the public, and the environment, while Priority Code 5 represents the lowest risk.

3.2.6 Because a license may authorize multiple types of use (i.e., multiple program codes), the inspection priority code for the license is the code

with the shortest routine inspection interval.

3.2.7 The performance of reactive inspections shall receive first priority in the inspection program followed by the performance of core, reduced, and special inspections.

## 3.3 Routine Inspections

3.3.1 Core Inspections: Routine inspections of licenses in priorities 1, 2, and 3 shall be conducted at intervals in years corresponding to the inspection priority. If approved, Priority 1 and 2 licensees may be extended to 50 percent of the routine inspection interval and Priority 3 licensees may be extended for up to one year in circumstances where the licensee has demonstrated high performance; however the last inspection date must be used when scheduling the next inspection.

3.3.2 Non-Core Inspections: Priority 5 licenses shall be inspected at 5-year intervals. Priority 5 licensees are not eligible for this extension; however, the last inspection date must be used when scheduling the next inspection.

3.3.3 Temporary Job Site Inspections: For a licensee authorized to work at a temporary job site, inspectors shall make every reasonable attempt to schedule an unannounced inspection of licensed activities at such a location(s). If a temporary job site inspection is not performed, a brief note will be written in the inspection records, giving an explanation for the missed temporary job site inspection. In certain cases, the “next inspection date” data element in Web-Based Licensing may indicate a reduced inspection interval.

3.3.4 Permanent Field Offices: If the license authorizes licensed activities to be conducted from 4 to 10 permanent facilities (main office plus 3 to 9 field offices) at least 2 locations must be inspected at the interval specified by the program code for the specific type of license. If the license authorizes licensed activities to be conducted from more than 10 permanent facilities (main office plus more than 9 field offices), about 20 percent of the locations should be inspected. Inspection of various field offices should be rotated to assess the licensee's entire program over several inspection cycles.

## 3.4 Initial Inspections

3.4.1 All initial inspections, regardless of the license priority, are to be conducted within 6 months of the receipt of licensed material, within 6 months of beginning licensed activities, or within 1 year of license issuance, whichever comes first. Licensees are informed to notify the department of their first receipt of licensed material. Initial inspections of

a new licensee or an existing licensee which obtained an amendment for Program Code 02240 (Medical Therapy – Other Emerging Technology) shall be announced.

3.4.2 To schedule the initial inspection, the date in the "next inspection date" data element in WBL shall be 12 months from the date the new license or amendment was issued. The "last inspection date" data element in the licensee folder in Web-Based Licensing shall be blank. If it is determined that the licensee has not possessed licensed material or performed any principal activities, the inspector should ensure that the date in the "next inspection date" data element in the licensee folder in Web-Based Licensing is 12 months from the date of the onsite visit. If the licensee does not yet possess licensed materials or has not yet performed any principal activities, the initial inspection may be rescheduled to within 18 months of license issuance. If it is determined that the licensee does not possess licensed material or has not performed principal activities, the inspector should:

3.4.2.1. Determine the licensee's plans for future possession of licensed material or plans to perform principal activities. Use this opportunity to discuss the license and applicable regulations with the licensee.

3.4.2.2. The inspector should discuss any unique license conditions and give the licensee an opportunity to ask any regulatory questions.

3.4.2.3 Remind the licensee to notify the Department within 30 days after the receipt of licensed material or initiation of principal activities, as required by license condition.

3.4.2.4 Document the contact and enter the record into the licensees file. The conversation record should include the licensee's plans for future possession of material or plans to perform principal activities.

3.4.2.5 Ensure that the due date is set for 18 months from license issuance.

3.4.3 Performing initial inspections. During the initial inspection, the inspector should interview licensee staff (management and technical) to determine if licensed material was received or if principal activities have been performed. Methods for determining if principal activities have been performed include, but are not limited to the following:

3.4.3.1 Performing a site tour,

3.4.3.2 Performing independent measurements, and/or

3.4.3.3 Contacting distributors of licensed material, such as local radiopharmacies, to see if they have distributed material to the licensee.

Note: If the licensee has possessed licensed materials or performed principal activities, then the inspector should conduct an inspection in accordance with this section and other applicable guidance.

3.4.4 If it is determined that the licensee has not possessed licensed material or has not performed principal activities, the inspector should:

3.4.4.1 Determine the licensee's plans for future possession of licensed material or plans to perform principal activities. In assessing the licensee's future plans, the inspector should determine if adequate facilities and equipment are in place to safely handle licensed material, as described in the license application.

NOTE: As defined in 10 CFR Part 30, principal activities, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

3.4.4.2 Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should discuss any unique license conditions and give the licensee an opportunity to ask any regulatory questions.

3.4.4.3 Remind the licensee to notify the Health Department within 30 days after the receipt of licensed material or initiation of principal activities, as required by license condition.

3.4.4.4 Remind the licensee of the requirement in 10 CFR 30.36(d) to provide written notification to the Health Department within 60 days if no principal activities under the license have been conducted for a period of 24 months.

3.4.4.5 Document the onsite inspection by completing the appropriate inspection record. The "program scope" description should include the licensee's plans for future possession of material or plans to perform principal activities.

3.4.4.6 Ensure that the due date is set for 12 months from the date of the onsite inspection. To achieve the goals of cost saving and efficient use of staff time and travel, the date of the next initial inspection attempt may vary by ± 6 months.

## 3.5 Reactive Inspections

3.5.1 Reactive inspections receive first priority in the inspection program.

3.5.2 Following the receipt of notification of an incident, allegation or special information such as a medical event, the RMPM or designee shall determine if an immediate inspection is warranted or if the issue is best covered during the next scheduled inspection.

3.5.3 A reactive inspection counts as a scheduled inspection only if the total licensed program is evaluated.

## 3.6 Special Inspections

The following activities require special inspections:

3.6.1 Expired and Terminated Licenses: In accordance with the criteria outlined in RMPP 1.3 *License Termination/Revocation*, notification that a license has expired or is being terminated may require that an inspection be conducted within 30 days of the date of notification. This is an announced inspection.

3.6.2 Reciprocity Inspections: Receipt of a request for reciprocity may require performance of an inspection. The priority of the license, the location of the activity, and the time to be spent in the state should be factors in determining the need for an inspection. Reciprocity inspections are required for Priority 1, 2, and 3 licenses and 20% of all reciprocity inspection must be performed in a given year.

3.6.3 Team Inspections: The RMPM shall schedule team inspections of major licensees within Vermont on an as-needed basis.

## 3.7 Significantly Expanded Programs

3.7.1 A license reviewer may request a special inspection, if during the licensing review process it is determined that the licensee's program has significantly expanded.

3.7.2 The license reviewer should make the RMPM aware of the following examples of changes in a licensee’s scope of use and shall ensure that the “next inspection date” data element in WBL is changed.

3.7.2.1 A change in the Radiation Safety Officer

3.7.2.2 A portable gauge user requesting to add a new storage facility and/or requesting additional gauges not approved on the initial application

3.7.2.3 A licensee has recently requested a significant increase in the types, quantities or forms, and uses of radioactive materials on the licenses and if these actions have resulted in the possession of RSRM.

3.7.2.4 The licensee authorizes a physical move of a facility or a new use at a temporary jobsite

3.7.2.5 The license authorizes new (i.e., since the previous inspection) satellite facilities where materials will be used or stored;

3.7.2.6 The licensee has increased the types of uses or disposal (i.e., incineration or decay-in-storage) of radioactive material;

3.7.2.7 The number of authorized users has significantly increased or decreased; and

3.7.2.8 The licensee has ceased activities at the entire site or in any building or area as defined in 10 CFR 30.36(d).

3.7.2.9 Requests for new medical procedure involving the use of sealed or unsealed radioactive material Proposed revisions to licensees' facilities, etc.

3.7.2.10 If during the licensing review process, the reviewer determines that the licensee will possess RSRM, the reviewer, in consultation with management and administrative staff, should add Program Code 01000 in WBL. The license reviewer should complete the RSRM checklist to determine whether an on-site security review should be conducted.

3.7.3 During routine inspections of licensed facilities, inspectors should evaluate if licensed activities have significantly increased or decreased since the last inspection. The RMPM may determine a special inspection is needed if there is a significant increase in activity discovered during the last inspection.

## 3.8 Abandonment of Licensed Activities

3.8.1 The RMPM will determine if an inspection will be scheduled based on the complexity of the licensed activities, and the types and quantities of licensed material if licensed activities are abandoned.

3.8.2 When a licensee does not respond to Department inquiries e.g., returned mail with no forwarding address and the licensee cannot be contacted by any other means, then a license will be considered abandoned.

3.8.3 If telephone contact is not established, then an inspector should be sent to the licensee's site.

3.8.4 The decision of when to send an inspector to a licensee's site should be based on the complexity of the licensed activities, and the types and quantities of licensed material. The RMPM and RCPD must take steps to terminate the license in these cases.

## 3.9 Reduced Inspection

3.9.1 At the discretion of the RMPM, other changes in inspection interval may be made to achieve efficiencies in the use of inspection resources and to reduce regulatory impact on the licensee.

3.9.1 This may include more frequent inspections to ensure that inspectors have the opportunity to sufficiently observe licensee operations and increase public confidence by increasing the inspection focus on higher risk activities, without significantly increasing the regulatory burden on licensees.

3.9.2 For example, rather than perform a single, large team, high impact inspection of the license at the normal interval, more frequent inspections may be performed by individuals or smaller teams that specifically focus on higher risk licensee activities.

3.9.2 The inspection interval shall not be extended beyond that specified by the priority system indicated in section 3.1. The interval between inspections may be reduced (shortened) and inspections conducted more frequently than specified in the priority system on the basis of poor licensee performance. The main consideration in reducing the inspection interval should be evidence of moderate to severe problems in the licensee's radiation safety program. Poor compliance history is also a consideration.

3.9.2.1 Poor Licensee Performance: Based on poor licensee performance the interval between inspections may be reduced and inspections conducted more frequently than specified in the priority system.

Poor performance is evidenced by moderate to severe problems in the radiation safety program, a poor compliance history, or a lack of management involvement or control over the radiation safety program. Reduction of inspection frequency shall be considered for licensees that meet one or more of the following conditions (this list is not all-inclusive):

3.9.2.1.1 A Severity Level I, II, or III violation on the most recent inspection;

3.9.2.1.2 Issuance of an order or escalated enforcement on the most recent inspection;

3.9.2.1.3 "Management Paragraph" appears in the cover letter transmitting the notice of violation on the most recent inspection (management paragraph is a paragraph that requires the licensee to address adequate management control over the licensed program);

3.9.2.1.4 An event requiring a reactive inspection;

3.9.2.1.5 Repetitive violations;

3.9.2.1.6 Enforcement conference where the outcome did not include escalated enforcement action but did indicate the need for the licensee to improve some aspect(s) of its compliance program;

3.9.2.1.7 Industrial radiography licensee or a well logging licensee, who is authorized to use radioactive material at temporary job sites and the current inspection, was limited to an office inspection and no temporary job site inspection was completed during the current inspection.

3.9.2.2 Follow-up Inspections: Licensees that meet the above criteria may have their inspection interval reduced by any length. A follow-up inspection should be conducted within 6 months of receipt of a licensee's corrective action(s) following an escalated enforcement action. (see RMPP 2.5)

3.9.2.3 Reduction Time Frame: The reduction shall be valid only until the next inspection, but the RMPM shall consider the results of the inspection and determine if the reduced frequency should be continued, changed or returned to normal. The recommendation to reduce the inspection frequency must be documented on the inspection report by the inspector and approved and signed by the RMPM.

3.9.2.4 Recording and Identifying Change in Inspection Priority: The designated inspection priority for these licensees should not be changed in the licensee folder in Web-Based Licensing. However, the "next inspection date" field in Web-Based Licensing should be changed to contain the reduced date for the next inspection.

## 3.10 Pre-Licensing Site Visit

3.10.1 Generally, pre-licensing site visits shall be conducted for new entities that do not have an existing Agreement State or NRC license, licensees changing ownership to an unknown entity, or licensees that are significantly expanding the size or scope of their existing license.

3.10.2 Reviewers must use the Pre-Licensing Checklist and guidance in RMPP 1.1 to determine if pre-licensing visits are needed.

3.10.3 The purpose of the pre-licensing site visit is to evaluate the applicant's intentions regarding the use of radioactive materials and to forward suspicious applications to the appropriate authority for follow-up, per the guidance in the Pre-Licensing Guidance Checklist. At a minimum, all storage and use locations must be visited.

3.10.4 By the end of the visit, the reviewer should have observed, collected, and documented sufficient information to provide a basis of confidence that the applicant will use the radioactive materials as specified in its license application. Pre-licensing site visits must be completed before the issuance of a license.

3.10.5 The new license should not be provided to the licensee/applicant during the site visit.

## 3.11 Change of Control

**3.11.1 New License:** New licenses that are issued solely as a result of a licensee's change of mailing address are not required to receive an initial inspection, if the licensee's place of use remains the same as on the previous license. The "last inspection date" and "next inspection date" data elements in WBL should remain the same as for the licensee's previous license.

**3.11.2 <u>Change of Control</u>**: New licenses that are issued as a result of a change of ownership or transfer of control are not required to receive an initial inspection unless:

3.11.2.1 The organization controlling the licensed activities changes substantially (i.e., changes in key personnel, authorities, or resources associated with the radiation safety program);

3.11.2.2 The licensee significantly increases the types, quantities, or forms of radioactive materials on the license;

3.11.2.3 The licensee significantly increases the different uses authorized on the license (i.e., adds brachytherapy to a diagnostic nuclear medicine license);

3.11.2.4 The licensee significantly increases the number of authorized users; or

3.11.2.5 The new license authorizes one or more new facilities.

If none of these conditions apply, then the "last inspection date" and "next inspection date" fields in WBL should remain the same as for the previous license.

## 4.0 RECORDS

Records are primarily filed electronically and Web-based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available and may include Department network files.

## 5.0 ATTACHMENTS TO RMPP 2.1

None

# Vermont Department of Health

# Radioactive Materials Program

## Radioactive Materials Program Procedure 2.2, Revision 0

## Inspection Preparation

**Prepared By:**_____ **Date**_____

**Reviewed By:**_____**Date**_____

**Approved By:**_____**Date**_____

**Effective Date:**

| Revision | Date | Description of Changes |
|---|---|---|
| 0 | | |
| | | |

# Table of Contents


**1.0 PURPOSE**

- **1.1 Applicability**
- **1.2 References**
- **1.3 Files**

**2.0 RESPONSIBILITIES**

- **2.1 Radiological Health Specialist**
- **2.2 Radioactive Materials Program Manager (RMPM)**
- **2.3 Radiation Control Program Director (RCPD)**

**3.0 PROCEDURE**

- **3.1 General**
- **3.2 Initial Inspections**
- **3.3 Routine Inspections**
- **3.4 Reactive Inspections**
- **3.5 Special Inspections**
- **3.6 Reduced Inspections**

**4.0 RECORDS**

- **4.1 Files**

**5.0 ATTACHMENTS TO RMPP 2.2**

- **2.2-1 Radioactive Materials Program Guidelines for Completing an Inspection Plan**

## 1.0 PURPOSE

### 1.1 Applicability

1.1.1 This procedure applies to an inspector preparing for the performance of an inspection.

1.1.2 Preparation for conducting initial, routine, special, reactive and reduced frequency is covered.

### 1.2 References

1.2.1 NRC Inspection Manual, Manual Chapter 2800, "Materials Inspection Program"

1.2.2 Vermont Radiological Health Rule

## 2.0 RESPONSIBILITIES

### 2.1 Radiological Health Specialist

2.1.1 Provides a list on a monthly basis, using Web-Based Licensing for the Radioactive Materials Program Manager (RMPM) of inspections due for the next 6 months. These are in accordance with their Priority Code and documented on the *Inspections Due for the Next 6 Months-By Priority Report.*

2.1.2 Maintains the files and WBL current with letters, forms, and reports.

2.1.3 Updates files.

2.1.4 Properly prepares for each inspection by following the guidance in Section 3 below.

### 2.2 Radioactive Materials Program Manager

2.2.1 May assign inspections to a qualified member of the inspection staff. This duty may be delegated to the RCPD. Maintains the *Inspections Due for the Next 6 Months-By Priority Report.*

2.2.2 Discusses with inspection staff any items from previous inspections and their proposed inspection plan, if required.

2.2.3 Approves inspection plans if required, before the inspection begins.

### 2.3 Radiation Control Program Director

2.3.1 Assigns inspections to a qualified member of the inspection staff, in the absence of the RMPM.

2.3.2 Approves travel plans as necessary.

## 3.0 PROCEDURE

### 3.1 General Inspection Process

3.1.1 This procedure is designed to provide guidance that is applicable to all types of licensed programs.

3.1.1.1 General inspection preparation should be completed in accordance with this procedure and other applicable RMPPs.

3.1.1.2 It is expected that inspectors understand and use the unique individual requirements for each type of inspection, such as use of an appropriate NRC Licensing Guide (NUREG-1556) Safety Audit or the appropriate Inspection Checklist and Inspection Procedure for the inspection type.

3.1.1.3 Scheduling of inspections is in accordance with RMPP 2.1 *Scheduling of Inspections*.

3.1.1.4 Inspection of licensees shall be conducted per RMPP 2.3 *Performance-Based Inspections*.

3.1.1.5 Checklists for the different inspections by licensee type are in the applicable NUREG 1556 series checklist. Inspections should be conducted following these checklists and procedures.

3.1.1.6 RMPP 2.7 *Assuring the Technical Quality of Inspections* provides detailed guidance on inspections and their reports.

3.1.1.7 Any new Regulatory Issue Summaries or Information Notices that may be applicable to the licensee since the last inspection.

3.1.2 It is not necessary for the inspector to review all the current licensing documents and procedures from the licensee file. However, to adequately prepare, an inspector shall review:

3.1.2.1 The license to determine:

3.1.2.1.1 If any unusual license conditions or tie-down commitments exist that would affect the approach to the

inspection, i.e. authorization for non-routine maintenance, use of material at temporary job sites,

3.1.2.1.2 If the licensee is authorized for activities at temporary job sites, prepare to make every reasonable attempt to include an unannounced inspection of licensed activities at any temporary jobsite(s).

3.1.2.2. The licensee's recent inspection and enforcement history, i.e., results of the last inspection and any outstanding open items, and to determine whether any events have been reported by the licensee during the current inspection cycle. Older issues preceding the last inspection should be reviewed, if warranted by circumstances such as incidents, noncompliance, or high radiation exposures.

3.1.2.3 The Nuclear Material Events Database (NMED) to determine if any incidents have occurred since the last inspection.

3.1.2.4. Any commitments made by the licensee or restrictions imposed by the Department as a result of an order or other enforcement action issued since the last inspection.

3.1.2.5. Any information regarding special inspection emphasis, i.e., license reviewer's request for an inspection regarding a significant licensing action. For example, an amendment for a new medical therapy modality under 10 CFR 35.1000 shall be inspected within 12 months of the date of amendment.

3.1.2.6 Any allegation trends and a follow-up of the licensee's evaluations and response to the allegation.

3.1.2.7 Any changes to the Regulatory Requirements since the last inspection that affect the licensee's program.

3.1.2.8 A copy of the applicable Sealed Source and Device Registration Certificates.

3.1.3 For a reactive inspection, the inspector should review specific information as determined by the RMPM on a case-by-case basis.

3.1.4 Inspectors should anticipate whether or not they will encounter protected information during an inspection of a licensee and be prepared to provide the minimum handling requirements for confidential information.

3.1.4 Anticipate security requirements, guidance, questions and answers, and/or

supplemental correspondence (e.g., licensee responses, requests for relief and final Department determinations).

3.1.5 If the licensee is authorized to possess risk significant radioactive material (RSRM), request the National Source Tracking System (NSTS) inventory record at least two days in advance.

3.1.6 The inspector should identify the location of the licensee, make travel arrangements, and discuss special aspects of the inspection with the RMPM, as necessary.

3.1.7 The inspector should prepare questions for interviews and consider the focus areas or focus elements in the applicable NRC inspection procedure.

3.1.8 If necessary, methods for determining if licensed activities have been performed effectively may include contacting distributors of radioactive material, such as local radiopharmacies, to see if they have distributed material to the licensee.

3.1.9 The inspector must be prepared to meet all entry requirements established by the licensee (i.e., view the licensee's safety video, use personal protective equipment, or meet any special requirements for entering sterile environments). Staff must also wear their assigned dosimetry and appropriate personal protective equipment (safety shoes, glasses, hearing protection and hard hats).

3.1.10 The inspector should obtain the appropriate inspection reports, select appropriate and calibrated radiation detection instrumentation, and use the appropriate Inspection Procedure(s) and safety audits from the NUREG 1556 series for the inspection and obtain any other documentation that may be useful.

3.1.11 Radiation detection instruments are assigned to individuals, with additional instruments in the Environmental Health Laboratory that can ensure appropriate instrumentation for potential surveys as related to the licensed activities being inspected. There are alpha, beta, gamma survey instruments, contamination and exposure rate instruments and radioisotope identification detectors available.

## 3.2 Initial Inspections

The licensee is informed to report the first receipt of licensed material to the Department. Initial inspections are conducted within six months following receipt of the notice from the licensee that licensed material has been received or one year following the issuance of the license whichever occurs first. All initial inspections of a new licensee, or any existing licensee which obtained an

amendment for Program Code 02240 (Medical Therapy – Other Emerging Technology) are to be announced. Preparation for routine inspections should be conducted in accordance with Section 3.1 and other applicable guides.

## 3.3 Routine Inspections

3.3.1 All routine inspections are unannounced unless specific instructions are received from the RMPM that an inspection is to be announced.

3.3.2 Preparation for routine inspections should be conducted in accordance with Section 3.1 and other applicable guides.

3.3.3 Routine inspection frequency is as determined by RMPP 2.1 *Scheduling of Inspections* and Attachment **1.1-6 Inspection Priority Codes Assigned to Program Codes** in RMPP 1.1 *Review of Initial License Application or an Amendment Request*.

3.3.4 While encouraged for use, an inspection plan is not required.

## 3.4 Reactive Inspections

3.4.1 Reactive inspections focus on limited issues, often related to specific incidents, that are not within the scope of preparation for a routine inspection. If the reactive inspection does not cover the activities normally reviewed during a routine inspection, then the scheduling window still applies based on the licensee's default inspection priority and is not changed by a reduction of inspection interval.

3.4.2 The RMPM shall promptly assess the preliminary information received concerning the incident to determine if a reactive inspection is necessary.

3.4.3 The RMPM will notify a Radiological Health Specialist of the incident and if an inspection is required.

3.4.4 The inspector will review appropriate specific information to prepare for a reactive inspection.

3.4.5 The inspector should also prepare for issues of compliance, which will generally be addressed after all safety issues and program weaknesses are identified and clearly understood.

3.4.6 **Reactive Inspections for Incidents.** The emphasis while preparing for reactive inspection in response to incidents is the analysis of the sequence of events and the conditions that existed at the time these events occurred. The analysis should lead to the determination of contributing factors and

root causes and to the formulation of corrective actions to prevent recurrence.

3.4.7 **Reactive Inspections for Medical Events.** Preparation for inspections of medical events shall be conducted in accordance with the guidance in RMPP 3.2 *Incident Response*.

3.4.8 **Reactive Inspections for Allegations.** Preparation for inspections of allegations shall be processed in accordance with RMPP 3.1 *Management of Allegations*.

## 3.5 Special Inspections

Special inspections (i.e., reciprocity, security, etc.) focus on limited issues that are not within the scope of a routine inspection. Preparation for these inspections may be under the supervision of the RMPM. Preparing for reciprocity inspections should be completed in accordance with this procedure and all applicable RMPPs. Narrative reports shall be prepared, if required by the RMPM, for special inspections. Inspection frequencies for special inspections are defined in RMPP 2.1 *Scheduling of Inspections*.

3.5.1 **Reciprocity Inspections.** The inspector should prepare for an unannounced inspection of actual field work and review appropriate information to use during inspection.

3.5.2 **Temporary Job Site and Permanent Field Office Inspections.** The inspector should prepare to perform an unannounced inspection of licensed activities at these location(s). Preparation for temporary job site and permanent field office inspections should be conducted in accordance with Section 3.1 and other applicable guides.

3.5.3 **Abandoned, Expired and Terminated License and Decommissioning Activities.** Notification that a license has expired or is being terminated requires prompt action (i.e., within 30 days) to ensure that licensed material has been properly transferred or disposed of, and that all areas where material was used may be safely released for unrestricted use.

3.5.3.1 Emphasis should be placed on security and control of radioactive materials while preparing for an inspection at these types of facilities.

3.5.3.2 Prepare to review the licensee's transfer, disposal, and closeout survey data; and/or prepare to perform confirmatory surveys.

3.5.3.3 Prepare to review records of radioactive material disposals and public dose that may be required to be submitted to the Department.

3.5.3.4 Prepare to verify that the licensee is complying with regulations for timely decontamination and decommissioning and meeting the required schedules for licensee action.

3.5.3.5 Abandoned licensed activities indicated by returned mail, unreturned telephone calls or email, disconnected telephone messages or unoccupied or abandoned spaces found upon site visit need to be investigated to the degree determined by the RMPM and RCPD in consultation with Department leadership and legal counsel with particular attention to any potential for health and safety risk.

3.5.4 **Team Inspections.** Team inspections will be conducted on an as-needed basis.

3.5.4.1 At the RMPM's discretion, inspection plans may be developed for all team inspections.

3.5.4.2 Inspection plans should be considered for team inspections of major, broad scope academic or medical licensees, large manufacturers, or in cases where team members from agencies outside the Department (other than NRC or other Agreement State radiation control agencies) are involved.

3.5.5 **Reduced Inspections.** Reduced inspections may be performed for a variety of reasons as determined by the Radioactive Material Program Manager.

3.5.5.1 The most common reason is due to poor licensee performance. All other reasons will be addressed with the Radiological Health Specialist assigned to the inspection by the Radiation Control Program Director.

3.5.5.2 Poor Performance History: The focus should be on the areas of poor performance and only other areas of the radiation safety program as time allows.

3.5.5.3 The inspection should be unannounced unless specific individuals and/or activities need to be reviewed that are not available or performed on a routine basis by the licensee.

3.5.5.4 All other preparation should be conducted in accordance with RMPP 3.1 and other applicable guides.

3.5.6 Inspections After Escalated Enforcement.

If escalated enforcement action has taken place for a particular licensee, a special inspection that focuses on the licensee's corrective actions in response to Severity Level III or above violation(s) shall be scheduled and conducted within 12 months of the issuance of the escalated enforcement action (Severity Level III or above).

## 3.6 Inspection Preparation Plan

See Attachment 2.2-1 **Inspection Plan** for completion of the inspection plan. The following items should be reviewed:

3.6.1 License: Differences between the license and the application, if any; and "tie-down" commitments and information submitted by the licensee that is not a "tie-down" condition in the license.

3.6.2 License File: Determine if the license has been amended since the last inspection. Note differences such as increased scope of operations, changes in principal staff, new/different facilities, new "tie-down" commitments or other special license conditions.

3.6.3 Regulatory Requirements: Determine changes in regulatory requirements since the last inspection that affect the licensee's program.

3.6.4 Results of Last Inspection: Review the results of the last inspection. If any enforcement action was taken, or if clear inspection form with minor noncompliance items was issued, note the items that the licensee committed to correct.

3.6.5 Guidance: Use appropriate Vermont guidance to determine specific requirements that should be reviewed during the inspection. [NOTE: This should include a review of the appropriate Inspection Procedures.]

3.6.6 Notices: Review the Department's and NRC's Information Notices and Regulatory Issue Summaries files and NRC's Office of Nuclear Materials Safety and Safeguards Letters to determine if there have been any recent issues concerning this type of licensee that should be reviewed during this inspection.

3.6.7 Nuclear Material Events Database (NMED): Review NMED for licensee events.

3.6.8 Allegations, if appropriate. If there was an allegation, the next inspection should address the issue.

3.6.9 Sealed source and device registrations should also be reviewed.

3.6.10 NRC and State RMP letters: Review the variety of STC, NMSS, RCPD and other NRC or State RMP letters for issues of relevance to the licensee.

4.0 RECORDS

**4.1 Files**

4.1.1 Records are primarily filed electronically and Web-based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available, and may include Department network files.

4.1.2 The completed inspection reports and any necessary correspondence mailed to and/or received from the licensee are placed in the licensees electronic and paper files.

**5.0 ATTACHMENTS TO RMPP 2.2**

Attachment 2.2-1 **Inspection Plan**

## Attachment 2.2-1: Inspection Plan

DIRECTIONS:

The following guidelines are provided to help complete the inspection plan and prepare for the inspection.

DEFINITIONS:

**Area:** The components of the licensee's program being inspected. Example areas include industrial radiography-field operations and Medical Licensee-Radiopharmaceutical Therapy or Radiation Therapy

**Activity:** Tasks performed by an individual within an area. Example activities are industrial radiography surveys, milking the generator, administration of I-131, or Gamma Knife patient treatment

**Element:** Observable aspects of an activity. Example elements are surveys of camera after source crank-in; use of shielded container, time, gloves, syringe shield, or survey meter.

LICENSEE ACTIVITY SELECTION GUIDELINES

A. Identify high priority areas and activities

B. Activities in progress are preferred

C. Identify medium and low priority activities that can be inspected concurrently

D. Give preference to high priority elements

INSPECTION METHOD

The preferred method is direct observation. Acceptable alternatives include:

A. Walk-through or demonstration

B. Review of activity documents

C. Interview selected licensee personnel

**Radioactive Materials Program**
**Inspection Plan**

**Licensee Information**

**License Number** _____

**Licensee Name and Address** _____

**Licensee Contact** _____
**(Name, Business e-mail, and Telephone)**

**License and Inspection Information**

**Amendment Number**_____ **Priority** _____

**Last Inspection Date**_____ **This Inspection Date**_____

**Type of Inspection:** ☐ Announced ☐ Initial ☐ Special

☐ Unannounced ☐ Routine ☐ Re-inspection

**Performance-Based Inspection Plan**

**1. Identify the higher priority areas and activities to be reviewed. Note lower priority areas that may be reviewed concurrently.**

---

**2. Indicate the major elements to be observed. List individuals/positions to be interviewed.**

---

**3. Check the documents that were reviewed during inspection preparation.**

- ☐ Previous Inspection Report
- ☐ Reading File
- ☐ NRC Inspection Procedure(s)
- ☐ License Conditions/Tie-downs
- ☐ SSD Sheets
- ☐ 10 CFR
- ☐ NUREG-1556
- ☐ Information Notices/Regulatory Issue Summaries
- ☐ NMED and allegation file, if appropriate

**4. List survey meters that will be used on the inspection.**

**Acknowledgements**

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Inspector Signature | Date | Approval Signature (Radioactive Materials Program Manager) | Date |

# Vermont Department of Health

# Radioactive Materials Program

## Radioactive Materials Program Procedure 2.3, Revision 0

## Performance-Based Inspection

**Prepared By:**_____ **Date**_____

**Reviewed By:**_____**Date**_____

**Approved By:**_____**Date**_____

**Effective Date:**

| Revision | Date | Description of Changes |
|---|---|---|
| 0 | | |
| | | |

# Table of Contents


**1.0 PURPOSE**

- **1.1 Applicability**
- **1.2 References**
- **1.3 Files**

**2.0 RESPONSIBILITIES**

- **2.1 Radiological Health Specialists**
- **2.2 Radioactive Materials Program Manager (RMPM)**
- **2.3 Radiation Control Program Director**

**3.0 PROCEDURE**

- **3.1 General**
- **3.2 Inspection Preparation**
- **3.3 Performance-Based Inspection**
- **3.4 Initial Inspections**
- **3.5 Routine Inspections**
- **3.6 Reactive Inspections**
- **3.7 Special Inspections**
- **3.8 Reduced Inspections**
- **3.9 Team Inspections**
- **3.10 Coordination with Other Agencies**
- **3.11 Security**
- **3.12 Pre-Licensing Visits**

**4.0 RECORDS**

**5.0 ATTACHMENTS TO RMPP 2.3**

**None**

# 1.0 PURPOSE

## 1.1 Applicability

1.1.1 Inspections conducted by the Vermont Radioactive Materials Program (RMP) are to be performance-based, meaning the inspector evaluates the licensee performing activities for which they are licensed.

1.1.2 This procedure describes how an RMP inspector is to conduct performance-based inspections. The NRC Inspection Procedures and Inspection Manual 2800 are to be used along with the additional guidance found in:

1.1.2.1 RMPP 2.1 *Scheduling of Inspections*

1.1.2.2 RMPP 2.2 *Inspection Preparations*

1.1.2.3 RMPP 2.4 *Documentation of Inspection Results*

1.1.2.4 RMPP 2.6 *Materials Inspections Checklists and Definitions*

1.1.2.5 RMPP 2.7 *Assuring the Technical Quality of Inspections*

1.1.2.6 RMPP 4.2 *Tracking Inspections*

1.1.3 A review of a licensee's program documentation or a walk-down (tour) of a facility is not a performance-based inspection.

1.1.4 This procedure applies to the observation of a licensee's program activities to determine if regulatory and technical objectives are being achieved.

1.1.5 This procedure helps the inspector identify and prioritize those activities that impact on a licensee's performance.

## 1.2 References

1.2.1 NUREG-1556 Volume 19, Revision 1, “Guidance for Agreement State Licensees About NRC Form 241 ‘Report of Proposed Activities in Non-Agreement States, Areas of exclusive Federal Jurisdiction, or Offshore Waters’ and Guidance for NRC Licensees Proposing to Work in Agreement States Jurisdiction (Reciprocity).”

1.2.2 NRC Inspection Manual Chapter 0620, “Inspection Documents and Records.”

1.2.3 NRC Inspection Manual Chapter 1220, “Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20.”

1.2.4 NRC Inspection Procedure 87103, “Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing.”

1.2.5 NRC Inspection Manual, Chapter 2800, "Materials Inspection Program."

1.2.6 NRC Management Directive 8.10, "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility."

1.2.7 Vermont Radiological Health Rule.

**1.3 Files**

1.3.1 Current Department and NRC Information Notices & Regulatory Issue Summaries

1.3.2 Licensee File

1.3.3 Records are primarily filed electronically and Web-based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available, and may include Department network files.

## 2.0 RESPONSIBILITIES

### 2.1 Radiological Health Specialists

2.1.1 For each initial, routine core and non-core inspection:

2.1.1.1 Reviews, as appropriate, application, license and inspection reports, and Department and NRC Information Notices.

2.1.1.2 Determines instruments needed to conduct independent measurements.

2.1.1.3 Conducts performance-based inspections by observing licensed activities in progress.

2.1.1.4 Reviews the inspection findings with the Radioactive Materials Program Manager (RMPM) and/or Radiation Control Program Director (RCPD), as necessary.

2.1.2 For each reactive, reduced, or special inspection:

2.1.2.1 Reviews relevant information based upon the required scope of the inspection.

2.1.2.2 Conducts an inspection with a focus on the required scope by observing licensed activities in progress.

2.1.2.3 Reviews the inspection findings with the RMPM and/or RCPD, as necessary.

2.1.2.4 Informs the licensee of pending initial inspections and reactive inspections, if necessary.

### 2.2 Radioactive Materials Program Manager (RMPM)

2.2.1 Within one week of submission, reviews the inspection findings with the assigned inspector(s), as necessary.

2.2.2 Determines if a reactive or special inspection is warranted, if it should be performed promptly or if it can be included in the next routine inspection. Assigns an inspector or team of inspectors to perform the inspection.

2.2.3 Provides inspection statistics to the RCPD quarterly. These may be generated using WBL.

### 2.3 Radiation Control Program Director (RCPD)

2.3.1 Performs an annual accompaniment inspection with each Radiological Health Specialist and documents the results. [See Appendix B in SA-102 for template.]

2.3.2 May perform duties of the RHS or RMPM in their absence.

## 3.0 PROCEDURE

### 3.1 General

3.1.1 An inspection will be considered to have been performed if:

3.1.1.1 The inspection involves a licensee that possesses or has possessed

licensed material since the last inspection, or that is performing or has performed licensed activities since the last inspection;

3.1.1.2 The inspection is an initial inspection that has been performed in accordance with this procedure;

3.1.1.3 Where inspections of temporary job site activities were not available to the inspector at the time of the inspection, this inspection should be recorded as an inspection of the main office and the inspection documentation should make note of this.

3.1.1.4 An inspection for licenses that have expired or are being processed for termination.

3.1.2 An inspection will not be considered to have been performed if the licensee or licensee's representatives are not available to assist with the inspection, and the inspector is unable to perform inspection activities. The inspector should determine when another attempt will be made to inspect the licensee, document the attempted inspection in accordance with RMPP 2.4 *Documentation of Inspection Results.*

3.1.3 Performing inspections should be completed in accordance with this procedure. This procedure is designed to provide guidance that is applicable to all types of licensed programs. It does not specify the unique individual requirements for each type of inspection that may be found in other Department or NRC guidance documents. All routine inspections are unannounced unless specific instructions are received from the RMPM or other factors (i.e., initial inspections and mobile unit at different locations) require that an inspection is to be announced.

3.1.4 Focus elements or focus areas in the NRC inspection procedures are selected as a performance expectation and address the activities or program areas most commonly associated with measures that prevent overexposures, medical events, or release, loss, or unauthorized use of radioactive material. The inspector should conduct the inspection in a manner that will develop conclusions about licensee performance relative to the following focus elements or focus areas.

3.1.5 If the inspector concludes that licensee performance is satisfactory from a general review of selected aspects of a focus element, the inspection effort expended in reviewing that particular focus element will be complete. If the inspector determines that the licensee did not meet the performance expectation for a given focus element, the inspector should conduct a more thorough review of that aspect of the licensee’s program. The increased inspection effort may include additional sampling, determination of

whether the licensee's procedures are appropriate, and a review of selected records maintained by the licensee documenting activities and outcomes.

3.1.6 The inspector should use a performance-based approach to evaluate the focus elements. A determination regarding safety and compliance with Department requirements should be based on direct observation of work activities, interviews with licensee workers, demonstrations by appropriate workers performing tasks regulated by the Department, independent measurements of radiological conditions at the licensee's facility, and, where appropriate, a review of selected records. Emphasis should be placed on observing licensee performance as it relates to staff training, equipment operation and adequacy, overall management of the licensed program, and integration of safety and security.

3.1.7 In reviewing the licensee performance, the inspector should cover the period from the last to current inspection. However, older issues preceding the last inspection should be reviewed if warranted by circumstances such as incidents, noncompliance, or high radiation exposures.

3.1.8 The inspector must be prepared to meet all entry requirements established by the licensee (i.e., view the licensee's safety video, use personal protective equipment, or meet any special requirements for entering sterile environments) prior to beginning the performance-based inspection.

3.1.9 Unless an inspector needs to intervene to prevent an unsafe situation, direct observation of work activities should be conducted such that the inspector's presence does not interfere with licensed activities. The inspector shall not under any circumstances knowingly allow an unsafe work practice which could lead to an unsafe situation to occur or continue in his or her presence in order to provide a basis for enforcement action.

3.1.0 Review of licensee records and other documents should be directed toward verifying that current operations are in compliance and further review of "historical" records should only occur if the current records are out of compliance and the inspector believes it necessary to determine the presence of a prevalent or persistent problem. If the inspector finds it appropriate when an apparent violation has been identified, the inspector should gather copies, while onsite, of all records that are needed to support the apparent violation. The inspector should be aware whether or not the information reviewed or gathered has been declared as proprietary information by the licensee.

3.1.11 Proprietary and/or patient information should not be taken from the licensee unless confidential, security-related or personally identifiable information has been removed. In the case of a medical incident only the information relevant to the incident should be included. Personally

identifiable patient information such as name, medical record and social security numbers are examples of Personally Identifiable Information (PII).

3.1.12 In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (i.e., licensee materials inventories), or make the licensing file more complete. Inspectors shall ensure that the licensee understands that the retained record will become publicly available and shall give the licensee the opportunity to provide redacted copies or to request withholding the information.

3.1.13 The inspector should advise the licensee of the inspection findings throughout the course of the onsite inspection and not wait until the exit meeting to inform licensee senior management. The inspector should allow ample time during the inspection for a licensee to correlate information about root cause, consequence, and corrective action for an apparent violation. The inspector shall clearly present apparent violations and confirm the licensee's understanding and agreement that an apparent violation occurred, preferably before leaving the site. The inspector shall also take the time to discuss any recommendations.

3.1.14 The inspector should keep the RMPM informed of significant findings (i.e., safety hazards, willfulness, and other potential escalated enforcement issues) identified during the course of the inspection. This will ensure that the inspector is following appropriate Department guidance under such circumstances.

3.1.15 The inspector should develop a general sense of the licensee's safety culture for licensed activities (i.e., workers have a "questioning attitude" and generally adhere to procedures, workers are duly cautious when engaged in licensed activities, worker relationships with supervisors are conducive to raising safety concerns).

## 3.2 Inspection Preparation

Preparation for inspections is defined in RMPP 2.2 *Inspection Preparation*. Attachment 2.2-1 is an example of an inspection plan.

## 3.3 Performance-Based Inspections

3.3.1 Entrance Meeting: The inspection begins with a meeting with appropriate licensee personnel. The inspector shall assure that licensee management (signer of the application for license or appropriate senior management) will be made aware of the inspection. In certain instances, the inspector

may choose to inform the licensee of his or her presence on site after initial observations of licensed activities currently in progress.

3.3.1.1 The inspector should inform the licensee's management representative of the purpose and scope of the inspection to be performed. This is often an opportune time for the inspector to identify personnel to be interviewed.

3.3.1.2 The licensee representative should be asked to identify any recent problems related to the licensed program.

3.3.1.3 When an inspection is likely to involve proprietary information, Personally Identifiable Information (PII) and patient information, the inspector should discuss how the information will be handled during the inspection.

3.3.1.4 If appropriate, the exit meeting should be scheduled during the entrance meeting.

3.3.1.5 The inspector should know whether the licensee has declared the information reviewed or gathered as proprietary, PII or patient related. In general, inspectors should use caution before retaining copies of licensee documents, unless they are needed to support apparent violations, expedite the inspection (i.e., licensee materials inventories), or make the licensing file more complete.

3.3.1.6 In all cases where licensee documents are retained beyond inspection, inspectors should follow the requirements of IMC 0620 "Inspection Documents and Records." Inspectors shall ensure that the licensee understands that the retained records will become publicly available and shall give the licensee the opportunity to provide redacted copies or to request withholding of the information.

3.3.2 Follow-up on Previous Items: Determine whether the licensee followed up on cited violations identified during the previous inspection. Determine whether the licensee took corrective actions as described in the licensee's response to the Notice of Violation (NOV) and followed up on safety concerns and unresolved issues identified during the previous inspection. Inspectors should ensure that corrective actions implemented from previous inspections are being followed to prevent recurrence of the violation by:

3.3.2.1 Review of the original NOV in the original inspection report and

verify the licensee instituted sufficient corrective actions to prevent recurrence and are in accordance with the disposition of the NOV.

3.3.2.2 Determine whether the violation will be closed during the current inspection and obtain information necessary to close the unresolved item.

3.3.2.3 Document the results of the follow-up inspection activity in an inspection report.

3.3.3 General Overview: The inspector should understand the current organization for radiation safety at the facility and the size of the current and anticipated radiation use program.

3.3.3.1 Examine the licensee's organization with respect to changes that have occurred in personnel, functions, responsibilities, and authorities since the previous inspection.

3.3.3.2 Identify the reporting relationship and management structure between the licensee's executive management, the RSO, and, if applicable, the chairperson and other members of the Radiation Safety Committee (RSC).

3.3.3.3 Interview cognizant personnel to determine the types, quantities, and use of radioactive material, frequency of use, staff size, etc., and anticipated changes in the radiation use program.

3.3.3.4 Determine if the licensee possesses material in accordance with a general license.

3.3.4 The Inspection: The inspector should observe licensee operations, interview staff and conduct document review to complement and support observations. Perform radiation surveys to obtain independent and confirmatory measurements.

3.3.4.1 Emphasis should be placed on observing licensee performance as it relates to staff training, equipment operation and adequacy, overall management of the licensed program, and integration of safety. In performance-based inspections, a problem with licensee performance leads the inspector to identify programs or procedures for evaluation. If there is no opportunity to observe work in progress that involves Department regulated activities, the inspector should ask the workers to demonstrate and explain

selected licensed activities. It is of utmost importance to inspect licensed activities at temporary job sites.

3.3.4.2 If an activity results in significant problems, licensee management should be informed as soon as possible. This will allow the licensee sufficient time to begin root cause analysis and possibly determine a corrective action prior to the exit meeting.

3.3.4.3 Perform a walk-through of the licensed facility to make general observations of the condition of the facility and the licensed activities being performed. The walk-through may be performed at any time during the inspection. The inspector may need to return to some portions of the facility at a later time to observe specific activities.

3.3.4.4 Conduct inspections of principal activities that are a potentially significant contributor to dose, regardless of shift.

3.3.4.5 Perform routine inspections, when applicable, at times of high use of licensed material.

3.3.4.6 Make direct observations of radiation safety systems and practices in use.

3.3.4.7 Review of licensee records and other documents should be directed toward verifying that current operations are in compliance and further review of records should occur only if the current records are out of compliance and it is necessary to determine the presence of a prevalent or persistent problem.

3.3.5 Independent and Confirmatory Measurements: Independent measurements are those performed by the inspector without comparison to the licensee’s measurements. Confirmatory measurements are those whereby the inspector compares his or her measurements with those of the licensee's.

3.3.5.1 The inspector should perform independent and confirmatory measurements in restricted, controlled, and unrestricted areas of the licensee's facility.

3.3.5.2 Independent measurements should be performed on all inspections, unless exceptional circumstances make it impossible to perform the measurements (i.e., inspector's detection equipment malfunctions during an inspection trip).

3.3.5.3 Measurements of dose rates at the boundaries of restricted areas should be performed at the surfaces of the most accessible planes.

3.3.5.4 Examples of measurements that may be performed include area radiation surveys, wipe samples, soil samples, leak tests, air flow measurements, etc. These measurements should be taken in licensed material use areas, storage areas, effluent release points, etc.

3.3.5.5 The inspector may ask the licensee to spot-check radiation levels in selected areas, using the licensee's own instrumentation, if the licensee possesses survey instrumentation. However, the inspector must use VDH's instruments for independent verification of the licensee's measurements.

3.3.6 Special License Conditions: If applicable, verify the licensee's compliance with any special license conditions that are unique to a particular practice, procedure, or piece of equipment used by the licensee. In these instances, the inspector should verify that the licensee understands the additional requirements and maintains compliance with the special license conditions.

3.3.7 Exit Meeting: The inspection concludes with an exit meeting with licensee management. If a senior management representative is unavailable for the exit meeting, the inspector should hold an exit meeting with appropriate staff onsite. Dependent on the results of the inspection, the inspector may hold another exit meeting directly with a senior management representative and the licensee's RSO. This meeting involving the licensee's management and RSO can be held by telephone.

3.3.7.1 When appropriate, the inspector should prepare **Department Form 591M Safety Inspection Report and Compliance Inspection** before the exit meeting so that the form can be properly executed during the exit meeting. VDH form 591M may be issued while still in the field for:

3.3.7.1.1 An inspection that results in no findings

3.3.7.1.2 To document a non-cited violation (NCV); or

3.3.7.1.3 To document a Severity Level IV (health and safety only) that does not require an amendment to the license to correct and is not willful or repetitive in nature. The Severity Level IV violation being documented in this manner must be corrected while the inspector is present or can be easily corrected within 30 days of the date of

the inspection. Any corrective actions must be listed on VDH Form 591M Part 1.

3.3.7.2 When VDH Form 591M is used to document the results of an inspection, VDH Form 591M Part 3 must also be completed. The inspector must ensure that each cited and non-cited violation on the form includes: a brief statement of the circumstances, including the date(s) of the violation or non-cited violation and the facts necessary to demonstrate that a requirement was not met; reference to the regulation, license condition or other legally binding requirement that was violated; and a description of the licensee's corrective action.

3.3.7.2 The results of the inspection and any unresolved items will be discussed with the licensee. During the meeting, the inspector shall explain any violation of Department requirements and the inspector's understanding of the licensee's corrective action plan for each violation. The inspector should explain safety-related concerns or unresolved items identified during the inspection, and the status of any previously identified violations.

3.3.7.3 Prompt corrective action must be initiated by the licensee for safety concerns or violations of significant regulatory requirements that affect safe operation of a licensee facility. The inspector should not leave the site until the concern is fully understood by the licensee and corrective action has been initiated, or the licensee has made a commitment to initiate corrective actions. If the inspector and the licensee disagree on the magnitude of the concern regarding safe operation of the facility, the RMPM should be notified immediately.

3.3.7.4 Although deficiencies identified in some areas (e.g., a worker's knowledge of radiation protection regulations) are not always violations, the inspector should bring such deficiencies to the attention of licensee management at the exit meeting and also in the cover letter transmitting the inspection report or Notice of Violation (NOV).

3.3.7.5 At the exit meeting, the inspector should verify whether the licensee considers any materials provided to or reviewed by the inspector to be proprietary in nature, including PII and patient information. If so, the inspector should assure proper handling of the information.

3.3.8 Evaluating Inspection Results: After returning from an inspection trip, the inspector shall discuss, either through verbal or written manner, the results

of the inspection(s) with the RMPM. The inspector should make an accurate determination of the actual condition of the activities inspected. The technical basis or root causes of identified problems must be emphasized, not just the symptoms or administrative indications. The reliability of both equipment and workers should be evaluated with respect to safety. Inspection findings should be evaluated for generic health and safety problems. Performance conditions should also be evaluated to predict their impact on future operations. Documentation for inspections is discussed in RMPP 2.4 *Documentation of Inspection Results*.

## 3.4 Initial Inspections

3.4.1 Initial inspections of a new licensee shall be announced and completed within 12 months of the date the new license or amendment was issued by the Department; however, as described below, if the licensee does not yet possess licensed materials or has not yet performed any principal activities, the initial inspection may be rescheduled to within 18 months of license issuance. Scheduling initial inspections are determined in RMPP 2.1 *Scheduling of Inspections*. If it is determined that the licensee has not possessed licensed material or performed licensed operations, the inspector should:

3.4.1.1 Determine the licensee's plans for future possession of licensed material or plans to perform licensed operations. In assessing the licensee's future plans, the inspector should determine if adequate facilities, personnel and equipment are in place to safely handle licensed material, as described in the license application.

3.4.1.2 Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should include a discussion on unique license conditions and give the licensee an opportunity to ask any regulatory questions.

3.4.1.3 Remind the licensee to notify the Department within 30 days after the receipt of licensed material or initiation of licensed operations, as required by license condition. Document the contact and enter the record into the file. The conversation record should include the licensee's plans for future possession of material or plans to perform principal activities.

3.4.1.4 Ensure that the due date is set for 18 months from license issuance

**3.4.2 Performing initial inspections**.

During the initial inspection, the inspector should interview licensee staff (management and technical) to determine if licensed material was received or if principal activities have been performed.

Methods for determining if principal activities have been performed include, but are not limited to the following: performing a site tour, performing independent measurements, and/or contacting distributors of licensed material, such as local radiopharmacies, to see if they have distributed material to the licensee.

If the licensee has possessed licensed materials or performed principal activities, then the inspector should conduct an inspection in accordance with this procedure and other applicable guidance.

If it is determined that the licensee does not possess licensed material or has not performed principal activities, the inspector should:

3.4.2.1 Determine the licensee's plans for future possession of licensed material or plans to perform principal activities. In assessing the licensee's future plans, the inspector should determine if adequate facilities and equipment are in place to safely handle licensed material, as described in the license application.

3.4.2.2 Use this opportunity to discuss the license and applicable regulations with the licensee. The inspector should discuss any unique license conditions and give the licensee an opportunity to ask any regulatory questions.

3.4.2.3 Remind the licensee to notify the Department within 30 days after the receipt of licensed material or initiation of principal activities, as required by license condition.

3.4.2.4 Remind the licensee of the requirement in 10 CFR 30.36(d) to provide written notification to the Department within 60 days if no principal activities under the license have been conducted for a period of 24 months.

3.4.2.5 Document the onsite inspection by completing the appropriate inspection record. The "program scope" description should include the licensee's plans for future possession of material or plans to perform licensed operations.

3.4.2.6 Ensure that the due date is set for 12 months from the date of the onsite inspection. To achieve the goals of cost saving and efficient use of staff time and travel, the date of the next initial inspection attempt may vary by ± 6 months.

3.4.3 Document the onsite inspection by completing a **Department Form 591M Safety Inspection and Compliance Inspection** for the exit interview or complete other inspection reports as described in RMPP 2.4 *Documentation of Inspection Results*. The "program scope" description should include the licensee's plans for future possession of material or plans to perform principal activities.

3.4.4 Ensure that the due date is set for 12 months from the date of the onsite inspection. To achieve the goals of cost saving and efficient use of staff time and travel, the date of the next initial inspection attempt may vary by ± 6 months.

New licenses excepted from an initial inspection. There are certain circumstances that require a new license to be issued to the licensee, but an initial inspection is not warranted.

3.4.5 New licenses that are issued solely as a result of a licensee's change of mailing address are not required to receive an initial inspection, if the licensee's place of use remains the same as on the previous license. The "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new license.

3.4.6. New licenses that are issued as a result of a change of ownership or transfer of control are not required to receive an initial inspection unless:

3.4.6.1 The organization controlling the licensed activities changes substantially (i.e., changes in key personnel, authorities, or resources associated with the radiation safety program);

3.4.6.2 The licensee significantly increases the types, quantities, or forms of radioactive materials on the license;

3.4.6.3 The licensee significantly increases the different uses authorized on the license (i.e., adds brachytherapy to a diagnostic nuclear medicine license);

3.4.6.4 The licensee significantly increases the number of authorized users; or

3.4.6.5 The new license authorizes one or more new facilities.

3.4.7 If none of these conditions applies, the "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new license.

3.4.8 New licenses that are issued because a licensee did not file a timely application for license renewal are not required to receive an initial inspection in accordance with this section, unless more than 6 months have elapsed between the date the initial license expired and the date the renewal application was submitted. The "last inspection date" and "next inspection date" for the licensee's previous license still apply to the new license.

## 3.5 Routine Inspections

3.5.1 Routine inspection of licensees shall be conducted at intervals in years corresponding to the inspection priority as defined in RMPP 2.1 *Scheduling of Inspections*.

3.5.2 If the licensee has possessed material or performed principal activities since the last inspection, the inspector should perform a routine inspection of the facility as defined in the program-specific inspection procedure using a performance-based inspection as discussed in Section 3.3.

3.5.3 If the licensee has not possessed material or performed principal activities since the last inspection, the inspector should follow the instructions in Section 3.4.

3.5.4 Inspectors should plan to conduct routine inspections close to the due date. However, to achieve the goals of cost saving and efficient use of staff time and travel, routine inspections may be scheduled within a window around their inspection due dates. Inspection of licensees in Priority Codes 1 and 2 may vary around their due date by ± 50 percent. Routine inspections of Priority Codes 3 and 5 licensees may vary around their due dates by ± 1 year.

3.5.5 Inspections will not be considered "overdue" until they exceed the scheduling window. In rare situations, routine inspections may be scheduled earlier than the window in order to achieve cost savings and efficiencies. For example, inspections may be scheduled before their window if the Department receives information that warrants earlier inspections. The bases for scheduling the inspection before the window should be documented in the inspection records and signed by the inspector's immediate supervisor and placed in the licensee file and in WBL.

## 3.6 Reactive Inspections

3.6.1 Reactive inspections focus on limited issues that are not within the scope of a routine inspection. Inspections performed to follow up on incidents (i.e., medical event, overexposure, and loss or release of significant

quantities of radioactive materials) take precedence over the routine inspection program. The RMPM shall promptly assess the preliminary information received concerning the incident and will determine if a reactive inspection is necessary.

3.6.2 Preparation for these inspections shall be under the direction of the RMPM. Narrative reports shall be prepared, if required, by the RMPM. The inspection frequencies for reactive inspections are defined in RMPP 2.1 *Scheduling of Inspections*. Performing reactive inspections should be completed in accordance with RMPP 3.1 *Management of Allegations* and/or RMPP 3.2 *Incident Response*.

3.6.3 The emphasis during the reactive inspection will be on the analysis of the sequence of events and the conditions that existed at the time these events occurred. The analysis should lead to the determination of contributing factors and root causes and to the formulation of corrective actions to prevent recurrence.

3.6.4 Issues of compliance will generally be addressed after all safety issues and program weaknesses are identified and understood.

3.6.5 It is particularly important that the inspector keep the RMPM informed of the inspection details and explain the exit meeting strategy before beginning the meeting. During the exit meeting, the inspector should explain the preliminary inspection findings including any apparent violations of regulatory requirements. The inspector should ask the licensee to confirm the licensee's and inspector's understanding of the findings. If the licensee does not provide additional information and disagrees with the preliminary findings and apparent violation(s), the inspector should assure the licensee that the inspector will convey the licensee's disagreement to the RMPM. The inspector should close the meeting and promptly leave the site without lingering for any further discussion before presenting these issues to the RMPM. The licensee's next opportunity to discuss the findings will be after the RMPM has reviewed these matters.

3.6.6 If a narrative inspection report is required, the report will include a discussion of inspector activities, reviews, observations, the sequence of events leading up to the incident, the contributing and root causes of the event, corrective actions taken or proposed by the licensee, and a discussion of the regulations applying to the incident. The inspector shall annotate inspection reports with the Nuclear Material Events Database (NMED) Event No. if the reactive inspection was initiated by a reportable event.

3.6.6.1 Incidents: Inspections of reportable incidents (e.g., medical events, overexposure, and loss or release of significant quantities of radioactive materials) take precedence over the routine inspection program. All reactive inspections will be performed using the guidance in RMPP 3.2 *Incident Response*. Reactive inspections of incidents will be performed using the guidance in Inspection Procedure (IP) 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy."

3.6.6.2 Medical Events: Inspections of medical events shall be conducted in accordance with the guidance in RMPP 3.2 *Incident Response*. Reactive inspections involving a medical event will be performed using the guidance in Management Directive 8.10, "NRC Medical Event Assessment Program."

3.6.6.3 Allegations: Allegations shall be processed in accordance with RMPP 3.1 *Management of Allegations*.

## 3.7 Special Inspections

3.7.1 Special inspections (i.e., reciprocity, temporary job site, team, etc.) focus on limited issues that are not within the scope of a routine inspection. Preparation for these inspections shall be under the direction of the RMPM. Narrative reports shall be prepared, if required by the RMPM, for special inspections. Inspection frequencies for special inspections are defined in RMPP 2.1 *Scheduling of Inspections*.

3.7.2 For a licensee authorized to work at a temporary job site, the inspector shall make every reasonable attempt to include an unannounced inspection of licensed activities at such a location(s).

3.7.2.1 Reciprocity Inspections: Performing reciprocity inspections should be completed in accordance with RMPP 2.2 *Inspection Preparations*, IMC 2800 "Materials Inspection Program" and IMC 1220 "Processing of NRC Form 241, "Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore waters," and Inspection of Agreement State Licenses under 10 CFR 150.20.

3.7.2.2 Temporary Job Site Inspections: For a licensee authorized to work at a temporary job site, inspectors shall make every reasonable attempt to include an unannounced inspection of licensed activities at such a location(s).

3.7.2.2.1 During the inspection of a licensee's principal place of business, the inspector should, through discussions with

the licensee and review of licensed material utilization records, ascertain if the licensee is working at the temporary job site location(s).

3.7.2.2.2 The inspector may contact the licensee's customer to schedule the temporary job site inspection. The licensee's customer should be requested not to notify the licensee of the inspection.

3.7.2.2.3 If an unannounced inspection of the location(s) is not possible, then the inspector should attempt to arrange an announced inspection at the temporary job site(s).

3.7.2.2.4 If a temporary job site inspection is not performed, a brief note will be written in the inspection records, giving an explanation for the missed temporary job site inspection. In certain cases, the "next inspection date" data element in Web-Based Licensing may indicate a reduced inspection interval.

3.7.2.3 Permanent Field Offices: If the license does not authorize licensed activities at the main office location, the inspection should include the main office location to verify the licensee's audit program was implemented to determine the performance of its field office activities. If an inspection identifies significant program weaknesses (indicative of poor program management/oversight), the RMPM should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.

3.7.2.3.1 If the license authorizes licensed activities to be conducted from two or three permanent facilities (main office plus one or two field offices), only one location must be inspected at the interval specified in this procedure for the type of license.

3.7.2.3.2 If the license authorizes licensed activities to be conducted from 4 to 10 permanent facilities (main office plus 3 to 9 field offices) at least 2 locations must be inspected at the interval specified in this procedure for the type of license.

3.7.2.3.3 If the license authorizes licensed activities to be conducted from more than 10 permanent facilities (main office plus more than 9 field offices), about 20 percent of the locations should be inspected.

3.7.2.3.4 Inspection of various field offices should be rotated to assess the licensee's entire program over several inspection cycles.

3.7.2.3.5 If the license does not authorize licensed activities at the main office location, the inspection should include the main office location to verify the licensee's audit program was implemented to determine the performance of its field office activities.

3.7.2.3.6 If an inspection identifies significant program weaknesses (i.e., Severity Level III or above violation(s), multiple Severity Level IV violations indicative of poor program management/oversight), the license reviewer should consider expanding the initial review to include additional satellite locations to determine the extent of the weakness.

3.7.2.4 Expired and Terminated Licenses and Decommissioning Activities: Notification that a license has expired or is being terminated (and an inspection is required in accordance with RMPP 1.3, *License Termination/Revocation*), requires prompt action (i.e., within 30 days) to ensure that licensed material has been properly transferred or disposed of, and that all areas where material was used may be safely released for unrestricted use.

3.7.2.4.1 Inspectors should be aware of the need for security and control of radioactive materials at these types of facilities. This may be done by review of the licensee's transfer, disposal, and closeout survey data; by confirmation that an authorized recipient has received the material; and/or by performance of an inspection that may include confirmatory surveys.

3.7.2.4.2 The inspector should also review records of disposals, burials, and public dose that may be required to be submitted to the Department on termination or retirement of the license. Such actions would be conducted as soon as appropriate after notification is received.

3.7.2.4.3 If an inspection is performed, the inspector should also verify that the licensee is complying with regulations for timely decontamination and decommissioning, and

meeting the required schedules for licensee action, as specified in the decommissioning timeliness rule.

3.7.2.5 Abandonment of Licensed Activities: Returned, undeliverable mail to licensees should trigger a prompt follow-up. The follow-up should include a telephone call to the licensee to establish the licensee's physical address. If telephone contact is not established, then an inspector should be sent to the licensee's site. The decision of when to send an inspector to a licensee's site should be based on the complexity of the licensed activities, and the types and quantities of licensed material.

3.7.2.6 Inspections After Escalated Enforcement: If escalated enforcement action has taken place for a particular licensee, a special inspection follow-up shall be scheduled and conducted within 6 months of the last inspection or sooner after completion of the escalated enforcement action, to assess the licensee's follow-up actions in response to the previous Severity Level III or above violations. The Department may perform this follow-up inspection as a part of a routine inspection. In determining when to conduct the follow-up inspection, the Department should consider the risk-significance, number, and severity level of the violations.

3.7.2.7 Significantly Expanded Programs: During routine inspections of licensed facilities, inspectors should evaluate if licensed activities have significantly increased or decreased since the last inspection. A license reviewer may request a near-term onsite inspection for a significant licensing action that was recently completed. Both the inspector and the reviewer should make their supervisors aware of the following changes in a licensee’s scope of work. Through interviews of licensee staff or observations of licensed activities, the inspector shall determine if:

3.7.2.7.1 The licensee has recently increased the types, quantities, and uses of radioactive material and if these actions have resulted in the possession of risk significant radioactive material (RSRM);

3.7.2.7.2 The licensee authorizes a physical move of a facility or a new use at a temporary jobsite;

3.7.2.7.3 The licensee authorizes new (i.e., since the previous inspection) satellite facilities where licensed materials will be used or stored;

3.7.2.7.4 The licensee has increased the types of uses or disposal (i.e., incineration or decay-in-storage) of radioactive material;

3.7.2.7.5 The number of authorized users has significantly increased or decreased; and

3.7.2.7.6 The licensee has ceased activities at the entire site or in any building area as defined in 10 CFR 30.36(d).

If any of the above items demonstrates a possibility that the licensed activities have significantly changed, then the inspector should document the changes to the licensee's program in the inspection records and notify the inspection supervisor. A license reviewer may request a special inspection, if, during the licensing review process, it is determined that the licensee's program has significantly expanded or activities have ceased. See the six points in the preceding paragraph. If during the licensing review process, the reviewer determines that the licensee will possess RSRM, the reviewer, in consultation with management and administrative staff, should add Program Code 01000. An onsite inspection must be performed to verify that the applicant has implemented the security requirements before the licensing action is issued allowing the applicant/licensee to take possession of RSRM.

## 3.8 Reduced Inspections

3.8.1 The inspection interval shall not be extended beyond that specified by the priority system indicated in RMPP 2.1 *Scheduling of Inspections*. The interval between inspections may be reduced and inspections conducted more frequently than specified in the priority system on the basis of poor licensee performance. If there was a reduction in inspection frequency, ensure that frequencies are reduced as discussed in RMPP 2.1 *Scheduling of Inspections*. The inspection should be performed in accordance with this procedure, however, special attention should be focused on the areas of poor performance. Other aspects of the program should only be focused on as time and opportunity allows.

3.8.2 At the discretion of the RMPM, other changes in inspection interval may be made to achieve efficiencies in the use of inspection resources and to reduce regulatory impact on the licensee. This may include more frequent inspections to ensure that inspectors have the opportunity to sufficiently observe licensee operations and increase public confidence by increasing the inspection focus on higher risk activities, without significantly increasing the regulatory burden on licensees. For example, rather than

perform a single, large team, high impact inspection of the license at the normal interval, more frequent inspections may be performed by individuals or smaller teams that specifically focus on higher risk licensee activities. This may also include deviations from the prescribed inspection interval to accommodate extenuating circumstances that prevent a timely inspection from being completed. The bases for altering the scheduling of inspections should be documented in the inspection records and signed by RMPM and placed in the licensee file and WBL.

## 3.9 Team Inspections

3.9.1 The Department shall schedule and conduct team inspections of major licensees within Vermont on an as-needed basis. The decision on whether to conduct a team inspection involving agencies outside VDH shall be made by the RMPM and RCPD.

3.9.2 Examples of situations where team inspections may be appropriate are:

3.9.2.1 Routine inspections of major licensees (i.e., broad-scope academic, broad-scope medical licensees, and large processor/ manufacturers). A team inspection should be considered when the size or complexity of operations at a broad-scope licensee goes beyond that which one or two inspectors can cover in a week. Team inspections are also appropriate when the team will include an expert in a specialty discipline other than health physics, such as a medical physicist, human factors specialist, fire protection specialist, engineer, or other specialized fields.

3.9.2.2 Reactive inspections of any type of licensee where one or more specialists are needed on the team (of three or more inspectors).

3.9.2.3 Routine inspections of major licensees within the year before license renewal. Team inspections are appropriate methods to assess a licensee's strengths and weaknesses, and to provide feedback to the licensing process. Such team inspections should include license reviewers on the team. However, pre-licensing visits are not considered inspections, and team inspections should not take the place of pre-licensing visits.

3.9.2.4 Inspections of any type (routine or reactive) that include team members from outside the Department, including other state agency or federal agency representatives.

## 3.10 Coordination with Other Agencies

3.10.1 The Department does not conduct inspections of licensee compliance with the requirements of other local, state or federal agencies, except the U.S. Department of Transportation (DOT). However, a Radiological Health Specialist (RHS) may identify concerns that are within another agency's regulatory authority.

3.10.1.1 If such concerns are significant and the licensee demonstrates a pattern of unresponsiveness, the RMPM should inform the appropriate liaisons within the other agency about the concerns.

3.10.1.2 Except for DOT regulations, it is important that all RHSs recognize and understand that they are not to make decisions regarding activities under the purview of other agencies.

3.10.1.3 Thus, in discussing the concerns with the licensee, RHS are cautioned not to judge whether a given condition is a violation of another agency's rules or regulations, but are to point out concerns to heighten licensee awareness. For example, if an RHS identified concerns for lack of fire protection, then it would be appropriate to encourage the licensee to advise the local fire department of conditions in the facility and to take prompt action to correct the situation.

3.10.1.4 The RHS should also advise the licensee of the obligation to inform the RMPM who may coordinate the information with the other lead agency.

## 3.12 Security Inspections

3.12.1 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.

3.12.2 Affected licensees may include manufacturers and distributors, self-shielded irradiators, open-air beam calibrators, pool-type irradiators, medical facilities with blood irradiators and/or gamma-ray stereotactic radiosurgery (gamma knife), radiopharmacies, industrial radiographers, and licensees transporting category 1 and 2 quantities of radioactive material.

3.12.3 The focus of this inspection is the security inspections of those licensed under 10 CFR Part 30, subject to Part 37 requirements when possessing certain aggregated category 1 and 2 quantities of radioactive material. (See Inspection Procedure 87137 for additional details.)

### 3.12 Pre-Licensing Site Visits

3.12.1 The purpose of the pre-licensing visit is to evaluate the applicant's intentions regarding the use of radioactive materials and to forward suspicious applications to the appropriate authority for follow-up, per the guidance in the Pre-licensing Checklist.

3.12.2 At a minimum, all storage and use locations must be visited.

3.12.3 By the end of the visit, the reviewer should have observed, collected, and documented sufficient information to provide a basis of confidence that the applicant will use the radioactive materials as specified in its license application.

3.12.4 Pre-licensing visits must be completed before the issuance of a license.

## 4.0 RECORDS

4.1 Letter with Notice of Violation or Department Letter or clear inspection form.

4.2 Inspection Report maintained in file and WBL.

4.3 Records are primarily filed electronically and Web-based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available, and may include Department network files.

## 5.0 ATTACHMENTS TO RMPP 2.3

None

# Vermont Department of Health

# Radioactive Materials Program

## Radioactive Materials Program Procedure 2.4, Revision 0

## Documentation of Inspection Results

**Prepared By:**_____ **Date**_____

**Reviewed By:**_____**Date**_____

**Approved By:**_____**Date**_____

**Effective Date:**

| Revision | Date | Description of Changes |
|---|---|---|
| 0 | | |
| | | |

# Table of Contents


**1.0 PURPOSE**

- **1.1 Applicability**
- **1.2 References**
- **1.3 Files**

**2.0 RESPONSIBILITIES**

- **2.1 Radiological Health Specialist (RHS)**
- **2.2 Radioactive Materials Program Manager (RMPM)**
- **2.3 Radiation Control Program Director (RCPD)**

**3.0 PROCEDURE**

- **3.1 Methods of Documenting Inspection Results**
- **3.2 Inspection Reports**
- **3.3 Reports to Licensees**
- **3.4 Reports for Special Inspections**

**4.0 RECORDS**

**5.0 ATTACHMENTS TO RMPP 2.4**

- **2.4-1 Department Form 591M Safety Inspection and Compliance Inspection**
- **2.4-2 Inspection Report Content**
- **2.4-3 Notice of Violation Letter**
- **2.4-4 Clean Inspection Report**
- **2.4-5 Security Related 591M Part 3**

## 1.0 PURPOSE

### 1.1 Applicability

1.1.1 This procedure is designed to ensure that reports of inspections clearly communicate significant inspection results to licensees, licensing staff, and the public. It is the Department's goal that all Radioactive Materials Program staff should be qualified in both licensing and inspections of all uses of radioactive materials in the State of Vermont. Significant findings in the inspection reports will be reviewed during the program staff meetings conducted by the Radiation Control Program Director (RCPD) and attended by all program staff.

1.1.2 This procedure will ensure that reports of inspections provide conclusions about the effectiveness of the program(s) and/or principal activities inspected. The depth and scope of the documented conclusions should be commensurate with the depth and scope of the inspection.

1.1.3 The documentation described in this procedure will provide a basis for enforcement action.

### 1.2 References

1.2.1 NRC Inspection Manual, Chapter 0610, "Nuclear Material Safety and Safeguards Inspection Reports."

1.2.2 NRC Inspection Manual Chapter 0620, "Inspection Documents and Records."

1.2.3 NRC Inspection Manual Chapter 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20."

1.2.4 NRC Inspection Manual, Manual Chapter 2800, "Materials Inspection Program."

1.2.5 NRC Management Directive 8.10, "NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility."

1.2.6 Vermont Radiological Health Rule

1.2.5 NRC Enforcement Manual.

### 1.3 Files

1.3.1 Letter with Notice of Violation Letter, Clean Inspection Report, and Department Form 591M.

1.3.2 Other elements of inspection reports maintained in the licensee file.

1.3.3 Records are primarily filed electronically and Web-based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available and may include Department network files.

## 2.0 RESPONSIBILITIES

### 2.1 **Radiological Health Specialist (RHS)**

2.1.1 Maintains files, records, letters, forms, and other records related to inspections.

2.1.2 Prepares the inspection documentation issued within 30 days of completing the inspection.

2.1.3 Prepares a Department letter transmitting the inspection findings to the licensee.

2.1.4 Tracks the inspection documentation until completed.

2.1.5 Updates the inspection history record and enters next inspection date in Web-Based Licensing (WBL).

### 2.2 Radioactive Materials Program Manager (RMPM)

2.2.1 Updates the data in WBL. Once the inspection is completed, record the inspection date, licensee name, license number, lead inspector, and accompanying inspector(s) in WBL.

2.2.2 Reviews a report of inspection findings and recommended enforcement action. If warranted due to the severity of the inspection findings, notifies the Radiation Control Program Director, as soon as possible.

### 2.2 Radiation Control Program Director (RCPD)

2.3.1 Concurs with the inspector's and/or RMPM's findings and recommendations or prescribes alternative actions.

2.3.2 Reviews and approves the narrative report of the inspection findings and transmittal letter, as necessary.

2.3.3 Signs all correspondence to the licensee related to the inspection report.

## 3.0 PROCEDURE

Review RMPP 2.3 *Performance-Based Inspections*, to determine if an inspection was performed. If an attempt was made, but the inspection was not performed, this needs to be documented to note the attempt in the license file. This procedure is designed to provide guidance that is applicable to all types of licensed programs. It does not specify the unique individual requirements for each type of inspection documentation. Documentation of inspections should be completed in accordance with this procedure and other applicable VDH and NRC guidance.

### 3.1 Methods of Documenting Inspection Results

3.1.1 Results of inspections are reported to the licensee with a **Department Form 591M Safety Inspection and Compliance Inspection** (Attachment 2.4-1) and may be followed up with additional documentation.

3.1.2 They may also be documented with a department letter as described in RMPP 2.7 *Assuring the Technical Quality of Inspections.*

3.1.3 The content of an inspection report should include that found in Attachment 2.4-2 **Inspection Report Content**.

3.1.4 Inspection Reports should also include either an Attachment 2.4-3 **Notice of Violation Letter** or Attachment 2.4-4 **Clean Inspection Report**.

3.1.5 Notes taken during the course of the inspection shall not be official documentation of the inspection performance. The RMPM may make an exception to this if the notes are determined by the RMPM to be sufficient documentation. If so, the notes will be placed in the licensee file and WBL.

### 3.2 Inspection Reports

3.2.1 Upon completion of an inspection for a licensee, a narrative report or an inspection memo shall be generated on **Department Form 591M Safety Inspection and Compliance Inspection**.

3.2.2 Inspection reports should be completed within 15 working days following the completion of the on-site portion of the inspection.

3.2.3 Narrative reports shall contain:

3.2.3.1 Sufficient detail to describe the inspection that was conducted

including operations observed to document the performance-based part of the inspection;

3.2.3.2 Compliance status of topics;

3.2.3.3 The status of follow-up items involving prior enforcement or reported licensee events;

3.2.3.4 Sufficient information to support cited violations, non-cited violations, and closed violations identified during a previous inspection;

3.2.3.5 Description of completed or anticipated corrective actions to any identified minor violations cited in Department Form 591M;

3.2.3.6 Sufficient description of the scope of the licensee's program for the RMPM, license reviewers, and other inspectors to evaluate the licensee's overall safety program; and

3.2.3.7 For inspections that include a review of Part 37 requirements with no violations, the inspector should include in a non-publicly available inspection record (e.g., Form 591M Part 3) describing the licensee's implementation of security requirements. This form is **Attachment 2.4-5 VDH Form 591M Security-Related**.

3.2.4 An inspection report shall contain sufficient information to provide a general overview of the current status of the licensee's radioactive material program, including but not limited to, use of licensed material, staff size and hours, any changes from information previously noted in a narrative report, and any other information deemed relevant by the inspector.

**3.3 Reports to Licensees**

3.3.1 Inspection findings shall be reported to the licensee upon acceptance of the inspection report by the RMPM or RCPD. Inspection findings should be sent to the licensee through a department letter unless a Department Form 591M was provided to the licensee at the conclusion of the inspection and that is deemed sufficient by the RMPM or RCPD. Any Form 591M completed in the field must be signed by a supervisor when the inspector returns to the office. The form does not need to be reissued unless the characterization of any findings changes during supervisory review.

3.3.2 **Department Form 591M Safety Inspection and Compliance Inspection** shall be used to document clear inspections and inspections

resulting in non-cited violations (Severity Level IV violations that are neither willful nor repetitive and that can be corrected while the inspector is present, or that the licensee agrees to correct).

3.3.3 The inspector will present Form 591M Part 1 to the licensee at the conclusion of the exit interview, or, on rare occasions where consultation with Department management is necessary, the inspector may transmit Form 591M Part 1 from the Department office.

3.3.3.1 The Form 591M, "Safety Inspection Report and Compliance Inspection," shall include the name of the responsible inspector.

3.3.3.2 The inspector shall sign the completed Form 591M Part 1. Supervisory review is required, but is not necessary prior to issuance of Form 591M Part 1, to the licensee.

3.3.3.3 If no changes are needed after supervisory review, the supervisor will sign the final signature block and the completed form will be put in WBL (only one form is maintained since it provides record of both the finding communicated to the licensee, and the final approved action).

3.3.3.4 If changes are needed after supervisory review, Form 591M Part 1 will be reissued to the licensee, and both the original Part 1 and the revised completed form will be put in WBL (both versions are maintained in order to provide record of both the initial finding communicated to the licensee and the final approved action).

3.3.4 Form 591M Part 1 may <u>not</u> be used to transmit non-cited or cited security-related violations.

3.3.5 The inspector must document findings with enough detail to make it clear what requirement was violated, how it was violated, who violated the requirement (use titles only, names should be avoided, if possible), and when it was violated (including dates, or period of time of non-compliance, if known). If the licensee provides immediate or long term corrective action for the violation, this information should also be included as part of the inspection record.

3.3.6 When Department Form 591M is used to document the results of an inspection, the inspector must ensure that for each cited violation, the form includes:

3.3.6.1 A brief statement of the circumstances, including the date(s) of the violation or the period of time of the non-compliance;

3.3.6.2 The facts necessary to demonstrate that a requirement was not met; and

3.3.6.3 The reference to the regulation, license condition or legally binding requirement that was violated.

3.3.7 The Severity Level IV violation being documented in this manner must be corrected while the inspector is present, or can be easily corrected within 30 days of the date of the inspection. Any corrective actions must be listed on the Form 591M Part 1.

3.3.8 Following are examples of cited violations on Department Form 591M:

3.3.8.1 10 CFR 20.1101 **r**equires the licensee to annually review the content and implementation of the radiation protection program. During years 2010 and 2011, the licensee did not complete the review. The licensee will complete the review in October 2012 for the period of January 2010 through September 2012. The licensee intends to complete future reviews in October of each year by completing NUREG-1556 Volume 9, Revision 2 Appendix L, Suggested Medical License Audit.

3.3.8.2 As required by 10 CFR 34.29, the licensee did not perform a quarterly physical inventory during the period from February 25, 2010 to October 24, 2010 to account for all sealed sources and devices containing depleted uranium. The licensee will implement an automated reminder system to notify the Radiation Safety Officer to perform the inventories.

**Note**: Attachment 2.5-1 of RMPP 2.5 contains examples of violations that may be cited on Department Form 591M.

3.3.8.3 VDH Form 591M shall include the name of the responsible inspector. The inspector shall sign the completed Department Form 591M. The inspector will present the Department Form 591M to the licensee at the conclusion of the exit interview or, as necessary, by facsimile, mail or electronic mail in accordance with State requirements.

3.3.9 Department Letters. A letter, signed by the inspector and/or the RMPM, shall be used if a Department Form 591M was not issued to document a

clear inspection. A Department letter shall be sent within 30 days of completion of the inspection if a Department Form 591M has not been issued. Department letters shall be sent along with a Notice of Violation(s) if any of the following situations are found:

3.3.9.1 Repetitive violations;

3.3.9.2 Violations involving willfulness;

3.3.9.3 Where an apparent Severity Level III or higher violation or problem is detected;

3.3.9.4 When an enforcement conference or a management meeting is to be held;

3.3.9.5 Where the licensee needs to take extensive corrective action(s) or make programmatic changes to address the violation(s);

3.3.9.6 Where the licensee needs to perform further evaluations before taking corrective action;

3.3.9.7 Where the corrective action includes a request for an amendment to the license;

3.3.9.8 When a specific message should be provided to the licensee;

3.3.9.9 If the inspector questions the effectiveness of the licensee's planned action or the ability of the licensee to carry out the corrective action;

3.3.9.10 Where it is appropriate to request a written response to the violation.

**3.4 Marking of Inspection Documentation**

3.4.1 Information relative to the licensee's physical protection measures (security-related information) is confidential information and needs to be protected.

3.4.2 The inspector should ensure that the NOV, documentation of findings (i.e., Form 591M Part 3 or narrative inspection report), and any other separate enclosure are appropriately protected, handled and marked in accordance with the following security-related information guidance:

3.4.2.1 Paper copies must be filed in the padlocked secure files cabinet and electronic files saved in the secure access only server folder.

3.4.2.2 Files must be Marked: “THIS DOCUMENT MUST BE KEPT IN SECURED ELECTRONIC AND/OR PAPER FILES ONCE FILLED OUT.”

3.4.2.3 Files must be maintained under the visual and physical possession of the user when outside of the electronic or padlocked file storage area.

3.4.3 All cover letters to licensees will be publicly available and should not contain confidential information. Security-related information should not be made available to the public.

### 3.5 Reports for Special Inspections

A narrative report should be completed documenting all special inspections. Reports should be completed and issued within 30 working days of the completion of the on-site portion of the inspection.

3.5.1 Escalated Cases: For escalated cases, the report should address all areas covered in the inspection.

3.5.2 Medical Events: For medical events the report should follow the guidance in NRC Management Directive 8.10, ”NRC Assessment Program for a Medical Event or an Incident Occurring at a Medical Facility”.

3.5.3 Allegations: For allegations the report should follow the guidance in RMPP 3.1 *Management of Allegations*.

3.5.4 Reactive and Reduced Inspections: A reactive and reduced inspection will not substitute for a routine inspection unless the scope of the inspection is comprehensive.

## 4.0 RECORDS

4.1 Inspection reports and inspection transmittal letters in licensee's file.

4.2 Records are primarily filed electronically and Web-based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available, and may include Department network files.

## 3 ATTACHMENTS TO RMPP 2.4

### 2.4-1 Department Form 591M Safety Inspection Report and Compliance Inspection

### 2.4-2 Inspection Report Content

### 2.4-3 Notice of Violation Letter

### 2.4-4 Clean Inspection Report

### 2.4-5 Security Related 591M Part 3

## Attachment 2.4-1

## Department Form 591M Safety Inspection Report and Compliance Inspection

VDH FORM 591M PART 1

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/ LOCATION INSPECTED

| 2. LICENSEE NUMBER | DATE(S) OF INSPECTION |
|---|---|

**LICENSEE:**

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Vermont Department of Health (VDH) rules and regulations and conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☐ 1. Based on the findings, no violations were identified.

☐ 2. Previous violation(s) closed

☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the VDH enforcement procedure to exercise discretion, were satisfied

____ Non-cited violation(s) were discussed involving the following requirements:

☐ 4.During the inspection certain of your activities, as described below and/or attached, were in violation of VDH requirements and are being cited in accordance with VDH enforcement Policy This form is NOTICE OF VIOLATION, which may be posted in accordance with 10 CFR 19.11 (Violations and corrective Actions)

Statement of Corrective Actions

**I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 18 V.S.A. § 130 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to the VDH will be required, unless specifically requested.**

| Title | Printed Name | Signature | Date |
|---|---|---|---|
| **LICENSEE REPRESENTATIVE** | | | |
| **VDH INSPECTOR** | | | |
| **VDH Radiation Control Program Director** | | | |

| VDH FORM 591M PART 2 | VERMONT DEPARTMENT OF HEALTH |
|---|---|
| **SAFETY INSPECTION AND COMPLIANCE INSPECTION** | |
| LICENSEE/ LOCATION INSPECTED | |
| LICENSE NUMBER | DATE(S) OF INSPECTION |
| (Observations) | |

**FORM 591M Part 3**
**VERMONT DEPARTMENT OF HEALTH**
File Information

## SAFETY INSPECTION AND COMPLIANCE INSPECTION

| | |
|---|---|
| 1. LICENSEE/LOCATIONS INSPECTED | 2. LICENSE NUMBER(S) |
| 3. DATES OF INSPECTION | 4. TYPE OF INSPECTION |
| 5. INSPECTION PROCEDURES USED | 6. INSPECTION FOCUS AREAS |

**SUPPLEMENTAL INSPECTION INFORMATION**

| | |
|---|---|
| 1. PROGRAM CODES | 2. PRIORITY |
| 3. LICENSEE CONTACT | 4. TELEPHONE NUMBER |

**Inspector Information**

| | |
|---|---|
| Name | Signature |
| Phone No. | Email address |

☐ Main Office inspection  Next Inspection Date_____

☐ Field Office Inspection_____ ☐

Temporary Job Site Inspection _____

Approved: _____

Radiation Control Program Director Signature / Date

## Program Scope

## Conclusions

# Attachment 2.4-2 Inspection Report Content
# Vermont Department of Health
# Radioactive Materials Program

The content for Radioactive Material Program Inspection Reports should consist of the applicable elements on this list. Details about these elements are in RMPP 2.4 *Documentation of Inspection Results*.

- Cover Letter on Department letterhead
    - Address, Date, Salutation
    - Subject
    - Introductory Paragraphs
    - Body
    - Closing
- Department Form 591M, Notice of Violation Letter or Clean Inspection Report (Attachments 2.4-1, 2.4-3, and 2.4-4)
- Report
    - Scope
    - Observations and Findings
        - Generic Issues, if any
        - Violations, if any
    - Conclusions
    - Exit Meeting Summary
        - Absence of Proprietary Information
        - Characterization of Licensee Response
        - Oral statements and Regulatory Commitments
    - Report Attachments
    - Key Points of Contact
    - List of Items Opened, Closed and Discussed (optional)
    - List of Documents Reviewed
    - List of Acronyms

# Attachment 2.4-3 Notice of Violation Letter
# Vermont Department of Health
# Radioactive Materials Program

Date:

Name of Licensee
Attn: Licensee Contact
Address
Street Address
City, State Zip Code

Dear [Insert salutation]:

This letter refers to the inspection conducted on [Insert Date] at your [Facility name] by [inspector's name].

This inspection was an examination of the principal activities conducted under your Vermont Radioactive Materials [License number], a selective examination of procedures and representative records, observations and interviews with personnel as they relate to radiation safety and to compliance with the Department's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities and interviews with personnel.

Based on the results of this inspection, the Department has determined that [insert number of violations] of Department requirements occurred. The violation(s) is/are cited in the enclosed Notice of Violation (Notice).

You are required to respond to this letter within 30 days and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the Department should consider, you may provide it in your response to the Notice. The Department review of your response to the Notice will determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

To the extent possible, your response should not include any personal, privacy, or proprietary information so that it can be made public without redaction.

If you have any questions or wish to discuss the inspection findings, please contact the undersigned at your earlier convenience

[Insert Radiological Health Specialist Inspector name phone number and email]

NOTICE OF VIOLATION

[Licensee Name]

[License Number]

During an inspection conducted on _____ [INSERT DATE(S)] ___ [INSERT NUMBER] violations of Department requirements were identified. The violations are listed below:

[INSERT VIOLATIONS WITH REGULATION AS APPROPRIATE]

This is a Severity Level _____ [INSERT SEVERITY LEVEL]violation.

_____ [INSERT LICENSEE] is hereby required to submit a written statement of explanation to the Vermont Department of Health ATTN: Radioactive Materials Program, 108 Cherry Street, Suite 201, Burlington Vermont 05402-0070, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time frame specified in this Notice, an order may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken.

If you contest this enforcement action, you should reply to Vermont Department of Health ATTN: Radioactive Materials Program, 108 Cherry Street, Suite 201, Burlington, Vermont 05402-0070.

To the extent possible your response should not include any personal privacy, proprietary information so that it can be made public without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire to not be placed in the public document and provide the legal basis to support your request for withholding the information from the public.

Dated: _____

Approved: _____ Radiation Control Program Director

# Attachment 2.4-4 Clean Inspection Report
# Vermont Department of Health
# Radioactive Materials Program

Date:

Name of Licensee
Attn: Licensee Contact
Address
Street Address
City, State Zip Code

Dear [Insert salutation]

This letter refers to the inspection conducted on [INSERT DATE] at your facility.

This inspection was an examination of the activities conducted under your Vermont Radioactive Materials [License number], as they relate to public health and safety, and to confirm compliance with the Department's rules and regulations and the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the findings, no violations of Department rules or regulations were identified.

You are not required to respond to this letter, however you should retain a copy for your records.

If you have any questions or wish to discuss the inspection findings, please contact the undersigned at your earlier convince.

Sincerely,

Radiation Control Program Director

**Attachment 2.4-5 VDH Form 591M Security-Related**
**Vermont Department of Health**
**Radioactive Materials Program**

## Official Use Only - Security-Related Information

| | Initial | | Announced | | Unannounced | | Routine | | Special | | Security |
|---|---|---|---|---|---|---|---|---|---|---|---|

**VDH FORM 591M PART 3** **Vermont Department of Health**

10 CFR 2.201 *File Information*

### SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| 1. LICENSEE/LOCATION INSPECTED: | 2. INSPECTED BY: |
|---|---|
| REPORT NUMBER(S) | **Vermont Department of Health**<br>Radioactive Materials Program<br>108 Cherry Street, Room 201<br>Burlington, VT 05402 |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| | | |

| 6. INSPECTION PROCEDURES | 7. INSPECTION FOCUS AREAS |
|---|---|
| | |

### SUPPLEMENTAL INSPECTION INFORMATION

| 1. PROGRAM CODE(S) | 2. PRIORITY | 3. LICENSEE CONTACT | 4. TELEPHONE NUMBER |
|---|---|---|---|
| | | | |

☐ Main Office Inspection — Next Inspection Date: _____

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

**PROGRAM SCOPE**

VDH FORM 591M PART 3 (Security-Related)

## Official Use Only - Security-Related Information

**THIS DOCUMENT MUST BE KEPT IN SECURED ELECTRONIC OR PAPER FILES ONCE FILLED OUT**

Supervisory Review By Radiation Control Program Director (RCPD) _____

[X] Non-Public

[X] Confidential-Security-Related, Non-Public

# Vermont Department of Health

# Radioactive Materials Program

## Radioactive Materials Program Procedure 2.6, Revision 0

## Materials Inspection Checklists and Definitions

**Prepared By:**_____ **Date**_____

**Reviewed By:**_____**Date**_____

**Approved By:**_____**Date**_____

**Effective Date:**

| Revision | Date | Description of Changes |
|---|---|---|
| 0 | | |
| | | |

## Table of Contents


1. **Purpose**
2. **Definitions**
3. **Attachments:**

   **Attachment 2.6-1 10 CFR Part 37 Inspection Checklist**

## 1.0 Purpose

1.1 To provide checklists that better assure quality inspections of radioactive materials licensees where the NRC NUREG 1556 Series does not provide an Audit. With this revision of the procedure, the only checklist in this procedure is **Attachment 2.6-1 10 CFR Part 37 Inspection Checklist**. There are audits and checklists in the NRC NUREG 1556 Series for all the license types in Vermont.

1.2 Inspections are to be performed using the applicable NRC inspection procedures found at https://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/, in conjunction with the guidance of NRC IMC 2800, found at https://www.nrc.gov/docs/ML1028/ML102800160.pdf.

1.3 Inspections are documented on Department Form 591M, as well as inspection reports. Form 591M and other inspection forms are found in RMPP 2.4 *Documentation of Inspection Results*.

1.4 Inspection Checklists attached to this procedure and in the NUREG 1556 Series are used during the inspection and may be helpful when writing inspection reports.

1.5 This procedure also serves to capture key terms and define them as they relate to the Vermont Radioactive Materials Program.

## 2.0 Definitions

2.1 Acute Performance Conditions: Conditions that have an obvious adverse impact on safety and/or reliability.

2.2 Department: The Vermont Department of Health (Department).

2.3 Core Inspection: All initial inspections of priority 1, 2, 3, and 5 licensees and all routine inspections of priority 1, 2, or 3 licensees.

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 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.

2.5 Initial Inspection: The first inspection after a new license is issued.

2.6 Initial Security Inspection: An inspection to verify that an applicant has implemented security requirements identified in the On-Site Security Review of the Risk Significant Radioactive Materials (RSRM) Checklist after the licensing action is issued allowing the applicant to take possession of RSRM.

2.7 Inspection: The act of assessing licensee performance to ensure the health and safety of workers and the public and to protect the environment. It is also used to determine if radioactive materials are used safely and whether the licensee is in compliance with rules, regulations, statutes, license conditions, and the license commitments incorporated in the license by "tie-down" conditions. Inspections include a visit to a licensee's facility and/or job site, observation of licensed activities, interaction with licensee personnel, and reporting of the inspection findings. Pre-licensing site visits or telephone communications are not inspections.

2.8 Inspection Document: A written record documenting the results of the inspection. Any material obtained or developed during an inspection that is considered to be a Department record.

2.9 Inspection Follow-Up Item: A matter that requires further inspection because of a potential problem, because specific licensee or Department action is pending, or because additional information is needed that was not available at the time of the inspection.

2.10 Inspection Plan: An inspection plan is a written outline listing the licensee's activities and programs that will be covered during an inspection.

2.11 Inspection Priorities: An inspection priority code is assigned to each radioactive materials license. The priority code (i.e., 1, 2, 3, or 5) is the interval between routine inspection, expressed in years. The same priority code is assigned to all licenses that authorize that particular type of code. The priority represents the relative risk of radiation hazard. Priority Code 1 represents the greatest risk to the health and safety of workers, members of the public, and the environment, while Priority Code 5 represents the lowest risk. Because a license may authorize multiple types of use (i.e., multiple program codes), the inspection priority code for the license is the code with the shortest routine inspection interval.

2.12 Inspection Report: A computer-generated inspection report used to document the inspection.

2.13 Inspection/Scheduling Window: A window in which scheduling and performing of inspections should be performed in accordance with NRC Inspection Manual Chapter 2800.

2.14 Inspector: A Radiological Health Specialist qualified to plan, perform, and document an inspection of a specific category of license and, where appropriate, to prepare enforcement documents and review the response to such a document for adequacy.

2.15 Latent Performance Conditions: Conditions that are underlying and usually obscure. If unchanged, these may result in acute conditions at some future time if

circumstances change.

2.16 Lead Inspector: A Radiological Health Specialist qualified to plan, supervise, and document an inspection by a team of inspectors. An inspector shall not act as a lead inspector in any category of license they are not qualified for, unless being evaluated or supervised by a qualified inspector. A lead inspector is responsible for review of a licensee's reply to a Notice of Violation (NOV).

2.17 Minor Violation: Minor violations are those that are less significant than a Severity Level IV violation. Minor violations do not warrant enforcement action and are not normally documented in inspection reports. However, minor violations must be corrected.

2.18 Noncompliance: A violation (see below).

2.19 Non-Core Inspection: Routine inspections of Priority 5 licensees, other than initial inspections.

2.20 Notice of Violation (NOV): A formal written notice that sets forth one or more apparent violations of a legally binding regulatory requirement and normally requires the recipient to provide a written response describing (1) the reasons for the violation or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken by the licensee or other person and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. The Department may waive all or portions of a written response to the extent that relevant information has already been provided to the Department in writing or documented in an inspection report or inspection record. The Department may require responses to NOVs to be under oath; however, normally, responses under oath will be considered necessary only for SL I, II, or III violations; or violations of Department Orders. A civil penalty may be issued in conjunction with an NOV.

2.21 Performance-Based Inspection (PBI): Observation of a licensee's program activities to determine if regulatory and radiation safety objectives are being achieved. This type of inspection can be applied to any functional area of any license. The only variable is the technical nature of the activities of different licensees. The principal measures of successful performance are safety and reliability. A performance-based inspection focuses on the safety and reliability of program activities.

2.22 Potentially Generic Issue: An inspection finding that may have implications for other licensees, certificate holders, or vendors whose facilities or activities are of the same or similar manufacture or style.

2.23 Precursor Performance Conditions: Conditions that are changing with time and will likely result in acute conditions at some future time. Precursors are similar to

latent conditions but are more definite in their eventual outcome.

2.24 Pre-Licensing Checklist: The purpose of this checklist is to provide a basis for confidence that a new applicant (i.e., an entity that has never had a license or is unknown) requesting a specific license, or a licensee requesting transfer or control to a new applicant or unknown entity, will store and use radioactive materials at locations as specified and under the authorization of the license.

2.25 Pre-licensing Site Visit: A site visit and face-to-face meeting with an entity to provide a basis for confidence that radioactive material will be used as specified. Staff should use the Pre-Licensing Checklist to determine which applicants require visits. The purpose of the pre-licensing visit is to evaluate the applicant's intentions regarding the use of radioactive materials and to forward suspicious applications to the appropriate authority for follow-up, per the guidance in the Pre-Licensing Checklist. At a minimum, all storage and use locations must be visited. By the end of the visit, the reviewer should have observed, collected, and documented sufficient information to provide a basis for confidence that the applicant will use the radioactive materials as specified in its license application. Pre-licensing visits must be completed before the issuance of a license. The new license will NOT be provided to the applicant during a Pre-Licensing Site Visit.

2.26 Reactive Inspection: A special inspection in response to an incident, allegation, or special information obtained by the Department (e.g., allegation, lost or stolen radioactive material, overexposure, medical events). These inspections may focus on one or several issues and need not examine the rest of a licensee's program. A reactive inspection counts as a routine inspection only if the total licensed program is evaluated.

2.27 Reduced Inspection: Changes in the inspection interval of a licensee made at the discretion of the Radioactive Material Program Manager, for several purposes, including but not limited to, poor licensee performance or due to a significant licensing action.

2.28 Regulatory Commitment: An explicit statement to take a specific action, agreed to or volunteered by a licensee, where the statement has been submitted in writing to the VDH and is "tied-down" to the license.

2.29 Reliability: The capability to perform as designed or intended when needed and for the duration required. A lack of reliability is generally only of concern when safety is adversely affected as a result. It is important for inspectors to recognize that reliability applies to both equipment and workers.

2.30 Requirement: A legally binding obligation such as a statute, regulation, license condition, or order.

2.31 Risk: The relationship between consequence and probability. The highest

probability coupled with the most severe consequence represents the highest risk.

2.32 Risk-informed: An approach to regulation taken by the Department, which incorporates an assessment of safety significance or relative risk. This approach ensures that the regulatory burden imposed by an individual regulation or process is appropriate to its importance in protecting the health and safety of the public and the environment.

2.33 Risk Significant Radioactive Material (RSRM) refers to the values in 10 CFR 37 Appendix A.

2.34 Routine Inspection: A periodic, comprehensive inspection performed at a specified frequency based on the activities authorized under the license.

2.35 Safety: Relative freedom from harm or hazard to the public, workers, or the environment. Safety is a relative measure of the hazard associated with a given activity. Inspectors need not be able to quantify levels of safety during an inspection. It is sufficient to identify whether or not an activity, condition, or trend is adverse to safety. Safety must not be dependent on any administrative classification system.

2.36 Security Requirements: Requirements mandated by regulation, order, license condition, or other legally binding requirement for certain licensees possessing or shipping RSRM.

2.37 Special Inspection: Those inspection activities where special guidance is needed. These activities include but are not limited to: (1) inspections of expired licenses, terminated licenses, and licenses undergoing decommissioning; (2) inspections of significantly expanded programs; (3) reciprocity inspections; (4) temporary job-site or field site inspections; (5) team inspections; (6) inspections of abandoned licenses; (7) general licensee's program inspections; (8) reactive inspections; and (9) follow-up to escalated enforcement.

2.38 Team Inspections: Inspections conducted by two or more inspectors or any inspection which includes an inspector from outside of Vermont (other than NRC or agreement state program representatives). A team inspection can be a routine inspection of a major licensee or a reactive inspection in response to a particular incident or event. Team inspections do not include those where a supervisor accompanies an inspector in order to evaluate the inspector’s performance.

2.39 Tie-down condition: A written commitment made by the applicant in an application for a license or amendment to a license that is made a condition of the license (i.e., the commitment is "tied-down" as a legal requirement). Signed letters or signed fax transmissions can be used.

2.40 Unresolved Item: A matter about which more information is required to determine

whether the issue in question is an acceptable item, or a violation.

2.41 Department Record: Any written, electronic, or photographic record under legal VDH control that documents the policy or activities of the Department or a Department licensee. The official records are maintained in WBL.

2.42 Vendor: A supplier of products or services to be used in a Department licensed facility or activity. The vendor may be an NRC, another Agreement State, or Department licensee or the vendor's product may be required to have an NRC Certificate of Compliance (e.g., certain transport packages such as waste casks or radiography devices). See NUREG-1556 Volume 18.

2.43 Violation: The failure to comply with a legally binding regulatory requirement such as a statute, regulation, order, or license condition.

2.44 Willfulness: There are two types of willfulness:

a. Deliberate misconduct, 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 license, applicant, contractor or subcontractor;

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.

## 3.0 Attachment:

**Attachment 2.6-1 10 CFR Part 37 Inspection Checklist**

# 10 CFR Part 37 Inspection Checklist

**Attachment 2.6-1**
**Vermont Department of Health**
**Radioactive Materials Program**
**Inspection Checklist**

**THIS DOCUMENT MUST BE KEPT IN SECURED ELECTRONIC AND/OR PAPER FILES ONCE FILLED OUT**

Security Inspections of materials licensees who possess Category 1 and Category 2 quantities of radioactive material, are required to be performed and documented in accordance with the guidance in NRC Manual Chapter 2800 and NRC Inspection Procedure 87137, "10 CFR Part 37 Materials Security Programs."

Also, please note, if you record notes on the exact location of Category 1 or 2 quantity, a device model number, possession limits or actual inventory, or any physical security measures, the notes should be controlled in accordance with NRC Regulatory Information Summary 2005-031 Revision 1.

**Licensee Name**:_____
**Date(s) of Inspection:** _____
**License No.** _____
**Inspection No.** _____
**Licensee Mailing Address:**_____
_____
_____
_____
**Licensee Address:** _____
_____
_____
**Location(s) Inspected:** _____
_____
_____
**Licensee Contact:** _____ **Telephone No.** _____
**RSO:**_____ **RSO Phone No.** _____
**RSO Email**:_____
**Reviewing Official:**_____ **RO Phone No.:**_____
**LLEA:** _____
**LLEA Contact:** _____
**LLEA Address:** _____
**LLEA Phone No.**_____
_____
_____
_____
_____
_____
_____

# 10 CFR Part 37 Subpart B
# Background Investigations and Access Authorization (AA) Program

- § 37.21 Personnel access authorization requirements for category 1 or category 2 quantities of radioactive material.
- § 37.23 Access authorization program requirements.
- § 37.25 Background investigations.
- § 37.27 Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material.
- § 37.29 Relief from fingerprinting, identification, and criminal history records checks and other elements of background investigations for designated categories of individuals permitted unescorted access to certain radioactive materials or other property.
- § 37.31 Protection of information.
- § 37.33 Access authorization program review.

**§ 37.21 Personnel Access Authorization (AA) Requirements**

☐ (a) 1-3: Licensee established, implemented, and maintains an access authorization program (before taking possession and currently).

☐ (b) AA program ensures appropriate individuals are trustworthy and reliable (T&R).

☐ (c) Licensee subjects the following to the AA program:
_____ Individuals who have unescorted access (UA) to Cat. 2 or greater
_____ Reviewing Officials (RO

☐ (c)(2)Licensee **does/does not** exclude from the AA program categories of individuals identified in § 37.29(a)(1) – (13)

_____
_____
_____
_____
_____

☐ (c)(3) Licensee approves for UA to radioactive material (RAM) only those individuals who require access.

☐ (c)(4) Licensee **does/does not** include individuals needing access to SGI-M under Part 73 in the AA program.

**§ 37.43 General security program requirements.**

☐ (d) (3) Individuals who only have access to confidential information such as the security plan or implementing procedures, and who do not have full UA to Cat. 1 or Cat 2 quantities, have been certified as T&R IAW § 37.25(a)(2) through (a)(7).(i.e., Background screening without fingerprints).

_____
_____
_____

**§ 37.23 Access Authorization (AA) Program Requirements**

(a) *Granting Unescorted Access (UA)*

☐ (2) T&R individuals have received training IAW § 37.43(c) prior to access to Cat. 1 or Cat. 2 quantities. ***(NEW)***

*(b) Reviewing Official(s) (RO)*

☐ (1) Reviewing Official(s) is/are the only one(s) who makes T&R determination allowing access to Cat. 1 or Cat. 2 quantities.

☐ (2) Prior to naming an RO, the licensee:

_____ Completed a background investigation;

_____ Had fingerprints performed by an appropriate provider; and ***(CHANGE)***

_____ Approved by licensee ***(CHANGE)*** and Submitted Certification, under Oath or Affirmation, that RO is T&R.

☐ Licensee requires RO to be recertified as T&R IAW § 35.25(b) every 10 years. ***(CHANGE)***

☐ (3) RO **permitted / qualified to be permitted** UA to Cat. 1 or Cat. 2 quantities and Confidential Information. ***(CHANGE)***

☐ (4) RO cannot approve other ROs (unless the RO is senior management). ***(CHANGE)***

☐ (5) An RO applicant does not need to undergo a new background investigation if they are already certified as T&R including fingerprinting, or relieved from the requirement by § 37.29(a).

(c) *Informed Consent* ***(CHANGE)***

☐ (1) Licensee obtains signed informed consent by subject prior to initiating a background investigation. ***(Licensees Can Use Sample Consent Form NUREG 2155, Annex B)***

_____ Consent includes authorization to share personal information in order to complete the background investigation.

_____ Prior to taking an adverse action, the licensee provided subject an opportunity to correct any inaccurate or incomplete information.

_____ N/A if T&R per § 37.25(b) (i.e., grandfathered).

_____ For recertification or re-investigation.

☐ (2) Subject can withdraw consent at any time. Licensee requires individual to be informed that:

_____ The licensee cannot proceed with remaining elements of background investigation that were not in progress.

_____ Withdrawal of consent is sufficient cause for denial or termination of UA.

_____

_____

_____

_____

(d) Personal History Disclosure ***(NEW)***

_____ Individuals are aware that when applying for UA, they must disclose the required personal information to enable the RO to make a T&R determination

_____ Individuals are aware that refusal to provide or falsification of personal history information is sufficient cause for denial or termination of UA.

(e) Determination Process

☐ (1) The RO is empowered to:

_____ Permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's UA based on an evaluation of the required personal history information.

_____ (2) Deny UA until the RO has evaluated all the information collected to meet the requirements until the individual is determined to be T&R.

_____ (2) Deny UA to any individual based on information obtained at any time during the investigation.

☐ (3) The licensee has documented the basis for concluding whether or not there is reasonable assurance that an individual is T&R.

☐ (4) The RO can terminate or administratively withdraw UA based on information obtained after the T&R determination.

☐ (5) Licensee maintains a list of individuals who have UA:

_____ Licensee removes individuals from T&R list ASAP and within 7 working days if they no longer require or meet UA requirements, and takes prompt actions to deny UA to material ***(NEW)***

(f) Procedures ***(NEW)***

☐ Licensee has developed, implemented, and is maintaining written procedures for implementing the access authorization program. Procedures include:

_____ Notification to individuals who are denied UA;

_____ Provisions for the review, at the request of the affected individual, of a denial or termination of UA;

_____ Provisions to ensure individual informed of grounds for denial or termination of UA and allow the individual an opportunity to provide additional relevant information.

(g) Right to correct and complete information ***(NEW)***

☐ (1) Prior to a final adverse determination, the licensee provides the subject the right to correct and explain information obtained as a result of the licensee's background investigation.

_____ Licensee maintains confirmation of receipt by the individual of this notification for a period of one year.

☐ Individuals are made aware of challenge procedures IAW § 37.23 (g)(2)

(h) Records. ***(NEW)***

☐ T&R records are maintained for 3 years from the date they are no longer required for UA.

☐ Licensee maintains AA procedures for 3 years after they are no longer needed or portions superseded.

☐ Licensee retains a list of persons approved for UA for 3 years after the list is superseded or replaced.

**§ 37.25 Background Investigations**

*(a) Initial Investigation.*

☐ Licensee has completed a background investigation prior to granting UA.

☐ Background investigations encompass at least 7 years preceding the date of investigation. ***(NEW)***

☐ Background investigations include:

_____ (1) Fingerprinting and an FBI identification and criminal history records check

IAW § 37.27;

_____ (2) Verification of true identify using official documentation and compares that information to personal information that was provided. ***(NEW)***

____ Licensee has documented the type, expiration, and identification number of the identification document, or maintains a photocopy.

____ Licensee certifies in writing that documentation was properly reviewed and maintains records for review during inspection.

_____ (3) Employment history verification, including military service, includes the most recent 7 years ***(NEW)***

_____ (4) Verification of participation in education process during the claimed period.

_____ (5) Character and reputation reference checks (plural) have been performed and are limited to whether the individual has been and continues to be T&R.

____ Unless other references are not available, reference checks do not include close family members or anyone who resides in the individual's household.

_____ (6) Licensee, to the extent possible, obtains information to corroborate that provided by the individual (e.g., seek references not supplied by the individual); ***(NEW: FOR ALL BACKGROUND INVESTIGATIONS)***

____ (7) If T&R applicant's previous employer, educational institution, etc., cannot be contacted, or cannot or will not provide information in a timely manner (e.g., >10 business days), then the licensee documents the refusal, unwillingness, or inability in the record of investigation and attempts to obtain information from an alternate source. ***(NEW)***

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

**§ 37.25 Background Investigations**

*(b) Grandfathering.*

☐ Licensee grandfathers individuals T&R'd for UA under Fingerprint Security Orders, but subjects them to a reinvestigation every 10 years.

☐ If licensee grandfathered individual T&R'd under Part 73 or Security Order requiring fingerprints, then they document that, and subject the individual to the reinvestigation requirement.

_____
_____
_____
_____
_____

**§ 37.25 Background Investigations**

*(c) Reinvestigation.*

☐ Licensee conducts reinvestigations on a 10 year frequency that consists of fingerprinting and an FBI criminal history records check. ***(NEW)***

_____
_____
_____
_____
_____

**§ 37.27 Requirements for Criminal History Records Checks**

*(a) General Performance Objectives*

☐ (1) Licensee fingerprints, submits records to NRC for transmission to the FBI, and uses information received from FBI to determine T&R, unless individual excepted under § 37.29, or grandfathered under § 37.25(b).

☐ (2) Licensee notifies individuals that fingerprints will be used to secure their criminal history record, and informs the individual of procedures to revise the record or add explanations to the record.

☐ (3) FP not required if reinstating an individual within 365 days of termination of UA, and termination was under favorable conditions.

☐ (4) If granted T&R based on T&R from different program (i.e., another licensee or M&D), then the licensee obtained criminal history records check file from other program to grant UEA IAW § 37.31(c).

☐ (5) Licensee uses information obtained as part of a criminal history records check solely for determining suitability for UA, or access to confidential information to grant UEA IAW § 37.31(c).

**§ 37.27 Requirements for Criminal History Records Checks**

*(b) Prohibitions*

☐ (1) Licensee does not base final T&R determination based on information received from FBI regarding an arrest more than 1 year old with no disposition, or an arrest that resulted in dismissal of the charge.

☐ (2) Licensee does use information received from FBI to infringe upon First Amendment rights, or discriminate based on race, religion, national origin, gender, or age.

**§ 37.27 Requirements for Criminal History Records Checks**

*(c) Procedures for processing fingerprint checks.*

☐ (1, 2, and 3) Licensee follows procedures outlined in 37.27 for processing finger print checks.

**§ 37.29 Relief from Elements of Background Screening**

☐ (a)(1-12) Licensee exempts individuals from fingerprinting, ID, and background screening requirements if they are individuals designated in § 37.29 (e.g., NRC, Congress, Governor or designee, State Rad Pro, IAEA, Emergency Response personnel, commercial vehicle drivers, package handlers and transportation facilities, and individuals with active security clearance, etc.) ***(NEW)***

___ (13) Licensee exempts Service Provider from fingerprinting, ID, and background screening requirements if Licensee obtains written verification of T&R from Service Provider prior to granting UA, and retains documentation for 3 years after no longer needing it. ***(NEW)***

☐ (b) Licensee exempts individuals from fingerprinting and ID and criminal history records check requirements if they have been favorably adjudicated by U.S. Gov. criminal history records check with in the last 5 years, under comparable Gov't program involving fingerprinting and criminal history records checks, provided the individual makes available appropriate documentation. ***(NEW)***

____ Licensee has received written confirmation from the agency employer that reviewed the criminal history records check and maintains it for 3 years from the date it is no longer needed. Examples include:

_____ NACI; _____ TWIC; _____ ATF; _____ H&HS Security Risk Ass.

_____ Hazardous. Material Security Threat for hazardous material endorsement for commercial drivers; ____ CBP Free & Secure Trade (FAST) program.

**§ 37.31 Protection of Information**

☐ (a) Licensee maintains a system of files and written procedures for protection of collected background and personal information from unauthorized disclosure.

☐ (b) Licensee does not disclose the record or personal information to persons other than:

____ Subject individual, or Subject's representative; or

____ Individuals who have a need to know in the course of granting or denying UA; or

☐ (c) Licensee provides personal information obtained during background screening to another licensee, ONLY if

____ (1) Subject individual provides a written request;

____ (2) Recipient licensee verifies information such as name, date of birth, SSN, gender, and other physical characteristics

☐ (d) Licensee makes background investigation records available to NRC to determine compliance with the regulations.

☐ (e) Licensee retains fingerprint and criminal history records (including data indicating no record) received from FBI, or a copy of those records, if the record has been transferred, for 3 years from the date no longer needed.

_____
_____
_____
_____
_____
_____

**§ 37.33 Access Authorization (AA) Program Review**

☐ (a) Licensee has conducted an annual review of all elements of the AA program content and implementation. ***(NEW)***

☐ (b) Licensee has documented the annual AA program review including recommendations for program improvement. The review includes:

____ Conditions adverse to proper performance (if identified);

____ Cause of the adverse condition;

____ Corrective actions recommended and taken; and

____ Preventative actions.

☐ (c) Annual AA review records are maintained for three years.

☐ T&R records licensee should have for each individual granted unescorted access (unless grandfathered) includes:*

____ Verification of Applicant's True Identify

_____ Photocopy of ID, or record of Type, Expiration, ID No. of ID

_____ Written certification that applicant's ID was properly reviewed

____ Signed Consent Form

____ Verification that applicant Meets All Background Screening Elements including
_____ Verification of 7 years work experience
_____ Verification of Education for the claimed period
_____ Verification of Character & Reputation Determinations
_____ Developed references

____ Fingerprint & Criminal History Records Received, Reviewed, and Approved

____ Documented Basis Documented

____ Security Training

____ Included on List Authorized for Unescorted Access

Note: T&R records for individuals granted access to confidential information must include all the above, except for fingerprinting and a criminal history records checks.

* Due to Grandfathering authorized by 10 CFR 37.25(b), T&R Records for long term (i.e., >3 years) employees who were originally T&R'd IAW the ICs may simply consist of a review of the individual's work history with the licensee, a fingerprint and criminal history records check, and a documented basis.

Note: The licensee can accept T&R reviews conducted by a Security Service Provider (e.g., contract security guard company) provided the Security Service Provider provides written verification that background screening has been performed that meet the elements of § 37.25(a)(2) through (a)(7) (i.e., background screening without fingerprinting)

_____

_____

_____

_____

# 37 Subpart C
# PHYSICAL PROTECTION DURING USE

- § 37.41 Establishment of a security program.
- § 37.43 General security program requirements (Development and maintenance of a plan, implementing procedures, training, protection of information)
- § 37.45 LLEA coordination and notification
- § 37.47 Establishment of security zones (Permanent and temporary, access control, Category 1 quantities)
- § 37.49 Monitoring, detection, assessment, and response.
- § 37.51 Maintenance, testing, and calibration. (Intrusion alarms, communication equipment, other components)
- § 37.53 Requirements for mobile devices.
- § 37.55 Security program review.
- § 37.57 Reporting of events (LLEA, VDH, NRC Operations Center)

**§ 37.41 Security program.**

☐ Licensee established a security program.

☐ Applicant/licensee established security program before taking possession of Cat. 1 or Cat. 2 material.

☐ Licensee notified VDH in writing at least 90 days before aggregating ≥ a Cat. 2 quantity.

☐ Licensee has established, implemented, and maintains a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to Cat. 1/2 quantities.

☐ Licensee's security program includes program features described in §§ 37.43, 37.45, 37.47, 37.49, 37.51, 37.53, and 37.55.

_____
_____
_____
_____
_____
_____

**§ 37.43 General security program requirements.**

(a) *Security plan* ***(NEW)***

☐ Written Security Plan has been developed which is specific to facilities and operations, and provides the licensee's overall security strategy to ensure the integrated and effective functioning of the security program.

☐ The security plan: ***(NEW)***

_____ (i) Describes the measures and strategies used to implement requirements; and

_____ (ii) Identifies security resources, equipment, and technology used to satisfy requirements

_____ Security plan, and revisions, are reviewed and approved by the individual with overall responsibility for the security program

_____ Affected individuals instructed on revised plan before the changes are implemented.

_____ Licensee retains copies of the security plan and revisions for 3 years after the plan or portion is no longer needed.

**§ 37.43 General security program requirements.**

(b) Implementing Procedures ***(NEW)***

☐ Licensee has developed and is maintaining written procedures that document how the requirements of this subpart and the security plan will be met.

☐ Written procedures and revisions have been approved in writing by the individual with overall responsibility for the security program.

☐ Licensee retains copies of the security procedures and revisions for 3 years after the procedure is no longer needed or superseded.

**§ 37.43 General security program requirements.**

(c) *Training*. ***(NEW)***

☐ Licensee conducts training to ensure that individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties.

☐ The training includes instruction in:

____ Security program and procedures including the purposes and functions of the security

measures employed;

____ Individual's responsibility to promptly report to the licensee any condition that causes or may cause a violation of Department requirements;

____ Individual's responsibility to promptly report to the licensee and LLEA any actual or attempted theft, sabotage, or diversion of Cat. 1 or Cat. 2 quantities of RAM; and

____ The appropriate response to security alarms.

____ Training is commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.

____ Refresher training provided within 12 months, and after significant changes, and includes:

- Review of general training requirements;
- Relevant security issues, problems, and lessons learned;
- Relevant results of NRC/VDH inspections, and
- Results of the annual security program review

___ Licensee maintains records of the initial and refresher training for 3 years from the date of the training. Training records include dates of the training, topics covered, a list of attendees, and related information.

_____
_____
_____
_____
_____

**§ 37.43 General security program requirements.**

(d) *Protection of Information*

☐ Licensee limits access to and unauthorized disclosure of their security plans, implementing procedures, and unescorted access list.

☐ Licensee has developed and maintains written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan and implementing procedures.

☐ (3) Before granting access to the security plan or implementing procedures, licensee has:

____ Evaluated an individual's need to know;

____ Determined that the individual is T&R IAW § 37.25(a)(2) through (a)(7).(i.e., Background screening without fingerprints)

☐ Relief from T&R requirements

____ Licensee **does/does not** subject individuals to a background investigation who have been relieved from the requirements per § 37.29 (a)(1) – (a)(7**)**

☐ Security service providers have been T&R'd by licensee based on:

____ Licensee's standard procedures, OR

____ Background investigation provided by service provider IAW § 37.29 (a)(2) – (a)(7**)**

☐ Licensee has documented the basis for granting individuals access to confidential information (e.g. security plan or implementing procedures).

☐ Licensee maintains a list of individuals who have access to the security plan or implementing procedures. ***(NEW)***

____ Individuals who no longer need access to confidential information are removed from the list ASAP and within 7 days, and prompt measures taken to restrict access to confidential information

☐ Licensee stores its security plan and implementing procedures in a manner to prevent unauthorized disclosure. Non-removable electronic media is password protected.

☐ Licensee retains a record for three years after no longer needed:

____ Copy of information protection procedures

____ List of individuals approved for access to the security plan and procedures

☐ Licensees who possess Safeguards information do so IAW § 73.21, and protect the information.

_____
_____
_____
_____
_____
_____
_____

**§ 37.45 LLEA Coordination**

☐ Licensee coordinates with LLEA ***(CHANGE – RELAXES REQUIREMENT FOR A PRE-ARRANGED PLAN AND REQUIRES COORDINATION EVERY 12 MONTHS)***

☐ Information provided to LLEA includes:

___ Description of facility and security measures

___ Cat. 1 or Cat. 2 quantities of Radioactive Material

___ Notification that the licensee will request a timely armed response in the event of actual or attempted theft, sabotage, or diversion

☐ Licensee notifies VDH within 3 business days if:

____ LLEA has not responded within 60 days of coordination request.

____ LLEA notified licensee that they do not plan to participate in coordination activities.

☐ Licensee coordinates with LLEA every 12 months, or when changes adversely affect potential vulnerability to theft, sabotage, or diversion.

☐ Licensee has documented LLEA coordination activities, and maintains a record for 3 years

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

**§ 37.47 Security Zones** ***(NEW TERM)***

☐ Licensee uses or stores material in a permanent or temporary security zone (SZ)

☐ Security zones limit unescorted access only to approved individuals by:
- ____ Isolating material with a continuous physical barrier ***(NEW CRITERIA)*** that allows access only through the established access control points; or
- ____ Direct control by approved individuals at all times; or
- ____ Combination of direct control and physical barriers.

☐ Licensee maintains continuous surveillance of Cat. 1 sources in temporary SZ, or any SZ in which barriers or intrusion detection have been disabled.

☐ Licensee uses approved individuals in a security zone to escort individuals who have not been approved for unescorted access

***(DIFFERENCE: LLEA NOT REQUIRED TO BE NOTIFIED FOR CAT. 1 SOURCE EXCHANGES)***

**§ 37.49 Monitoring, detection, and assessment**

(a) Monitoring and detection

☐ Licensee maintains the capability to continuously monitor and detect without delay all unauthorized entries into the SZ
- ____ Licensee's detection scheme is sufficient to detect the most reasonably foreseeable means to gain unauthorized access.
- ____ Licensee can continuously monitor in the event of a loss of the primary power source, or provide for an alarm and response if a loss of primary power occurs. ***(CHANGE)***

☐ Monitoring and detection performed by:

____ Monitored intrusion detection system linked to onsite/offsite central monitoring facility; or

____ Intrusion detection which annunciates locally to alert nearby personnel. or

____ Continuously monitored video surveillance system , or

____ Direct visual surveillance by approved individuals located within the security zone; or

____ Direct visual surveillance by a licensee designated individual located outside the security zone.

☐ Licensee can detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide: ***(NEW)***

____ Cat. 1: Immediate detection of any attempted unauthorized removal of the radioactive material from the SZ, by electronic sensors linked to an alarm; or continuous monitored video surveillance; or direct visual surveillance.

____ Cat. 2: Weekly verification through physical checks, tamper indicating devices, or other means.

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

**§ 37.49 Monitoring, detection, and assessment**

(b) *Assessment.*

☐ Licensee immediately assesses each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

(c) *Personnel communications and data transmission*

☐ Electronics or personnel for monitoring, detection, and assessment are able to:

____ Maintain continuous capability among site security systems; and

____ Provide alternative communication and data transmission in the event of loss of primary communications or data transmission.

____ Backup methods are not subject to the same failure mode as primary systems.

(d) *Response*

☐ Licensee immediately responds to actual or attempted unauthorized access or theft, sabotage, or diversion of RAM, and without delay requests an armed response from LLEA.

**§ 37.51 Maintenance, testing, and calibration.*(NEW)***

☐ Licensee implements maintenance and testing program for intrusion alarms and communication components, the systems are maintained in an operable condition, and are inspected and tested at the manufacturer's suggested frequency.

____ Testing is performed on a 12 month frequency if not suggested by manufacturer.

____ Maintenance and testing records are maintained for 3 years.

**§ 37.53 Requirements for mobile devices.**

☐ For mobile devices, licensee has two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

☐ For devices in or on a vehicle or trailer, licensee disables the vehicle when not under direct surveillance by licensee (unless site requirements prohibit the disabling of the vehicle). ***(RELIEF FROM PREVIOUS REQUIREMENT)***

____ Licensee uses method other than removal of ignition key to disable vehicle.

**§ 37.55 Security program review. *(NEW)***

☐ Licensee performs an annual review of the content and implementation of the RAM security program, and takes comprehensive actions to correct non-compliances.

____ Annual security review is documented, and maintained for 3 years.

____ Annual review conditions adverse to proper performance, the cause of the

condition(s), and, when appropriate, recommend and taken corrective actions.

____ Licensee reviews findings and takes C/A as necessary

Note: Licensee must review both the AA and Security Program on an annual basis. Therefore, the licensee may simply combine these reviews into one annual review.

**§ 37.57 Reporting of events.** ***(NEW)***

☐ Licensee immediately notifies LLEA after determining that an actual or attempted theft/sabotage/diversion occurred.

____ Following LLEA notification, notifies, VDH at (800) 439-8550, NRC at (301) 415-5100 ASAP, and no later than 4 hours. 10 CFR 37.57

___ Following the telephonic notification, Licensee submits a written 30-day report to VDH .

☐ Licensee assesses any suspicious activity related to possible theft/sabotage/diversion and makes similar notifications to LLEA and VDH/NRC.

# 10 CFR Part 37 Subpart D
# Physical Protection In Transit

- § 37.71 Additional requirements for transfer of category 1 and category 2 quantities of radioactive material.
- § 37.73 Applicability of physical protection of category 1 and category 2 quantities of radioactive material during transit.
- § 37.75 Preplanning and coordination of shipment of category 1 or category 2 quantities of radioactive material.
- § 37.77 Advance notification of shipment of category 1 quantities of radioactive material.
- § 37.79 Requirements for physical protection of category 1 and category 2 quantities of radioactive material during shipment.
- § 37.81 Reporting of events.

**§ 37.71 Transfer of Cat. 1 & Cat 2 quantities** ***(NEW – REQUIRES USE OF NRC'S LICENSE VERIFICATION SYSTEM (LVS))***

☐ Prior to transferring a Cat. 1 or Cat. 2 quantity, the licensee verifies with the NRC license verification system or the license issuing authority, that the transferee's license authorizes receipt of the type, form, and quantity of RAM, AND, IF Cat. 1 quantity, the receipt address is authorized.

_____ Licensee documents verification (verification not required for inter-organizational transfers).

____ IF emergency, and could not reach issuing authority/verification system inoperable, THEN can accept written certification by transferee that they are authorized to receive the type, form, and quantity of RAM. Must include license number, revision, issuing agency, expiration date, and for a Cat. 1 facility, authorized address. Must perform follow-up confirmation by the end of the next business day.

____ Verification documentation maintained for 3 years.

Note: The inspector uses the LVS to verify that the shipping licensee verified that the receiving licensee is authorized to receive the type, form, and quantity of material prior to shipping the material. The inspector does this by entering the LVS; Clicking on "*Query Verification Activity"*; Then entering licensee information and date range; the Verification Information will then be displayed. This enables the inspector to verify that the license conducted a proper verification before shipping the Cat. 1 or Cat. 2 material.

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

**§ 37.73 Applicability of Physical Protection During Transit**

☐ 73(a) Cat 1 shipments shall comply with physical protection requirements in §§ 37.75(a) and (e); 37.77; 37.79(a)(1) and (b)(1); and 37.81(a), (c), (e), (g) and (h).-

☐ 73(b) Cat 2 shipments shall comply with physical protection requirements in §§ 37.75(b) through (e); 37.79(a)(2), (a)(3), (b)(2), and (c); and 37.81(b), (d), (f), (g), and (h). Also, if meet 71.97(b), then also comply with 71.97.

☐ 73(c) Shipper responsible for security unless transferee assumes responsibility in writing.

☐ 73(d) Licensee import/export shipments of Cat. 1, complies with §§ 37.75(a)(2) and (e); 37.77; 37.79(a)(1) and (b)(1); and 37.81(a), (c), (e), (g), and (h) for the domestic portion of the shipment.

☐ 73(e) Each licensee that imports or exports category 2 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in §§ 37.79(a)(2), (a)(3), and (b)(2); and 37.81(b), (d), (f), (g), and (h) for the domestic portion of the shipment.

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_

**§ 37.75 Shipment Preplanning & Coordination** ***(CHANGE)***

***§ 37.5 Definitions. (NEW)***

- ***Safe haven*** means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.
-
- ***Mobile device*** means a piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.
- ***Movement control center*** means an operations center that is remote from transport activity and that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.
- ***No-later-than arrival time*** means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival time may

not be more than 6 hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

☐ 75(a) Cat 1 shipments ***(NEW)***
_____ Preplan & Coordinate shipment departure & arrival times with receiving licensee
_____ Preplan & Coordinate shipment departure & arrival times with governors of all transit states.
_____ Discuss States' intention to provide law enforcement escorts
_____ ID safe havens, and
_____ Document preplanning and coordination activities.

☐ 75(b) Cat 2 shipments
_____ Coordinate shipment arrival with receiving licensee
_____ Document preplanning and coordination activities.

☐ 75(c) Cat 2 shipments
_____ Receiver confirms receipt with originator
_____ Receiver must notify originator if shipment not received by intended arrival time.

☐ 75(d) Cat 2 late shipments ***(NEW)***
_____ Originator notifies Receiver of new "no-later-than" arrival time

☐ 75(e) Coordination and Planning Shipment records
_____ Retain copy of record and revisions for 3 years.

**Difference:** The rule does not require training of the individuals instead requiring the individuals to have access to procedures.
**Difference:** The rule does not require that the licensee assure the trustworthiness and reliability of drivers or document that the carrier employs the measures.

## § 37.77 Advance Notification of Cat. 1 Shipments *(NEW)*

☐ Advance notification to NRC, VDH and governor of affected states

☐ 77(a) Notification in writing

_____ To governor: by mail, postmarked 7 days before transport, or other means, at least 4 days prior to transport

_____ To NRC, by mail, secure email to RAMQC SHIPMENTS@nrc.gov, or secure fax to (301) 816-5151

_____ To VDH by mail or secure email (VDH_secure_email@vermont.gov )

☐ 77(b) Advanced Notification Required Information

_____ Name, address, and telephone number of the shipper, carrier, and receiver;

_____ License numbers of the shipper and receiver;

_____ Description of RAM contained in the shipment, including radionuclides and quantity;

_____ Point of origin of the shipment and the estimated time and date that shipment will commence;

_____ Estimated time and date that the shipment is expected to enter each State along the route;

_____ Estimated time and date of arrival of the shipment at the destination; and

_____ Point of contact, with a telephone number, for current shipment information.

☐ 77(c) Shipment Notification revisions

_____ Licensee notifies VDH/NRC and governors regarding shipment revisions as soon as possible

☐ 77(d) Shipment Cancellation Notification ***(NEW)***

_____ Licensee notifies VDH/NRC and governors regarding shipment cancellation as soon as possible

☐ 77(e) Cat. 1 Shipment Record Retention

_____ Licensee retains copies of advance notifications and revisions for 3 years

☐ 77(f) Cat. 1 Shipment Protection of Information

_____ State Officials, State employees, and others (licensee or not), who receive schedule information (37.77(b)) protect information against unauthorized disclosure as specified in 73.21.

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

**§ 37.79 Physical Protection of Cat. 1 & 2 Shipments** ***(CHANGE)***

☐ 79(a)(1) Cat. 1 Shipments by road

_____ Licensee establishes a movement control center

_____ Maintains position information from a remote location.

_____ Monitors shipments 24 hours a day, 7 days a week;

_____ Has ability to communicate immediately with the appropriate law enforcement agencies.

_____ Establishes redundant communications to enable transport to contact escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.

_____ Utilizes continuous monitoring by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center.

_____ Movement control center provides positive confirmation of the location, status, and control over the shipment.

_____ Movement control prepared to promptly implement preplanned procedures in response to deviations from authorized route or upon notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. Procedures include identification of and contact information for the appropriate LLEA along the shipment route.

_____ Individual accompanies driver when driving period greater than maximum in 24 hours as established by DOT Federal Motor Carrier Safety Administration (may be another driver)

_____ Licensee who made arrangements for Cat. 1 Shipment has developed written normal and contingency procedures to address:

_____ Notifications to the communication center and law enforcement agencies;

_____ Communication protocols that include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

_____ Loss of communications; and

_____ Responses to an actual or attempted theft or diversion of a shipment.

**Difference:** The rule does not require training of the individuals instead requiring the individuals to have access to procedures.

**Difference:** The rule does not require that the licensee assure the trustworthiness and reliability of drivers or document that the carrier employs the measures.

_____

_____

_____

☐ 79(a)(2) Licensee Cat. 2 Shipments by road

_____ Licensee maintains constant control and/or surveillance during transit and has capability for immediate communication to summon assistance.

☐ 79(a)(3) Carrier Cat. 2 Shipments by road

_____ Carrier has established package tracking systems that allows the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

_____ Carrier maintains constant control and/or surveillance during transit and has the capability for immediate communication to summon appropriate response or assistance; and

_____ Carrier has established tracking systems that requires an authorized signature prior to releasing the package for delivery or return.

☐ 79(b) Cat. 1 Shipment by rail

_____ Rail shipment monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center.

_____ Rail communications center provides positive confirmation of the location of the shipment and its status.

_____ Rail communications center implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures include contact information for the appropriate LLEA along the shipment route.

_____ Include periodic reports to the communications center at preset intervals.

☐ 79(b) Cat. 2 Shipment by rail

_____ Carrier has established package tracking system which allows the shipper or transporter to identify when and where the package was last and when it should

arrive at the next point of control.

_____ Carriers maintains constant control and/or surveillance during transit and has capability for immediate communication to summon appropriate response or assistance; and

_____ Carrier has established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

**Difference:** The rule does not require procedures or training as the railroad will have its own training and procedures that must be followed.
**Difference:** The rule does not require that the licensee assure the trustworthiness and reliability of drivers or document that the carrier employs the measures.

☐ 79(c) Cat. 2 Rail Shipment Investigations ***(NEW)***

_____ Immediately conducts investigation, in coordination with the receiving licensee, of shipment that has not arrived by the designated no-later-than arrival time

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

**§ 37.81 Reporting of Events** ***(NEW)***

☐ 81(a) Event Reporting Cat 1 Shipments.

____ Notifies LLEA (last confirmed location) VDH and NRC Ops Center within 1 hour of lost or missing Cat. 1 shipment

____ Licensee provides VDH and NRC on status of investigation

☐ 81(b) Event Reporting Cat 2 Shipments.

____ Notifies VDH and NRC Ops Center within 4 hours of lost or missing Cat. 2 shipment

____ Licensee provides VDH and NRC updates on status of investigation

____ Licensee immediately notifies VDH and NRC Ops Center, if after 24 hours, a lost or missing shipment has not been located and secured.

☐ 81(c) Event Reporting Cat 1 Shipments.

____ Notifies designated LLEA upon discovery of actual theft/sabotage/diversion of Cat. 1 quantity. Notifies VDH and NRC Ops center ASAP after LLEA notification.

☐ 81(d) Event Reporting Cat 2 Shipments.

____ Notifies VDH NRC Ops center ASAP upon discovery of actual theft/sabotage/diversion of Cat. 2 quantity.

☐ 81(e) Event Reporting Recovery of Cat 1 Quantity.
____ Notifies VDH and NRC Ops center & LLEA ASAP upon recovery of any lost or missing Cat. 1 quantity of RAM.

☐ 81(f) Event Reporting Recovery of Cat 2 Quantity.
____ Notifies VDH and NRC Ops center & ASAP upon recovery of any lost or missing Cat. 2 quantity of RAM.

☐ 81(g) Event Reporting 30 Day Report Following Telephonic Notification
____ Telephonic notifications required by paragraphs (a) through (d) followed within 30 days by a written report

☐ 81(h) Event Reporting Additional Substantive Information.
____ After filing a 30 day report, if licensee learns of additional substantive information, on the loss or theft, then licensee shall file that information within 30 days.

# Subpart F – Records

**§ 37.101 Form of records.** ***(NEW)***

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

**§ 37.103 Record retention.**

**Difference:** The rule does not require records to be maintained after the license is terminated.

**Appendix A to Part 37—Category 1 and Category 2 Radioactive Materials**

Table 1 – Category 1 and Category 2 Threshold[1]

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

**Difference:** The radioactive material and thresholds are the same; however, the rule provides the Ci value to 3 figures.

_____
_____
_____
_____
_____

# Attachment 1:  Reminders

## New Procedures & Documents the Licensee Must Maintain

____Access Authorization Procedures & Documents
- _____Photocopy of ID, or record of Type, Expiration, ID No. of ID
- _____ Written certification that applicant's ID was properly reviewed
- _____ Signed Consent Form
- ____ Documented basis for concluding an individual is T&R and can be granted access to the security plan and implementing procedures
- ____ Documented basis for concluding an individual is T&R and can be granted unescorted access to the security zone.
- ____ List of individuals authorized to access confidential information
- ____ List of individuals authorized for unescorted access to the security zone(s)

____Security Plan
____Implementing Security Procedures
____Procedures for the Protection of Confidential Information
____LLEA Information (coordination documents)
____Procedures for Shipping (e.g., Notifications and Coordination)

# Attachment 2
# Part 37 Time Requirements

Time Requirements: Immediate

- Must maintain capability to continuously monitor and detect without delay all unauthorized entries into security zones."
- Immediately Detect Attempts to remove Cat. 1 Material
- Prompt measures must be taken to ensure an individual who no longer needs unescorted access is prevented from gaining access
- Individuals who no longer require access must be removed ASAP from access authorization list.

Time Requirements: 4 Hours

- Following LLEA notification, notifies VDH ASAP at (800) 439-8550, and no later than 4 hours.

Time Requirements: 3 Days

- Notify NRC/VDH within 3 days, if
  -LLEA has not responded to a coordination request in 60 days, OR
  -LLEA notifies licensee that the LLEA does not plan to participate in coordination activities

Time Requirements: 4 & 7 Days

- Advanced Notification to VDH/NRC & Governors of Cat. 1 Shipment:
  - 4 Days – Phone or Email
  - 7 Days if Mailed
- When no longer required, Remove individual from access authorization list ASAP, but no later than 7 working days

Time Requirements: Weekly

- Perform Weekly Verifications to ensure Cat. 2 Material is Present
  - Verification through physical checks, tamper indicating devices, etc.

Time Requirements: 10 Days

- Time licensee allows individual to challenge FBI & Criminal History Records Check: 10 days
- If a previous employer, educational institution, etc. fails to provide information within 10 business days (or unwilling or unable), licensee can document that and attempt to obtain the information from an alternate source.

Time Requirements: 90 Days

- Licensee notified VDH in writing at least 90 days before aggregating $\geq$ a Cat. 2 quantity.

Time Requirements: 12 Months

- Security Refresher training (or when significant changes occur)
- LLEA Coordination (or when significant changes occur)
- Alarm Testing (If there is no manufacturer's suggested frequency)

Time Requirements: Annually

- Each licensee shall periodically (at least annually) review:
  - The access control program content and implementation, AND
  - The security program content and implementation.

Time Requirement 365 Days

- Fingerprinting not required if individual returns to same facility within 365 days, and termination was under favorable conditions.
- 1 Year – Prior to Background Screening Adverse Action, Must Notify Individual and Provide Opportunity to Correct Record. Record of Confirmation of receipt Must be Maintained by Licensee for 1 Year
- Licensee does not base final T&R determination based on information received from FBI regarding an arrest more than 1 year old with no disposition, or an arrest that resulted in dismissal of the charge.

Time Requirement 3 Years:

- Maintain for 3 Years:
  - Implementing Security Procedures after no longer needed, and superseded portions
  - Training, Initial and Refresher
  - Information protection procedures
  - List of individuals approved for access to the security plan or implementing procedures.
  - Alarm System maintenance and testing activities
  - Results of annual review of the security program
  - Efforts to verify that a receiving licensee is authorized to receive material
  - Transportation: documentation for preplanning and coordination
  - Copy of the advance notifications and revisions

Time Requirement 5 Years

- Fingerprinting, and the identification and criminal history records checks not required for individual favorably adjudicated under comparable U.S. Government criminal history records check within the last 5 years

Time Requirement 7 Years

- Background Investigations – 7 Years, or time since 18th Birthday, whichever is shorter

Time Requirement 10 Years

- Reviewing Official Recertification
- T&R Recertification

Inspection Meeting

Licensee: _____

Docket No. _____ License No. _____ Inspection No. _____

Type of Meeting: ❑ Entrance ❑ Exit ❑ Other _____

Date of Meeting: _____

Please Print

| **Name:** | **Title:** | **Phone No.** |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |
| 9. | | |
| 10. | | |
| 11. | | |
| 12. | | |
| 13. | | |
| 14. | | |
| 15. | | |

# Vermont Department of Health

# Radioactive Materials Program

## Radioactive Materials Program Procedure 4.2, Revision 0

## Tracking Inspection Reports & Correspondence

**Prepared By:** _____ **Date:** _____

**Reviewed By:** _____ **Date:** _____

**Approved By:** _____ **Date:** _____

**Effective Date:** _____

| Revision | Date | Description of Changes |
|---|---|---|
| 0 | | |
| | | |

# Table of Contents


**1.0 PURPOSE**

- **1.1 Applicability**
- **1.2 References**
- **1.3 Files**

**2.0 RESPONSIBILITIES**

- **2.1 Radiological Health Specialist**
- **2.2 Radioactive Materials Program Manager (RMPM)**
- **2.3 Radiation Control Program Director (RCPD)**

**3.0 PROCEDURE**

- **3.1 Assignment of Inspection**
- **3.2 Performance of Inspection and Initiation of Tracking**
- **3.3 Tracking Inspection Report Completion and Transmittal of Correspondence**
- **3.4 Receipt of Corrective Action(s) and Negative Evaluation or Missed Deadline**
- **3.5 Receipt of Acceptable Information and Close-out of Inspection Tracking**

**4.0 RECORDS**

**5.0 ATTACHMENTS TO RMPP 4.2**

- **None**

## 1.0 PURPOSE

### 1.1 Applicability

1.1.1 This procedure applies to tracking inspections that are performed, completion of the inspection report, and transmittal of correspondence, if any.

1.1.2 Tracking shall begin upon notification from the Radiological Health Specialist that an inspection has become due and ends with completion of an inspection report and:

1.1.2.1 The issuance of a clear inspection form Attachment 2.4-4 **Clean Inspection Report**, or

1.1.2.2 Transmittal of a Department letter or other form designating a clear inspection such as an RMPP 2.4 Attachment 2.4-1 **Department Form 591M Safety Inspection Report and Compliance Inspection**, Attachment 2.4-4 **Clean Inspection Report** (or other documentation of "no response required" by the licensee due to action already taken), or

1.1.2.3 The final letter documenting acceptance of the proposed corrective actions.

### 1.2 References

Vermont Radiological Health Rule

### 1.3 Files

Records are primarily filed electronically and Web-based Licensing (WBL) is the primary residence of these records.

## 2.0 RESPONSIBILITIES

### 2.1 Radiological Health Specialist

2.1.1 Prepares a list from Web-Based Licensing (WBL) on a monthly basis for the Radioactive Materials Program Manager (RMPM) of inspections due for the next 6 months in accordance with the Priority Codes in RMPP 1.1 Attachment 1.1-6 **Inspection Priority Codes Assigned to Program Codes**.

2.1.2 Maintains files in WBL related to the inspections conducted.

## 2.2 Radioactive Materials Program Manager

2.2.1 Responsible for tracking dates of performance for:

2.2.1.1 the inspection
2.2.1.2 correspondence sent to the licensee
2.2.1.3 issuance of clear inspection form
2.2.1.4 reply due dates for licensee requests for information
2.2.1.5 reply from licensee, and
2.2.1.6 final acceptance and inspection closure

2.2.2 Ensuring the overall tracking activities of inspection staff.

2.2.3 Maintaining the *Inspections Due for the Next 6 Months-By Priority Report* and ensuring inspections are completed when due.

## 2.3 Radiation Control Program Director (RCPD)

2.3.1 Provides guidance to the Radioactive Materials Program staff relative to inspection tracking.

2.3.2 May assume the duties of the RMPM or assign to others as necessary.

# 3.0 PROCEDURE

## 3.1 Assignment of Inspection

Inspections will be performed by Radiological Health Specialists based on 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.

## 3.2 Performance of Inspection and Initiation of Tracking

Once the inspection has been performed, the Radiological Health Specialist informs the Radioactive Materials Program Manager of the licensee name, license number, the date of the inspection, and the name(s) of all inspectors. The exit meeting date may be used for inspections longer then one day. The Radiological Health Specialist enters this information into Web-Based Licensing.

## 3.3 Tracking Inspection Report Completion and Transmittal of Correspondence

3.3.1 For routine inspections, the time period for completion of the inspection checklist/report and transmittal of correspondence to the licensee, if any, is

30 days (see note below).

3.3.2 If a clear inspection form was issued, then no other correspondence will normally be sent to the licensee (a Form 591M may have also been left at the time of the exit interview – provided there are no findings, an NCV, or Severity Level IV).

3.3.3 The Radiological Health Specialist will enter the date the inspection report was completed and the date the inspection letter was sent.

3.3.4 The date the inspection reply is due should be obtained from the letter and entered into the Radioactive Materials Program WBL database for those licensees who must respond to a Notice of Violation.

**Note**: Escalated enforcement actions may require a faster turn-around time (i.e.; within 10 days).

## 3.4 Receipt of Corrective Action(s) and Negative Evaluation or Missed Deadline

3.4.1 Receipt of Corrective Action(s): Once the corrective actions are received, the receipt date should be logged into the Radioactive Materials Program WBL database. Each Radiological Health Specialist shall be responsible for checking the pending inspection completions report to determine the current status of received correspondence. An evaluation should be performed as soon as possible by the Radiological Health Specialist, but no longer than 30 days, from receipt of the information.

3.4.2 Negative Evaluation: If the corrective action(s) are not satisfactory or the information is incomplete, then a telephone conference call should be conducted. Subsequently, a follow-up letter or email should be sent to the licensee requesting additional information by a specified date and documenting the results of the conference call. The Radiological Health Specialist should enter the specified due date into the Radioactive Materials Program WBL database.

3.4.3 Missed Deadline: If a deadline is missed, the Radiological Health Specialist shall, as soon as possible, follow up with the licensee to request submittal of the corrective action information. A new due date for the requested information should be established. The Radiological Health Specialist should modify the 'Inspection Reply Due' date upon request of the Radioactive Materials Program Manager. If deadlines are missed more than twice, the RMPM and RCPD may consider responses including enforcement actions, reduced inspection frequency or increasing the severity level or civil penalty of a violation.

## 3.5 Receipt of Acceptable Information and Close-out of Inspection Tracking

3.5.1 Receipt of Acceptable Information: Once the licensee provides the corrective actions , the receipt date should be logged into the Radioactive Materials Program WBL database. Each Radiological Health Specialist shall be responsible for checking the pending inspection completions report to determine the current status of received correspondence.

3.5.2 Close-out of Inspection Tracking: If the corrective action(s) are satisfactory, then a 'Close Out' letter should be sent to the licensee, normally within 30 days, stating that the action(s) will be evaluated on the next inspection. Once this final reply acknowledgement letter is sent and the date logged in the Radioactive Materials Program WBL database by the Radiological Health Specialist, the tracking is closed out for the licensee. The Radiological Health Specialist should file the inspection report and related correspondence in the Department license file and WBL.

## 4.0 RECORDS

4.1 Clear inspection form or Notice of Violation-filed in Department inspection file

4.2 Licensee Corrective Actions/Reply, if applicable-filed in Department license file

4.3 RMP letter accepting Corrective Actions/Reply-filed in Department license file

4.4 Inspection Report(s) - filed in Department license file

4.5 Records are primarily filed electronically and Web-based Licensing (WBL) is the primary residence of these records. An alternative/backup means of filing must be available, and may include Department network files.

## 5.0 ATTACHMENTS TO RMPP 4.2

**None**