

State of Vermont Department of Health

Radioactive Materials Program

Procedure 4.1, Revision 0



Renewal Notices, Receipt and Tracking of Licensing Actions

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Approved By: _____ **Date:** _____

Effective Date: _____

Revision	Date	Description of Changes
0		

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Table of Contents

1.0 PURPOSE

- 1.1 Applicability
- 1.2 References
- 1.3 Files
- 1.4 Definitions

2.0 RESPONSIBILITIES

- 2.0 Radiological Health Specialist
- 2.1 Radioactive Material Program Manager (RMPM)
- 2.2 Radiation Control Program Director (RCPD)

3.0 PROCEDURE

- 3.1 Receipt of Licensing Action
- 3.2 Completeness Review
- 3.3 Assignment of License Reviewer
- 3.4 Request for Additional Information
- 3.5 Receipt of Additional Information or Missed Deadline
- 3.6 Writing the License, Secondary Review, and Documentation
- 3.7 Signing the License and File Documentation

4.0 RECORDS

- 4.1 Records to be Maintained
- 4.2 Records Retention

5.0 ATTACHMENTS TO RMPP 4.1

None

Renewal Notices, Receipt and Tracking of Licensing Actions

1.0 PURPOSE

1.1 Applicability

- 1.1.1 This procedure applies to all records related to license applications, renewals, amendments, and terminations including renewal notices, receipt of licensing actions, acknowledgement letters, and tracking of licensing actions.
- 1.1.2 Licensing actions shall be tracked from their receipt until a licensing action is completed or a determination is made to deny the request.

1.2 References

- 1.2.1 Vermont Radioactive Materials Rule.
- 1.2.2 Department Form 313 - filed in Vermont license file.
- 1.2.3 Deficiency Letter - filed in Vermont license file.
- 1.2.4 License - filed in Vermont license file.

1.4 Definitions

- 1.4.2 Request for Additional Information (RAI): A communication with the applicant that documents a request for additional information needed to process the licensing request. Problems with the submission, the rule or regulatory guidance that is applicable, and the specific action requested of the licensee or applicant must be clearly stated.
- 1.4.3 License Reviewer: A Radiological Health Specialist qualified to review, process, and document a specific category of licensing action. A license reviewer shall not perform a secondary review for any category of license for which they are not qualified.
- 1.4.3 Licensing Action: A request or application received from an applicant or a licensee as follows:
 - 1.4.3.1 An application for a license to receive, possess, and use licensed radioactive materials;
 - 1.4.3.2 An application for renewal of a license;
 - 1.4.3.3 An amendment request to a license, e.g., change in administration,

authorized use and/or user(s), RSO, quantity of material, add isotopes, facilities, etc.; and/or,

1.4.3.4 A request for termination of a license.

1.4.5 Processing: Reviewing the application for license or amendment, requesting additional information if appropriate, and either issuing or denying, with or without prejudice, the requested license or amendment.

2.0 RESPONSIBILITIES

2.1 Radiological Health Specialist

- 2.1.1 Responds to requests for license applications and uses the schedule in RMPP 1.1 *Review of Initial Application for License or an Amendment Request* for prioritization of license reviews.
- 2.1.2 Receives, logs, and acknowledges the receipt of an application, including application fee, for a new license in the licensee/applicant file.
- 2.1.3 Prepares the renewal letter to notify the licensee that the license will expire in 90 days.
- 2.1.4 Records dates as provided for receipt and tracking of all licensing actions, including transmittal of timely filed letters for renewals.
- 2.1.5 Sends out acknowledgement letters for receipt of termination requests in a timely fashion (if possible, within 15 working days).
- 2.1.6 Assigns due date (90 or 180 days) for each licensing action based on type of action (see RMPP 1.1) and enters this information into the Radioactive Materials Program database, in consultation with Radioactive Materials Program Manager, (RMPM) as needed.
- 2.1.7 Prepares a list for the Radioactive Materials Program Manager that shows the status of each licensing action.
- 2.1.8 Performs secondary review of licenses prepared by other Department licensing staff members.

2.2 Radioactive Materials Program Manager

- 2.2.1 Responds to requests for license applications and uses RMPP 1.1 for prioritization of license reviews.
- 2.2.2 Conducts license reviews or secondary reviews as assigned by the

Radiation Control Program Director.

- 2.2.3 Conducts completeness review for renewals and signs timely filed letter for renewals as assigned by the Radiation Control Program Director.

2.3 Radiation Control Program Director

- 2.3.1 Provides guidance to Radioactive Material Program Manager on prioritizing and reviewing licensing actions.
- 2.3.2 Assigns licensing actions and completeness reviews to Radiological Health Specialists for secondary review of license applications.

3.0 PROCEDURE

3.1 Receipt of Licensing Action

- 3.1.1 Upon receipt of a licensing action, the primary reviewer will determine the type of licensing action (i.e., new application, renewal, amendment request, or termination request) and based on the prioritization schedule in RMPP 1.1, identifies a priority and due date. The RMPM will provide additional guidance in prioritization as needed.
- 3.1.2 If the application is for a renewal or new application or significant amendment, a more detailed review is required.
- 3.1.3 All primary (and secondary) reviews are documented using RMPP 1.1, Attachment 1.1-4 **License Review Job Aid**.
- 3.1.4 Acknowledgement letters shall be sent for new applications and termination requests.
- 3.1.5 A fee must accompany the initial application.

3.2 Assignment of License Reviewer

The RMPM or designee will assign licensing actions to qualified license reviewers based on workloads, experience levels, and the priority assigned to the licensing action.

3.3 Secondary Review

- 3.3.1 A secondary review must be performed for all licensing actions to identify any deficiencies in the license application, renewal, amendment, or termination documentation before the licensing review can proceed to supervisory review and RCPD approval.

- 3.3.2 A secondary review using the guidance in RMPP 1.1, Attachment 1.1-4 **License Review Job Aid** is to verify the licensee used appropriate regulatory guidance and forms to complete the application.
- 3.3.3 A secondary review determines if additional information is required (e.g., emergency response procedures, attestation, training and experience, leak test results, etc.), and if the application was signed by a duly authorized representative of the company or institution.
- 3.3.4 Timely filed letters shall be sent for renewal applications that are deemed to be complete.

3.4 Requests for Additional Information

- 3.4.1 The qualified reviewers shall review the licensing action request and determine if additional information is needed.
- 3.4.2 Requests for additional information will be handled with a letter or a documented phone call to the licensee or applicant that indicates a due date for submittal of the information within 30 days or less.
- 3.4.3 A due date for the additional information shall be entered into the licensee database.

Note: If the information needed is not extensive, the request may be communicated by phone or email and the licensee or applicant may submit via fax as long as the fax is signed. The license reviewer will need to document the phone call in the license file.

3.5 Receipt of Additional Information or Missed Deadline

- 3.5.1 Once the requested information is received, the receipt of the information shall be logged into the database.
- 3.5.2 Each qualified reviewer shall be responsible for checking his/her pending licensing actions to determine the current status.
- 3.5.3 In the event that a deadline is missed, the license reviewer shall, in a timely fashion (if possible, within 5 working days), follow up with the licensee or applicant to determine the status of the requested information.
- 3.5.4 If no response is received within 60 days, the licensing request may be considered abandoned and any relevant information documented in the licensee database.

- 3.5.5 The license reviewer will send an abandonment letter to the licensee notifying them of the action taken.

3.6 Writing the License, Secondary Review, and Documentation

- 3.6.1 Writing the License: The qualified license reviewer shall write the license action using the standard license conditions and license template to develop or modify the license. The initial Department issued license will not have an Amendment Number.
- 3.6.2 Secondary Review: The primary reviewer shall forward the licensing action file with the draft license to the RMPM or designee to assign or make a secondary review. The secondary reviewer will note any issues of concern with the initial license reviewer.
- 3.6.3 Supervisory Review: Before a licensing action is signed and approved by the RCPD, the RCPD must make a supervisory review as documented on the Administrative Qualitative Checklist (Attachment 1.1-5).
- 3.6.4 Documentation: When all issues are satisfactorily resolved, the secondary reviewer documents agreement with the proposed licensing action.

3.7 Signing the License and File Documentation

- 3.7.1 Signing Approval of the Licensing Action: The license can be signed by the RCPD or by an individual designated by the RCPD after the secondary review and the supervisory review.
- 3.7.2 File Documentation: The licensing action file should be given to a qualified license reviewer for logging the completion of the licensing activity, inserting the licensing request, any deficiency letters, response(s), transmittal letter, and licensing action into the Vermont license file. For renewals, a new license file will be created containing the renewal application, supporting information, and the most recent inspection report. All files will be maintained in a secure electronic file under the control of the Radiation Control Program Director.

4.0 RECORDS

4.1 Records to be Maintained

- 4.1.1 License Application (Department form 313) - filed in Vermont license file.
- 4.1.2 Request for Additional Information - filed in Vermont license file.

4.1.3 License - filed in Vermont license file.

4.2 Records Retention

4.2.1 Web Based Licensing is the primary electronic file repository.

4.2.2 Records may also be kept in other secure electronic forms with access only to RMP staff.

5.0 ATTACHMENTS TO RMPP 4.1

None