4.3 Licensing Program Elements

The Vermont Department of Health will conduct its licensing program using the U.S. Nuclear Regulatory Commission (NRC) Licensing Guidance, NUREG-1556 Series, as the basis for reviewing new license applications, license renewals, and amendments. Additionally, the Radioactive Materials Program Procedures will be used for administrative licensing functions.

The Radioactive Material Program Procedures (RMPPs) are broad and relate to all licensing activities, while the NUREG-1556 Series focuses on specific licenses or licensing activities and provides guidance to staff and for applicants and licensees when submitting a new application, renewal, or an amendment to an existing license.

Most licensing administrative guidance is provided through RMPP Section 1, along with an RMPP from Section 4. The RMPPs are listed here and are found in this Section 4.3.

RMPP No.	Title
RMPP 1.1	Review of Initial Application for License or an Amendment Request
RMPP 1.2	Renewal of Licenses
RMPP 1.3	License Termination/Revocation
RMPP 1.4	NRC Licenses Affected by Agreement States
RMPP 4.1	Renewal Notices, Receipt, and Tracking of Licensing Actions

In Section 4.3.1, the guidance for technical reviews (NUREG-1556 Series) and information for license applicants are addressed. The procedure for assuring the technical quality of licenses, RMPP 1.1 *Review of Initial Application for License or an Amendment Request* is in Section 4.3.5.

RMPP 1.2 *Renewal of Licenses*, RMPP 1.3 *License Termination/Revocation*, RMPP 1.4 *NRC Licenses Affected by Agreement States*, and RMPP 4.1 *Renewal Notices, Receipt, and Tracking of Licensing Actions* are included in Section 4.3.6 Administrative Licensing Procedures.

Since Vermont is not seeking an Agreement providing responsibility for evaluating radiation safety information on sealed sources or devices, registration for distribution, the technical evaluation of a proposed license for a low level radioactive waste land disposal site, or conducting the evaluation of a regulatory program for 11e.(2) byproduct material including uranium or thorium mining facilities, the content of Section 4.3.2, 4.3.3, and 4.3.4 is simply a statement about this lack of applicability.

4.3.1 Procedures for the Technical Evaluation of Proposed Uses of Radioactive Material

This section of the application provides technical procedures that address radiation safety issues necessary for the safe and secure storage, possession, and use of licensed materials. These documents include standard review plans, checklists, and licensing guides.

They address:

- Assessment of the applicant's facilities and safety equipment, training and experience in the use of the materials for the purpose requested, and proposed managerial controls;
- Security requirements for radioactive materials in quantities of concern, including requirements for pre-licensing site visits 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;
- Information exchange between the program's inspection staff and licensing staff; and
- The specific required qualification of license reviewers within the staff qualification plan.

They also provide guidance for the evaluation of technical issues in license applications including places and conditions of storage, places and conditions of use, and decommissioning of facilities and equipment. In addition, the procedures address environmental considerations, security against unauthorized removal, and safety equipment. They address the qualification of users, licensee operating and emergency procedures, appropriate surveys, personnel monitoring under the close supervision of technically qualified individuals, and preparations for transport. 10 CFR 35.1000 Emerging Technology issues are addressed by utilizing the guidance provided on the NRC's "Medical Uses Licensee Toolkit" at https://www.nrc.gov/materials/miau/med-use-toolkit.html .

Procedures that address license fees, license file maintenance, and other materials program administrative issues are found in Sections 4.3.5 and 4.3.6.

The U.S. Nuclear Regulatory Commission's (NRC) NUREG-1556 Series documents are used by Vermont Department of Health License Reviewers and Inspectors. The NUREG-1556 Series Volumes provide detailed instructions and examples for licensees and applicants in the preparation of their radioactive materials applications.

All administrative licensing actions are to be performed with the guidance contained in NUREG-1556 Volume 20 "Guidance About Administrative Licensing Procedures," and the Vermont Radioactive Materials Program Procedures (RMPPs) 1.1-1.4 and 4.1.

A tabulation of the applicable NUREG-1556 Volumes is provided below in Table 4.3-1

TABLE 4.3-1 NUREG-1556 VOLUMES

NOTE: The most up-to-date volumes can be found at: https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/

Volume No.	Volume Title
1	Program-Specific Guidance About Portable Gauge Licenses https://www.nrc.gov/docs/ML1617/ML16175A375.pdf
2	Program-Specific Guidance About Industrial Radiography Licenses https://www.nrc.gov/docs/ML1606/ML16062A091.pdf
4	Program-Specific Guidance About Fixed Gauge Licenses https://www.nrc.gov/docs/ML1618/ML16188A048.pdf
5	Program-Specific Guidance About Self-Shielded Irradiator Licenses https://www.nrc.gov/docs/ML1817/ML18176A007.pdf
7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Electron Capture Devices and X-Ray Fluorescence Analyzers https://www.nrc.gov/docs/ML1806/ML18065A006.pdf
9	Program-Specific Guidance About Medical Use Licenses https://www.nrc.gov/docs/ML1632/ML16328A214.pdf
11	Program-Specific Guidance About Licenses of Broad Scope https://www.nrc.gov/docs/ML1705/ML17059D332.pdf
12	Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution https://www.nrc.gov/docs/ML1813/ML18136A704.pdf
13	Program-Specific Guidance About Commercial Radiopharmacy Licenses https://www.nrc.gov/docs/ML1635/ML16356A040.pdf
14	Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v14/
15	Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses https://www.nrc.gov/docs/ML1618/ML16181A003.pdf
16	Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees https://www.nrc.gov/docs/ML1618/ML16181A003.pdf
17	Program-Specific Guidance About Special Nuclear Material of Less Than Critical Mass Licenses https://www.nrc.gov/docs/ML1819/ML18190A207.pdf
18	Program-Specific Guidance About Service Provider Licenses https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v18/
19	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 State Jurisdiction (Reciprocity) https://www.nrc.gov/docs/ML1617/ML16175A107.pdf
20	Program-Specific Guidance About Administrative Licensing Procedures https://www.nrc.gov/docs/ML0102/ML010250252.pdf
21	Program-Specific Guidance About Possession Licenses for Production of Radioactive Materials Using an Accelerator https://www.nrc.gov/docs/ML1814/ML18143A670.pdf

The NUREG-1556 Series documents contain directions for applicants and licensees on forms used to apply for a license, an amendment or renewal to an existing license, and communications with the Department. Table 4.3-2 provides the forms necessary when applying for a radioactive materials license. The forms and communications are to be sent to:

Vermont Department of Health Contact Information:

Telephone: **802-863-7280**

Email address: **Envhealth@vermont.gov**

Mailing Address: **108 Cherry Street Suite 201, P.O. Box 70, Burlington Vermont 05401**

Attn: **Radioactive Materials Program**

Table 4.3-2 NRC and Department Forms

NRC Form	Department Form	Purpose
313	313	Application for a Radioactive Materials License
313A (RSO)	313A (RSO)	Radiation Safety Officer (Preceptor Attestation)
313A (AMP)	313A (AMP)	Authorized Medical Physicists (Preceptor Attestation)
313A (ANP)	313A (ANP)	Authorized Nuclear Pharmacist (Preceptor Attestation)
313A (AUD)	313A (AUD)	Authorized User-Diagnostic (Preceptor Attestation) No WD
313A (AUS)	313A (AUS)	Authorized User Therapy (Preceptor Attestation)
313A (AUT)	313A (AUT)	Authorized User Written Directive Required (Preceptor Attestation)
314	314	Disposition of Materials
3	3	Notice to Employees
4	4	Cumulative Occupational Dose History
5	5	Occupational Dose Records for a Monitoring Period
241	241	Reciprocity Application

4.3.2 Procedures for the Evaluation of Radiation Safety Information on Sealed Sources or Devices and Registration for Distribution – Not Applicable

The State of Vermont is not applying for authority to regulate the evaluation of radiation safety information on sealed sources or devices nor registration for distribution. As such, there are no procedures in this section of the application.

4.3.3 Procedures for Conducting the Technical Evaluation of a Proposed License for a Low-Level Radioactive Waste Land Disposal Site – Not Applicable

The State of Vermont is not applying for regulatory authority to conduct the technical evaluation of a proposed license for a low-level radioactive waste land disposal site. As such, there are no procedures in this section of the application.

4.3.4 Procedure for Conducting the Evaluation of a Regulatory Program for 11e.(2) Byproduct Material Including Uranium or Thorium Mining Facilities

The State of Vermont is not applying for authority to conduct the evaluation of a regulatory program for 11e.(2) byproduct material including uranium or thorium mining facilities. As such, there are no procedures in this section of the application.

4.3.5 Procedures for Assuring the Technical Quality of Licenses

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

4.3.6 Administrative Licensing Procedures

Administrative licensing procedures describe the administrative processing steps useful to assure all procedural requirements are completed in licensing activities. There are six administrative procedures for licensing: RMPP 1.1 *Review of Initial Application for License or an Amendment Request*, RMPP 1.2 *Renewal of Licenses*, RMPP 1.3 *License Termination/Revocation*, RMPP 1.4 *NRC Licenses Affected by Agreement States*, and RMPP 4.1 *Renewal Notices, Receipt, and Tracking of Licensing Actions*. Copies of the procedures follow in this order.

Vermont Department of Health Radioactive Materials Program

Radioactive Materials Program Procedure 1.1, Revision 0

Review of an Initial Application for License or an Amendment Request

Prepared By: _____ **Date:** _____

Reviewed By: _____ **Date:** _____

Approved By: _____ **Date:** _____

Effective Date: _____

Revision	Date	Description of Changes
0		

Radioactive Materials Program Procedure 1.1, Revision 0

Review of an Initial Application for License or an Amendment Request

Table of Contents

*** These are maintained separately as Security-Related Materials**

1.0 PURPOSE

1.1 Applicability

1.1.1 The purpose of this procedure is to define the process for reviewing all types of specific license requests and license amendments (refer to Attachment 1.1-6 for Program Codes for each license type) received by the Vermont Department of Health (Department) and those transferred to the Department from the Nuclear Regulatory Commission (NRC). Applications for license renewal are covered by RMPP 1.2 *Renewal of Licenses* and license termination is covered by RMPP 1.3 *License Termination/Revocation*.

1.1.2 Appropriate NUREG-1556 checklists and procedures that shall be used during the review process will be identified.

1.1.3 The process for issuing a specific license or an amendment to a license and standard license conditions will be provided after a thorough and equitable evaluation of the application.

1.1.4 The process for denying (state's initiative) or abandoning (applicant's or state's initiative) a request for licensing action shall be defined.

1.1.5 This procedure does not address the qualifications required to review a specific license of each type; refer to RMPP 5.1 *Qualifications and Training* for these guidelines. For this procedure, qualification of the license reviewer for a specific license type is verified by the Radiation Control Program Director prior to determining the reviewer.

1.2 References

1.2.1 Vermont Radioactive Materials Rule.

1.2.2 NUREG-1556, "Consolidated Guidance About Materials Licenses".

1.2.3 Title 10 of the Code of Federal Regulations (10 CFR).

1.3 Files

The following records will be maintained by the Radioactive Materials Program, primarily in an electronic format for each licensee:

1.3.1 Specific License.

1.3.2 License Application and/or Amendment Request Submittal.

1.3.3 Any Deficiency Letters.

1.3.4 License Transmittal Letter.

1.3.5 Any Requests for Additional Information (RAI).

1.4 Definitions

1.4.1 Agency: The Radioactive Materials Program (RMP) of the Vermont Department of Health (Department).

1.4.2 Amendment (License Amendment): Any change to any of the content of a radioactive materials license once issued by the Department constitutes an amendment.

1.4.3 Application Request: A request for an application for a license from a prospective applicant on VDH Form 313.

1.4.4 Denying with Prejudice: Denial on the basis that the applicant for license is not qualified and shall not reapply for a license unless there has been a material change to the circumstances and substance of the license application, e.g., a minor applying for a license to possess and use radioactive material or a non-medical qualified individual applying for a license to use radioactive material in the diagnosis and/or treatment of humans will have their licenses denied with prejudice and may only reapply if and when the applicants meet the age and medical qualifications, respectively.

1.4.5 Denying Without Prejudice: Denial on the basis that the application for license was deficient and denied, but that the applicant may reapply after correcting the deficiencies.

1.4.6 License Review: The processing of any licensing action (i.e., new application, amendment, renewal, termination) and serves two capacities – primary review and secondary review.

1.4.7 License Reviewer: A Radiologic Health Specialist or other Radioactive Materials Program staff member qualified to review, process, and document a specific category of licensing action. A license reviewer shall not perform a review for any category of license for which they are not qualified.

1.4.8 Licensing Action: A request or application received from an applicant or a licensee as follows:

An application for a license to receive, possess, and use licensed material;

An application for renewal of a license;

An amendment request to a license, e.g., change in administrations, authorized use, and/or user(s), Radiation Safety Officer (RSO), quantity of material, isotopes, facilities, etc.; and/or,

A request for termination of a license.

1.4.9 Manufacturing and Distribution (M&D): Refers to licenses for manufacturing and distribution of byproduct, source, and/or special nuclear material.

1.4.10 Possession Only License: A license issued by the Vermont Department of Health that authorizes the licensee to possess specific radioactive material but does not authorize its use. A possession only license is issued for a licensee that has ceased principal operations which used radioactive material and has begun or is preparing to decommission its storage and usage facilities and dispose of, or transfer remaining radioactive material to an authorized recipient, or as shielding material (depleted uranium) used for medical therapy linear accelerators and technetium-molybdenum generators.

1.4.11 Primary Review: A primary review is that conducted initially for a licensing action by a qualified license reviewer. It is conducted using RMPP 1.1, other relevant RMPPs, and relevant content from NUREG 1556 and is documented on the **License Review Job Aid**.

1.4.12 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 of 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.

1.4.13 Pre-Licensing Site Visit: A site visit and face-to-face meeting with an entity with the purpose of providing 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 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.

1.4.14 Regulatory Guide: Guidance published by the NRC or the Department Radioactive Materials Program, in which each guide defines an acceptable program or part of a program, for the possession and specific use of radioactive materials. An applicant is not obligated to follow one of these guidance documents when developing their program and applying for a license or amendment; however, if not followed, the applicant must demonstrate that the proposed program is at least equivalent to the one described in the guidance document.

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

1.4.16 Secondary Review: A secondary review is conducted by a qualified license reviewer as a quality control activity. It is meant to assure the license review conducted by the primary reviewer is complete and accurate. The secondary reviewer must be a qualified license reviewer other than the person conducting the primary review. It is done using RMPP 1.1, other RMPPs as appropriate, and applicable guidance from NUREG 1556. It is documented using the **License Review Job Aid**.

1.4.17 Supervisory Review: This is the final required review of licensing activity.

1.4.18 Tie-down: A license commitment that is additional to the standard license conditions stated on the license.

1.4.19 *Written Directive: An* authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in 10 CFR 35.40.

2.0 RESPONSIBILITIES

2.1 Radiological Health Specialist (RHS)

2.1.1 May serve as primary reviewer of license applications and amendments for licenses for which qualified. Through review, the RHS receives, logs, and saves licensing action information and makes requests for additional information from the applicant/licensee.

2.1.2 May also serve as secondary reviewer, though not for license applications and amendments for which the RHS was primary reviewer.

2.1.3 Maintains the computer-based and other files and tracks the application for a license during processing.

2.1.4 Responds to requests for license applications and amendments by transmitting an application (Department Form 313), internet address of the regulations, and a copy of, or reference to, specific guidance within 30 days of the licensing actions.

2.1.5 Reviews the application or amendment, determines if it is complete, requests additional information as needed, and prepares the license or amendment for secondary review and license or amendment approval by the Radiation Control Program Director (RCPD) or designee.

2.1.6 The suggested time to complete all licensing actions (i.e., new license applications and existing license amendments, renewals, and terminations is):

Priority	Goal Time Increment	Licensing Action
R - Rush	As Soon As Possible	Assigned by RMPM License Termination License Expiration
H - High	90 days	New RSO New Authorized User New Use* Possible Violations
M - Medium	180 days	Initial License Renewal - In Entirety New Equipment New Change Practice
L - Low	180 days	Delete AU or RSO Delete Use, Isotopes, Place of Use*

2.1.7 Recommends whether an application is deficient and should be denied either with or without prejudice.

2.1.8 Provides findings during the primary or secondary review of license applications and amendments to the Radioactive Materials Program Manager or RCPD as appropriate.

2.2 Radioactive Materials Program Manager (RMPM)

2.2.1 Generally manages the Radioactive Materials Program and for license applications and amendments, assigns the licensing actions to a qualified Radiological Health Specialist. This responsibility can be designated if necessary to the RCPD.

2.2.2 May perform primary or secondary reviews of license applications and amendments.

2.2.3 May initiate consultation with and seek concurrence of the Department of Health Legal Division on license application or amendment denials, with or without prejudice.

2.2.4 The responsibilities of the RMPM may be designated to the RCPD in the RMPM's absence.

2.3 Radiation Control Program Director (RCPD)

2.3.1 Approves and signs licenses and license amendments. This responsibility may be designated to the RMPM in the absence of the RCPD.

2.3.2 May perform secondary license reviews if qualified as a license reviewer for the license type.

2.3.3 The responsibilities of the RCPD relative to the Radioactive Materials Program may be designated to the RMPM in the absence of the RCPD.

3.0 PROCEDURE

3.1 Receipt of a License Application or Request for a License Amendment

Upon receipt of an application for license or a request for a license amendment the following shall be performed:

3.1.1 Timeliness of review - Within 30 days of receipt of a request for a licensing action, the Department should perform an acceptance review of the licensing request and take the following actions:

3.1.1.1 Issue an acknowledgement of receipt within 30 working days of the receipt and make an entry for such in Web-Based Licensing (WBL).

3.1.1.2 Confirm that all necessary sections of the application (Department Form 313) are completed and the form has been signed by the applicant's certifying official.

3.1.1.3 Confirm that attachments identified by the applicant are included in the submittal.

3.1.1.4 Identify any requests for expedited review for safety-significant concerns (e.g., change in the Radiation Safety Officer or amendment requests resulting from identification of safety-significant violations) or business reasons (e.g., change of ownership).

3.1.2 After the acceptance review, send the applicant an acknowledgement letter that the license is under review and, if applicable, the current license will remain in effect until the licensing action is complete.

3.1.3 Note any administrative deficiencies or omissions that were identified during the primary review that could delay the technical review of the licensee's action.

3.1.4 Once issues and deficiencies have been identified in an application, the license reviewer should use the most efficient process available to fully communicate issues to

the licensee. The reviewer should use the telephone, facsimile, or e-mail to communicate with licensees, thereby reducing reliance on formal letters.

3.1.5 Ensure that each requested item for additional information is clear (i.e., provide a description of the deficiency and a statement of what is needed); is essential to protect safety; and is limited to Department regulatory requirements and NUREG-1556 and other guidance.

3.1.6 Any significant or complex deficiencies in an application for either a new license or license amendment should be described in a deficiency letter to the applicant. Deficiency letters can be sent by regular mail, e-mail, or facsimile. The letter to the applicant should contain a statement that specifies that the Department will assume the applicant does not intend to pursue its application if the Department does not receive a reply within 30 calendar days from the date of the letter.

3.1.7 If a response to the deficiency letter is received within 35 calendar days from the date of the letter, proceed with review of the response.

3.1.8 If a response to the deficiency letter is not received within 35 calendar days from the date of the letter, the application can be considered abandoned for failure to provide the requested information. This abandonment is without prejudice to the resubmission of the application. Prompt action (5 working days) should be taken to void the application. The voiding of this application should be closely coordinated with the Department of Health Legal Division.

3.1.9 Inform the applicant or licensee that the technical review may identify additional omissions in the submittal and technical issues that require additional information.

3.1.10 Provide the applicant or licensee with an estimated time for completion of the licensing action. These are only estimates based on the specific type of licensing action. The estimated time for completion should account for any expedited review.

3.1.11 Inform the applicants that they are subject to Department licensing fees as outlined in **VDH Form 313** (Attachment 1.1-1.7).

3.1.12 Priority: An action priority shall be assigned to the application or request in accordance with the priority schedule here in RMPP 1.1 and with the concurrence of the RMPM.

3.1.13 Assignment of Reviewer: The processing and review of an application or amendment request shall be assigned to a Radiological Health Specialist qualified to conduct such a review.

3.1.14 Follow-Up on Mail Returned from Licensees: Mail that is returned to the Department may indicate several problems, ranging from clerical errors to the loss of control of licensed material. The steps below must be followed in such situations:

- Mail returned to the Department as undeliverable should be checked to ensure that the address is the same as on the application/license.

- Any pending application related to the license should be checked for the correct mailing address.

- For mail returned to the Department for any reason other than a Department clerical error, the procedure will be the same as for an expired license (RMPP 1.3).

- When the licensee cannot be located, send a certified letter to the address in the licensee file requesting clarification.

- Determine if the applicant has made any deliveries or has made any shipments of radioactive materials.

- **Under no circumstance will a license be issued if the location of use and mailing address is incorrect.**

  As with new licensees, applicants requesting quantities of radioactive materials in excess of 10 CFR 37 Appendix A Category 1 and Category 2 quantities, shall have an initial inspection within one year of the application issue date. The first inspection date is entered in WBL and the licensee file as a reminder.

3.2 Processing an Application for License

3.2.1 The application and all appended and referenced material shall be reviewed. State of Vermont rules, policies, procedures, NUREG-1556 applicable volumes, and applicable parts of 10 CFR shall be used, as appropriate, by the reviewer to evaluate the applicant and the application.

3.2.1.1 The **Pre-Licensing Checklist** (Attachment 1.1-1) shall be used on all new license applications as well as transfer of control (change of ownership) applications. *Note that change of ownership or transfer of control is generally considered a new application unless the entities are well known as would be the case if one medical licensee assumes ownership of or merges with another medical licensee.* Once completed, the checklist must be placed in the licensing folder with the license.

3.2.1.2 A checklist to address requests for **Risk-Significant Radioactive Material** (Attachment 1.1-2) must also be completed and placed in the licensing folder.

3.2.2 If additional information is needed, a Request for Additional Information (RAI) should be used. If the RAI is not addressed as necessary, a meeting with the applicant and/or a visit to the proposed facility(s) must be completed by the reviewer.

3.2.3 The reviewer shall use the **Licensing Job Aid** (Attachment 1.1-4) to verify all aspects of the licensing review have been completed and ensure that the review of the application includes the following commonly missed items:

- Application signed by upper management;
- Facility diagrams or sketches, including but not limited to, hoods, shielding, ventilation, work areas, storage areas, location of nearest occupied area, and physical security of radioactive material;
- Number, type, and range of survey instruments including procedures for calibration, checks for operability, and maintenance;
- Training and experience records for all Authorized Users (AUs);
- Preceptor and attestation statements for all new AUs, RSOs, and Authorized Medical Physicists (AMPs);
- Training and experience records, duties, responsibilities, and the availability of the RSO;
- Training and experience records for the Radiation Safety Committee Chair, if appropriate;
- Records to be retained and responsibility for records retention assigned;
- Frequently missed records include training for new employees, annual refresher training, survey instrument calibrations and source checks, and dose calibrator constancy, accuracy, linearity, and geometric variation checks for medical licenses;
- Procedures for receipt of radioactive material, especially to include off-hours and weekends.

3.2.4 Following this primary review, a secondary review will be conducted for quality assurance purposes by a qualified license reviewer other than the person doing the primary review.

3.2.5 The secondary review must also be conducted using the Licensing Job Aid and include a thorough evaluation of the completeness and accuracy of the licensing action file contents including the Pre-licensing Checklist and the Risk-Significant Radioactive Materials Checklist.

3.2.6 Upon completion of the primary and secondary review of the application and any supplemental material requested by the reviewer, a recommendation to issue a license or deny the application shall be made to the RCPD who will conduct the Administrative Qualitative Checklist and approve or deny the license application or amendment.

3.2.7 If the RCPD approves issuance of the license or license amendment, the prepared license will be signed by the RCPD or designee.

3.2.8 All submitted and referenced information shall be tied-down. A tie-down license condition is used for procedures, radiation detection equipment, use locations, etc., that are not already specifically identified on the license.

3.2.9 If the recommendation is to deny the application and the Department of Health Legal Division concurs, the primary reviewer, RMPM or RCPD, in concert with the Department of Health Legal Division shall prepare a notification to the applicant. The notification shall state the reason for denial and if a new application would be accepted from the applicant.

3.3 Pre-licensing Site Visit

3.3.1 The purpose of a Pre-licensing site visit is to establish a basis for confidence that radioactive materials will be used as specified.

3.3.2 Pre-licensing site visits are conducted for new entities that do not have an existing NRC or Agreement State license, licensees changing ownership to an unknown entity, or licensees that are significantly expanding the size or scope of their existing license. They are also used 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** (Attachment 1.1-1).

3.3.3 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.

3.4 Processing a Request for License Amendment

3.4.1 A request for an amendment to a specific license must be submitted using Department Form 313. The request should be accompanied with a letter on company letterhead plus attachments. The request shall be signed by the individual in the position,

or higher, that signed the application for license or the request shall be returned for proper signature. Alternatively, the licensing action request may be signed by an individual delegated by the person who signed the application or higher.

3.4.2 The primary review of the request for amendment shall determine if the request is so broad that it should be processed as a rewrite of the current license or as a new license. If it is determined that either a rewrite or a new license is appropriate and the RMPM concurs, the request shall be returned to the licensee and an appropriate application shall be requested.

3.4.3 A request from a medical licensee to add a qualified Authorized User to their license shall be accompanied by records of the individual's training and qualifications. Records of training shall be signed by the preceptor and shall not be just a letter stating that these procedures had been performed at another licensed facility.

3.4.4 A request to add an Authorized User to a license shall be accompanied by records of the individual's training and qualifications, especially as related to the AU's uses of radioactive materials.

3.4.5 A request to delete an Authorized User must require an evaluation to determine that the authorized material and uses are approved for other Authorized Users on the license.

3.4.6 A request to add or replace a Radiation Safety Officer (RSO) or Chair of the Radiation Safety Committee (RSC) shall include training and experience records and duties, responsibilities, and if appropriate, availability and delegation of authority.

3.4.7 A request to add isotopes, quantities, physical form, use, facilities, instrumentation, or the authorized place of use shall be reviewed in the same way as a request for a partial specific license for that activity.

3.4.8 A checklist to address requests for **Risk-Significant Radioactive Material**, (Attachment 1.1-2), must also be completed when the amendment includes any radioisotope listed in the Risk-Significant Radioactive Material Table in Attachment 1.1-2 and the checklist must be placed in the licensing folder.

3.4.9 As with new license applications, license renewals, and license terminations, a secondary review must be conducted and documented using the **Licensing Job Aid** (Attachment 1.1-4).

3.4.10 A license is normally amended in its entirety and includes new tie-down license conditions as appropriate. The RCPD shall sign to approve the amendment.

3.5 Processing a Request for Possession Only License (License Termination)

3.5.1 A Possession Only License is a license issued that authorizes the licensee to possess specific radioactive material but does not authorize its use. A Possession Only License is issued for a licensee that has ceased principal operations using radioactive material and has begun or is preparing to decommission its storage and usage facilities and dispose of or transfer the remaining radioactive material to an authorized recipient. It may also be issued for shielding material (depleted uranium) used for medical therapy linear accelerators and technetium-molybdenum generators.

3.5.2 If a licensee requests that its license be converted to possession-only status, determine whether the licensee has permanently ceased operations. If the licensee has permanently ceased operations, the licensee is required to begin decommissioning pursuant to 10 CFR 30.36(d), 40.42(d), and 70.38(d). Determine whether the licensee can proceed with decommissioning.

3.5.2 If the licensee can proceed with decommissioning, instruct the licensee to proceed with decommissioning and license termination. Do not amend the license to authorize possession only. If the expiration date has not passed, the license should be amended to limit activities to decommissioning only. (Expired licenses do not need to be amended because by rule, decommissioning is the only activity authorized.) If decommissioning is the only activity authorized, change the program code to DECOMMISSIONING.

> NOTE: Reviewers should coordinate with inspection and decommissioning staff concerning site reviews and inspection activities before the program code is changed.

3.5.3 If the licensee cannot proceed with decommissioning (e.g., demonstrates that all reasonable options for radioactive waste disposal have been exhausted), review the licensee's application using the checklist in Enclosure (1) from NRC'S Policy and Guidance Directive PG 1-27 "Reviewing Requests to Convert Active Licenses to Possession-Only Licenses." When each item on the checklist has been adequately addressed, issue a possession-only license and change the program code to POSSESSION-ONLY: PERMANENT. Change the authorized use condition in the license to read, "Possession and storage only until termination of the license." The license should have a two-year expiration date and may be renewed if the licensee continues to demonstrate that it cannot divest itself of the radioactive material, although it has taken all reasonable actions within its ability to dispose of the material.

3.6 Handling of Information

3.6.1 A reviewer may receive information from an applicant or licensee that is marked as "proprietary," "confidential," "restricted," or "is the express property of Company X." The reviewer will need to determine whether the information is necessary to the licensing action. If the information is not necessary, it should be returned to the applicant. If the information is necessary, the reviewer needs to ensure that the applicant has submitted a formal request for withholding the information (Attachment 1.1-3 **Checklist for Requests to Withhold Information from Public Disclosure**). The reviewer evaluates

the applicant's request for withholding the information. If the request is denied, in whole or in part, the applicant is given the option of withdrawing the information or application. If the applicant decides not to withdraw the information or application, the reviewer notifies the applicant in writing that the request for withholding information from the public has been denied and that the reviewer will disregard any references concerning the proprietary status of the information.

Documents that contain personally identifiable information, security-related confidential information, and/or proprietary information should be protected from public disclosure. Licensees and other entities should have sufficient internal controls to prevent release of information to limit the risk that personal, confidential, and proprietary information could be released to someone with malevolent intent. Methods to prevent the inadvertent release of confidential information include (1) restricting access to electronic recordkeeping systems that contain such information, (2) controlling the reproduction, distribution, and destruction of potentially confidential records, and (3) releasing confidential information only to those individuals who have a need to know the information to perform their jobs and who are made aware of the security-related nature of the information.

3.6.2 If the information is necessary, the reviewer needs to ensure that the applicant has submitted a formal request for withholding the information in accordance with 1 V.S.A. § 317 that includes the following guidance:

3.6.2.1 The applicant shall request withholding at the time the document is submitted and shall comply with the document marking and affidavit requirements set forth below. The Department has no obligation to review documents not so marked to determine whether they contain information eligible for withholding.

3.6.2.2 The applicant shall ensure that the document containing information sought to be withheld is marked as follows:

- The first page of the document, and each successive page containing such information, must be marked to be readily visible, at the top, or by electronic watermark or other suitable marking on the body of the page, with language substantially similar to: "confidential information submitted under 1 V.S.A. § 317", "withhold from public disclosure under 1 V.S.A. § 317", or "proprietary", to indicate that it contains information the applicant seeks to have withheld.

- Each document or page, as appropriate, containing information sought to be withheld from public disclosure must indicate, adjacent to the information, the basis (*i.e.,* trade secret, personal privacy, etc.) for proposing that the information be withheld from public disclosure under paragraph 3.6.2 of this section.

3.6.2.3 The Department may waive the affidavit requirements on request, or on its own initiative, or in circumstances when the Department, in its discretion, deems it appropriate. Otherwise, except for personal privacy information, which is not subject to the affidavit requirement, the request for withholding must be accompanied by an affidavit that:

- Identifies the document or part sought to be withheld;
- Identifies the official position of the person making the affidavit;
- Declares the basis for proposing the information withheld, encompassing considerations set forth in 1 V.S.A. § 317;
- Includes a specific statement of the harm that would result if the information sought to be withheld is disclosed to the public; and
- Indicates the location(s) in the document of all information sought to be withheld.

3.6.2.4 Any part of the application that the reviewer has determined should be withheld from public disclosure should be handled in accordance with 3 V.S.A. § (c) (25) and the applicant should be notified in writing that the Department plans to honor the request; however, the notification needs to inform the applicant that the Department may have cause to review the determination in the future, for example, if the scope of a records request is in accordance with Vermont's Access to Public Records and Documents law 3 V.S.A. §§ 315-317.

3.7 Assuring the Technical Quality of Licensing Actions

3.7.1 All license applications, license amendments, license renewals, and license terminations shall be provided a primary, secondary, and supervisory review prior to the licensing action being signed and approved utilizing the **License Review Job Aid** for the primary and secondary review and the **Administrative Qualitative Checklist** for supervisory review (Attachments 1.1-4 and 1.1-5).

3.7.2 Upon completion of the primary review, the primary license reviewer will notify the Radioactive Materials Program Manager for secondary review assignment. This may be assigned to any qualified radioactive materials program license reviewer. The secondary review will utilize Attachment 1.1-4 **License Review Job Aid**.

3.7.3 License reviewers should compare similar Vermont radioactive materials licenses as a means to provide an additional quality check to ensure completeness.

3.7.4 The final review to assure the technical quality of licensing actions is the supervisory review. It is conducted by the Radiation Control Program Director before signing and approving the licensing action.

4.0 RECORDS

4.1 Records to be Maintained

4.1.1 Applications for license plus attachments are kept in the license file and are maintained by the Radioactive Materials Program Staff in a secure electronic environment accessible to Vermont Department of Health Radioactive Materials Program personnel only.

4.1.2 Requests for amendments are maintained in the appropriate specific 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 1.1

1.1-1 Pre-Licensing Checklist*****

1.1-2 Risk-Significant Radioactive Material Checklist*

1.1-3 Checklist for Requests to Withhold Information from Public Disclosure

1.1-4 License Review Job Aid

1.1-5 Administrative Qualitative Checklist

1.1-6 Program Codes

1.1-7 Department Form 313 Application for Radioactive Materials License

*** These are maintained separately as Security-Related Materials**

Vermont Department of Health Radioactive Materials Program
Attachment 1.1-1 to RMPP 1.1, Revision 0:
Pre-Licensing Checklist

PRE-LICENSING GUIDANCE

This document is maintained separately as security-related materials

Vermont Department of Health Radioactive Materials Program

ATTACHMENT 1.1-2 TO RMPP 1.1

RISK-SIGNIFICANT RADIOACTIVE MATERIAL CHECKLIST

This document is maintained separately as security-related materials

Vermont Department of Health Radioactive Materials Program

ATTACHMENT 1.1-3 TO RMPP 1.1

CHECKLIST FOR REQUESTS TO WITHHOLD INFORMATION FROM PUBLIC DISCLOSURE

Name:	License Number:
To request that the Department withhold information contained in an application from public disclosure, the applicant must submit the information and application, including an affidavit, in accordance with 1 V.S.A. 317. The applicant should submit all the following:	
☐	**A proprietary copy of the information**. Brackets should be placed around the material considered to be proprietary. This copy should be marked as proprietary.
☐	**A non-proprietary copy of the information**. Applicants should white out or black out the proprietary portions (i.e. those in the brackets), leaving the non-proprietary portions intact. This copy should not be marked as proprietary.
☐	**An affidavit that:**
☐	Is notarized.
☐	Clearly identifies (such as by name or title and date) the document to be withheld.
☐	Clearly identifies the position of the person executing the affidavit. This person must be an officer or upper-level management official who has been delegated the function of reviewing the information sought to be withheld and authorized to apply for withholding on behalf of the company.
☐	States that the company submitting the information is the owner of the information or is required, by agreement with the owner of the information, to treat the information as proprietary.
☐	Provides a rational basis for holding the information in confidence.
☐	A letter that fully addresses the following issues:
☐	• Is the information submitted to, and received by, the Department in confidence? Provide details.
☐	• Does the applicant customarily treat this information, or this type of information, as confidential? Explain why.
☐	• Would public disclosure of the information be likely to cause substantial harm to the competitive position of the applicant? If so, explain why in detail. The explanation should include the value of the information to your company, amount of effort or money expended in developing the information, and the ease or difficulty of others to acquire the information.

Vermont Department of Health Radioactive Materials Program

ATTACHMENT 1.1-4 TO RMPP 1.1

License Review Job Aid

1. Review submittal within 30 days of receipt of application.

2. Review using applicable guidance to ensure the licensee submitted all required information from:

    a. NUREG-1556 Consolidated Guidance About Materials Licenses;
    b. NUREG-1757 Volume 1 & 2 Consolidated Decommissioning Guidance;
    c. NUREG-1757 Volume 3 for Financial Assurance, Recordkeeping, and Timeliness;
    d. RMPP 1.1-1.4 and RMPP 4.1; and
    e. NRC Medical License Toolkit https://www.nrc.gov/materials/miau/med-use-toolkit.html#et .

3. Determine if subject to:

    a. Financial Assurance;
    b. Emergency Plan;
    c. Environmental Assessment; or
    d. Change of Ownership (References: 10 CFR 30.34(b), 40.46, 70.25, and NUREG-1556 Volume 15 for change of ownership).

4. For amendments and renewals, compare with previous license and markup to show changes. Review licensee inspection/enforcement history.

5. For new licenses and change of ownership, ensure that the Pre-licensing Checklist has been completed.

6. For all license actions, ensure that the Risk Significant Radioactive Material (RSRM) Checklist has been completed.

7. Review list of escalated enforcement actions for licensees and individuals. Go to https://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/individuals/.

8. Review license tie downs and inspection documentation.

9. For license terminations:

    a. Account for all radioactive material and locations of use and/or storage;
    b. Confirm all materials have been properly transferred or disposed, that a thoroughly documented survey for the presence of radioactive materials (contamination or radiation) has been performed, and the site can be released for unrestricted use;
    c. Determine if any incidents (spills/contamination) have occurred and the records of remediation and/or disposition of the radioactive materials (Department Form 314) are completed if applicable; and
    d. Ensure licensee has submitted records in accordance with 10 CFR 30.36(k)(4), 40.61, and 70.51.

10. Notify the Radiation Control Program Director immediately with concerns and/or violations identified during the review.

11. Ensure completed Department forms are included and signed by licensee management:

    a. Department form 313 – New Licenses (required);
    b. Department form 313 – License Renewal (or equivalent); and
    c. Department form 314 – License Termination (or equivalent).

12. Ensure that sealed source model numbers are registered.

13. Complete security related information and mark as appropriate.

14. Obtain second reviewer concurrence.

15. Ensure the document will be properly delivered through the mail.

16. Draft license following license generation forms and compare with sample licenses.

17. Update license expiration date on license.

18. Confirm proper program code and inspection priority.

19. Draft cover letter and print letter and license.

20. Use Administrative Quality Checklist for Licensing Actions for QA/QC review of letter and license.

Administrative Qualitative Checklist

1. Spell check has been run. Spelling of names on cover letter and license are consistent.

2. Issue date on the license and cover letter match.

3. Cover letter and license contain proper "Official Use Only- Security Related Information (OUO-SRI)" banner, as required.

4. Mailing address identified on cover letter matches address in item 2 of the license.

5. License contains correct page numbers and amendment number. All initial licenses will be Amendment 0.

6. License conditions are correctly numbered on the license.

7. Document(s) are added to the tie-down conditions of the license, such as licensee commitments. Dates for all licensee commitments are correctly referenced in the tie down conditions of the license.

8. Cover letter has the correct license numbers, date specified, and signatures.

9. Licensing worksheets (checklists) are completed prior to Web Based Licensing processing. All electronic signatures (reviewer and supervisor) are completed.

10. All information on the Web Based Licensing (WBL) worksheet is filled out and correct (Program Codes, Contact, RSO, Address, etc.….).

11. Error reduction techniques are utilized, such as: re-read/proof read/secondary review after printing which ensures that the printed license matches the screen and is appropriate prior to mailing the license.

Vermont Department of Health Radioactive Materials Program

ATTACHMENT 1.1-6 to RMPP 1.1

Inspection Priority Codes Assigned to Program Codes

From US NRC Inspection Manual 2800 Enclosure 1

Enclosure 1 - Inspection Priority Codes Assigned To Program Codes

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
01000	Vary[2]	RSRM Licensee	Licensee subject to ICs or Security Order requirements
01100	3	Academic Type A Broad	Radiation Safety Committee (RSC)-approved users;33.13
01110	5	Academic Type B Broad	Radiation Safety Officer (RSO)-approved users; 33.14
01120	5	Academic Type C Broad	Authorized Users specifically named in the license; 33.15
02110	2	Medical Institution Broad	RSC-approved users for possession and use of a wide range of radionuclides in medical research, diagnosis, and therapy and research and development.
02120	3	Medical Institution–Written Directive (WD) Required	Used as primary code and may be used with the secondary codes for research and development, as appropriate. Used as secondary code when the license also authorizes certain medical therapy modalities.
02121	5	Medical Institution–WD Not Required	Used as primary code *only* for diagnostic nuclear medicine and diagnostic types of use under 35.1000.
02200	3	Medical Private Practice–WD Required	[Same remark as 02120]
02201	5	Medical Private Practice–WD Not Required	[Same remark as 02121]
02210	3	Eye Applicators Strontium-90 (Sr-90)	Institution or Private Practice
02220	3	Mobile Medical Service–WD Not Required	Use as a primary code if the license authorizes the mobile service *only*. Use as a secondary code if the license authorizes medical use at a central facility (i.e., institution or private practice facility) in addition to the mobile service.
02230	2	High-Dose Rate Remote After loader (HDR)	Use as a primary code.

[2] The Priority Code for the Security-Related Inspection varies depending on the Priority Code of the associated Program Code for health and safety inspections. The security-related inspection interval shall be the same as the health and safety interval for the related materials program category.

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
02231	2	Mobile Medical Service–WD Required	Use as a primary code. Includes mobile HDR and non-HDR modalities under 10 CFR Part 35
02240	2	Medical Therapy–Other Emerging Technology	Medical therapy modalities used under 10 CFR 35.1000, i.e., liquid sources, microspheres, and intravascular brachytherapy devices.
02300	5	Teletherapy	Treatment of human subjects only
02310	2	Gamma Stereotactic Radiosurgery (GSR)	Treatment of human subjects *only*
02400	5	Veterinary–Nonhuman Subjects	Routine diagnosis or therapy on animals. No animal research.
02410	5	*In-Vitro* Testing Laboratories	Licenses are issued to individuals or facilities which are not included in larger programs described by Program Codes 02110 or 02120.
02500	2	Nuclear Pharmacies	Receive bulk material used to prepare single use dosages or multi-dose products which are distributed to authorized medical licensees. Sealed sources are re-distributed in the original packaging to authorized clients.
02511	5	Medical Product Distribution – 32.72 Prepared Radiopharmaceuticals	Distribution of prepared radiopharmaceuticals to authorized medical licensees.
02513	5	Medical Product Distribution – 32.74 Sources and Devices	Therapy sources, calibration and reference sources
02600	-[3]	Production of PET Radioactive Drugs – 30.32(j) (Secondary Code)	Used as secondary code to identify those entities that meet the criteria in 10 CFR 30.32(j). See primary code for inspection priority
02700	5	Radium-226 Luminous Products & Sources up to 10 Times 31.12(a)(4) & (5)	For luminous products containing Ra-226 authorized under 10 CFR 31.12
02710	3	Radium-226 Luminous Products & Sources Greater Than 10 Times 31.12(a)(4) & (5)	For luminous products containing Ra-226 authorized under 10 CFR 31.12
03110	3	Well Logging Byproduct and/or Special Nuclear Material (SNM) Tracer and Sealed Sources	Use of sealed or unsealed sources for exploration of oil, gas, or minerals in wells.

[3] Program Code 02600 is used only as a secondary code

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
03111	3	Well Logging Byproduct and/or SNM Sealed Sources Only	Exploration of oil, gas, or minerals in wells; study of subsurface potable aquifers.
03112	3	Well Logging Byproduct Only – Tracers Only	Exploration of oil, gas, or minerals in wells
03113	3	Field Flooding Studies	Injection of unsealed byproduct materials for tracing oil and gas reservoirs
03120	5	Measuring Systems Fixed Gauges	Non-portable gauges for measurement or control of material density, flow, level, thickness, or weight, etc.
03121	5	Measuring Systems Portable Gauges	Moisture/density gauges contain gamma and neutron sources used for measurements in soils, compacted soils and road surfacing materials.
03122	T[4]	Measuring Systems Analytical Instruments	i.e., x-ray fluorescence analyzers
03123	T	Measuring Systems Gas Chromatographs	Quality control testing of samples from industrial process and environmental conditions.
03124	T	Measuring Systems Other	instrument calibrators, Krypton-85 (Kr-85) leak detectors
03130	5	Inspection Systems	Fixed or mobile non-intrusive inspection systems
03210	2	Radionuclide Production Using an Accelerator	Covers activities that take place once radioactive materials are produced by the accelerator. It does not include the operation of the accelerator.
03211	2	Manufacturing and Distribution Broad – Type A	RSC-approved users under 10 CFR 33.13
03212	5	Manufacturing and Distribution Broad – Type B	RSO-approved users under10 CFR 33.14
03213	5	Manufacturing and Distribution Broad – Type C	Authorized Users specifically named in the license under 10 CFR 33.15
03214	5	Manufacturing and Distribution Other	Smaller firms that require a more restrictive license.
03215	3	Manufacture, Assembly, Disassembly, Repair of Products Containing Radium-226	For certain items and self-luminous products containing Ra-226 authorized under 10 CFR 31.12

[4] Priority T denotes a telephone contact made by an inspector to evaluate the radiation protection program for Program Codes 03122, 03123, 03124, 03220, 11210, 22130, 22160, and 22161. The telephone contact interval is 5 years.

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
03218	3	Nuclear Laundry	Cleaning of protective clothing contaminated with radioactive materials.
03219	3	Decontamination Services	Cleaning of scrap materials for authorized release for unrestricted use.
03220	T	Leak Test Service Only	Commercial service organizations provide leak test kits to clients, perform measurement of leak test samples from clients, and issue reports of leak test results.
03221	5	Instrument Calibration Services Only – Source Less Than Or Equal To 100 Curies	Commercial calibration service
03222	5	Instrument Calibration Services Only – Source Greater Than 100 Curies	Commercial calibration service
03225	5	Other Services – Source Less Than Or Equal To 100 Curies	Commercial servicing for industrial gauge, and HDR licensees
03226	2	Other Services – Source Greater Than 100 Curies	Commercial servicing for teletherapy, irradiators, and GSR units containing a total activity in the unit during servicing that is greater than 100 curies.
03231	2	Waste Disposal (Burial)	Commercial and non-commercial
03232	3	Waste Disposal Service Prepackaged Only	pick up, transfer, and storage; opening packages not authorized
03233	2	Waste Disposal Service Incineration	Commercial operation
03234	2	Waste Disposal Service Processing and/or Repackaging	receipt, open, compact, re-package, and transfer to authorized burial
03235	-[5]	Incineration, Non-Commercial	(Secondary Code)
03236	2	Waste Treatment Service (Other Than Compaction)	Includes multiple, complex physical and chemical waste treatment processes
03240	5	General License Distribution – 32.51	For fixed gauges authorized under 10 CFR 31.5
03241	5	General License Distribution – 32.53	For luminous aircraft safety devices authorized under 10 CFR 31.7
03242	5	General License Distribution – 32.57	For calibration and reference sources authorized under 10 CFR 31.8
03243	5	General License Distribution – 32.61	For ice detection devices authorized under 10 CFR 31.10

[5] Program Code 03235 is used only as a secondary code for certain licensees authorized to operate a noncommercial incinerator to dispose of radioactive waste

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
03244	5	General License Distribution – 32.71	For certain *in-vitro* clinical testing kits authorized under 10 CFR 31.11
03250	5	Exempt Distribution – 32.11: Exempt Concentrations and Items	For residual material in a product authorized under 10 CFR 30.14
03251	5	Exempt Distribution – 32.14: Certain Items	For manufactured products authorized under 10 CFR 30.15
03252	5	Exempt Distribution – 32.17: Resins	For synthetic plastic resins authorized under 10 CFR 30.16
03253	5	Exempt Distribution – 32.18: Small Quantities	For individual quantities authorized under 10 CFR 30.18
03254	5	Exempt Distribution – 32.22: Self-Luminous Products	For devices authorized under 10 CFR 30.19
03255	5	Exempt Distribution – 32.26: Smoke Detectors	For devices authorized under 10 CFR 30.20
03256	5	Exempt Distribution – 32.21 Carbon-14 Urea Capsules	For *in vivo* diagnostic use authorized under 10 CFR 30.21
03310	2	Industrial Radiography Fixed Location	Permanent radiographic installation (PRI) or designated field station. Use as secondary code, except when the license authorizes the PRI *only*.
03311	2	Industrial Diagnostic Systems	A sealed source used for diagnostic scanning at industrial sites
03320	1	Industrial Radiography Temporary Job Sites	Use as primary code for multiple temporary customer locations
03510	5	Irradiators Self Shielded Less Than Or Equal To 10,000 Curies	Not external beam
03511	5	Irradiators Other Less Than Or Equal To 10,000 Curies	Panoramic (in air or under water) units; includes converted teletherapy units
03520	5	Irradiators Self Shielded Greater Than 10,000 Curies	Not external beam
03521	2	Irradiators – Other Greater than 10,000 curies	Panoramic (in air or under water) units; includes sterilization (mega-curie) units
03610	3	Research and Development Broad – Type A	RSC-approved users under 10 CFR 33.13
03611	5	Research and Development Broad – Type B	RSO-approved users under 10 CFR 33.14
03612	5	Research and Development Broad – Type C	Authorized users specifically named in the license under 10 CFR 33.15
03613	2	Research and Development Broad – Multisite Multiregional	Master Materials Licenses
03620	5	Research and Development Other	Non-human research subjects
03710	5	Civil Defense	Instrument calibration and training
03800	3	Byproduct Material Possession Only – Permanent Shutdown	Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning not authorized

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
03810	3	Byproduct Material Standby – No Operations	Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized
03900	D[6]	Decommissioning of Byproduct Material Facilities	(See IMC 2602) D&D may have been authorized according to an approved plan under 10 CFR 30.36
11200	5	Source Material Other Less than 150 Kilograms	Research or manufacturing of consumer products
11210	T	Source Material Shielding	Possession and use
11220	5	Source Material Military Munitions Indoor Testing	Depleted Uranium (DU); results in fragmentation of DU
11221	5	Source Material Military Munitions Outdoor Testing	DU
11230	5	Source Material General License Distribution – 40.34	DU products and devices authorized under 10 CFR 40.25
11300	5	Source Material Other Greater than 150 Kilograms	Research or manufacturing of consumer products
11700	5	Rare Earth Extraction and Processing	Generates waste products containing source material not related to the nuclear fuel cycle
11800	2	Source Material Possession Only – Permanent Shutdown	Principle activities ceased, license termination request pending; packaging and shipping operations authorized; decontamination and decommissioning (D&D) not authorized
11810	2	Source Material Standby – No Operations	Principle activities ceased, licensee undecided about terminating the license, packaging and shipping operations authorized, D&D not authorized
11900	D	Decommissioning of Source Material Facilities	(See IMC 2602) D&D may have been authorized according to an approved plan under 10 CFR 40.42
21310	5	Critical Mass Material – University	Greater than 350 grams of enriched Uranium-235 (U-235), greater than 300 grams of Uranium-233 (U-233), greater than 200 grams of Plutonium, or any combination thereof

[6] The Priority D denotes a decommissioning inspection as determined under IMC 2602, Decommissioning Inspection Program, for Program Codes 03900, 11900, 21325, and 22200. These inspections are scheduled at times when the licensee is performing decommissioning activities at the site.

Program Code	Priority Code	Category Title	Remarks (from NUREG-1556, Vol. 20, Appendix G)
21320	5	Critical Mass Material – Other Than Universities	Greater than 350 grams of enriched U-235, greater than 300 grams of U-233, greater than 200 grams of Plutonium, or any combination thereof
21325	D	Decommissioning of Critical Mass – Other Than Fuel Fabrication	(See IMC 2602) D&D may have been authorized according to an approved plan under 10 CFR 70.38
22110	3	Special Nuclear Material Plutonium – Unsealed, Less than Critical Mass	Less than 200 grams, total, for biological and chemical testing and instrument calibration
22111	3	Special Nuclear Material, U-235 and/or U-233 – Unsealed, Less than a Critical Mass	Less than 350 grams U-235 and/or less than 300 grams U-233 for biological and chemical testing and instrument calibration
22120	5	SNM Plutonium – Sealed Neutron Sources, Less than 200 Grams	Plutonium-beryllium howitzer for instrument calibration, teaching and demonstration purposes, and industrial applications
22130	T	Power Sources with Byproduct and/or Special Nuclear Material	Heat or power generators for remote locations
22140	5	Special Nuclear Material Plutonium – Sealed Sources in Devices	Gauges
22150	5	Special Nuclear Material Plutonium – Sealed Sources Less than a Critical Mass	Less than 200 grams, total, for biological and chemical testing and instrument calibration
22151	5	Special Nuclear Material, U-235 and/or U-233 Sealed Sources, Less than a Critical Mass	Less than 350 grams U-235 and/or less than 300 grams U-233 for biological and chemical testing and instrument calibration
22160	T	Pacemaker – Byproduct, and/or Special Nuclear Material – Medical Institution	Surgical implantation, follow up, recovery, and disposal of devices
22161	T	Pacemaker – Byproduct, and/or Special Nuclear Material – Individual	Possession of a surgically implanted device by the recipient while in the United States

Vermont Department of Health Radioactive Materials Program

ATTACHMENT 1.1-7 TO RMPP 1.1

APPLICATION FOR RADIOACTIVE MATERIALS LICENSE - Form 313

Instructions

See the appropriate **NUREG-1556** Consolidated Guidance http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/, for detailed instructions for completing the application. Please also read the instructions below before completing this form. Type or print legibly and attach any additional information. You may submit electronic copies of the application and additional information.

Guidance for items 1 through 11 in this application is contained in each of the volumes of the NUREG-1556 Series. Different volumes exist for different activities. The applicant must follow the specific guidance in that specific volume to complete items 1 through 11. The NUREG-1556 Guidance volumes are found at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/.

Fees: Applicants should refer to the Health Department website for the appropriate fee schedule.

Certification: The certifying individual must be a company senior officer, who has signature authority, and is responsible for the safe use of radioactive material in the State of Vermont.

Retain a copy and submit this application in duplicate to:

Vermont Department of Health, Radioactive Materials Program
Environmental Health Division
108 Cherry Street, P.O. Box 70, Burlington Vermont 05402-0070

If this is an application for a NEW license, it must include remittance for the appropriate annual fee.

APPLICATION FOR RADIOACTIVE MATERIALS LICENSE - Form 313

1. This is an application for (*check appropriate box)*	2. Name and Mailing Address of Applicant:
A. New License ☐ B. Amendment to License Number _____ ☐ C. Renewal of License Number _____ ☐	

3. Address(es) Where Licensed Material Will be Used, Possessed, or Stored:

_____

4. Contact Person for this Application: _____

Business Telephone Number: _____Business Email :_____

Submit items 5 through 11 on 8-1/2" x 11" paper. The type and scope of information to be provided is as described in the appropriate **NUREG-1556 series**.

5. Radioactive Material: A. Element and Mass Number B. Chemical or Physical Form C. Maximum Amount That Will Be Possessed at Any One Time.	6. Purpose(es) for which licensed material will be used:
7. Individual(s) responsible for Radiation Safety Program, their training and experience:	8. Training for individuals working in or frequenting restricted areas:
9. Facilities and Equipment:	10. Radiation Safety Program:

11. Waste Management: Fee Category_____ *See VDH Website for Fee Schedule	12. License Fees*_____	Amount Enclosed $_____

13. Certification (must be completed by applicant). The applicant understands that all statements and representations made in this application are binding upon the applicant. The applicant and any official executing this certification on behalf of the applicant, named in Item 2, certify that this application is prepared in accordance with Chapter 6, Subchapter 5, Radioactive Materials Rule of the Vermont Department of Health and that all information contained herein is true and correct to the best of their knowledge and belief.

WARNING: THE STATEMENTS CONTAINED OR REFERENCED HEREIN ARE MADE SUBJECT TO THE PROVISIONS *OF 18 V.S.A. § 130 (Relating to Penalties for Unsworn False Statements to Government Authorities).*

Certifying Officer Typed or Printed Name	Signature
Certifying Officer Title	Date

State of Vermont Department of Health

Radioactive Materials Program

Radioactive Materials Program Procedure 1.2, Revision 0

Renewal of Licenses

Prepared By: _____ **Date:** _____

Reviewed By: _____ **Date:** _____

Approved By: _____ **Date:** _____

Effective Date: _____

Revision	Date	Description of Changes
0		

Radioactive Materials Program Procedure 1.2, Revision 0

Renewal of Licenses

Table of Contents

Renewal of Licenses

1.0 PURPOSE

1.1 Applicability

1.1.1 The purpose of this procedure is to define the steps required for renewal of a specific license under Vermont Department of Health (Department) authority, including those transferred from the Nuclear Regulatory Commission (NRC). This procedure also defines when an expedited renewal form is allowed rather than renewal in entirety. Timely and untimely applications for renewal are also discussed.

1.1.2 For the purpose of this procedure, qualification of the license reviewer for a specific license type is verified by the Radiation Control Program Director (RCPD) prior to determining the reviewer.

1.2 References

1.2.1 NUREG-1556 Series, "Consolidated Guidance About Materials Licenses".

1.2.2 Title 10 of the Code of Federal Regulation (10 CFR).

1.2.3 Vermont Radioactive Materials Rule.

1.3 Files

The following records will be maintained by the Radioactive Materials Program, primarily in an electronic format for each licensee:

1.3.1 Specific License;

1.3.2 License Application and/or Amendment Request Submittal;

1.3.3 Deficiency Letter;

1.3.4 License Transmittal Letter;

1.3.5 Requests for Additional Information; and

1.3.6 Financial assurance documents

1.3 Definitions

1.4.1 Renewal in Entirety: Based on the review of the application, the inspection

history, the current license, or a significant change in the applicable rule, the preparation of a total license revision is warranted. An example is a license that has been amended numerous times since the last renewal, such that the scope of the program has changed.

1.4.2 Expedited Renewal: The renewal of a license where the application, the inspection history, and the current license demonstrate that there has not been a significant change in the scope of the licensed program.

1.4.3 License Review: License review is the processing of any licensing action (i.e., new application, amendment, renewal, termination) and serves two capacities – primary review and secondary review.

1.4.4 License Reviewer: A Radiologic Health Specialist or other Radioactive Materials Program staff member qualified to review, process, and document a specific category of licensing action. A license reviewer shall not perform a review for any category of license for which they are not qualified.

1.4.5 Timely Renewal: The receipt of an application for renewal of a license that has been postmarked 30 days or more before the license's expiration date. The license remains in effect until processing of the application for renewal has been completed.

2.0 RESPONSIBILITIES

2.1 Radiological Health Specialist

2.1.1 Notifies a licensee that their license(s) will expire in 90 days and sends appropriate guidance document(s).

2.1.2 Informs the Radioactive Materials Program Manager (RMPM) or designee of licensees that have not submitted renewal applications at least 30 days prior to expiration and of any licenses that have expired.

2.1.3 Receives, logs, and acknowledges the receipt of an application for license renewal and informs the applicant that the application is considered to be timely if that is the case.

2.1.4 Sends the applicant for license renewal a request for additional information (RAI) and reviews the information submitted by the applicant in response to the RAI.

2.1.5 Maintains the records file with renewal documentation.

2.1.6 Completes the license renewal review in the time frame specified in RMPP 1.1.

2.1.7 Provides information of important findings in the renewal application to the Radioactive Materials Program Manager (RMPM) or the Radiation Control Program Director (RCPD) in the absence of the RMPM.

2.1.8 Performs secondary reviews of license renewal applications as needed, but only of license renewals for which not a primary reviewer. Secondary review is documented using the **Licensing Job Aid** (Attachment 1.1-4 in RMPP 1.1).

2.2 Radioactive Materials Program Manager (RMPM)

2.2.1 Assigns a licensing action for processing to a qualified Radiological Health Specialist.

2.2.2 Reviews the renewal application to see if it is valid and processes the renewal application, as assigned.

2.2.3 Recommends whether a renewal application is deficient and should be denied either with or without prejudice. Denial with prejudice requires additional consultation with VDH leadership and legal counsel.

2.2.4 Provides information of important findings in the renewal application to the Radiation Control Program Director.

2.2.5 Performs primary and secondary reviews of license renewal applications as needed.

2.3 Radiation Control Program Director (RCPD)

2.3.1 Reviews, approves, and signs licenses. This responsibility can be delegated to the RMPM in the RCPD's absence.

2.3.2 Performs primary and secondary reviews of license renewal applications for licenses for which qualified as a license reviewer as needed.

2.3.3 Following consultation with, and concurrence of, the Department of Health Legal Division, denies, with or without prejudice, a renewal application for license.

3.0 PROCEDURE

The review of an application for renewal of a specific license shall be conducted by a

Radiological Health Specialist qualified to conduct such a review. All applications will have a secondary independent review performed by a qualified Vermont Department of Health license reviewer prior to submission for approval.

3.1 License Expiration

3.1.1 Ninety (90) days prior to a license's expiration date, the licensee shall be notified of the pending expiration date using Attachment 1.2-2 and that if an application for renewal is postmarked at least 30 days prior to the expiration date, the application will be timely.

3.1.2 If the renewal application is postmarked less than 30 days prior, but not after the expiration date, the RMPM shall determine if the application should be considered timely.

3.1.3 If the application is found to be timely, the licensee is informed by letter that activities authorized by the current license may continue until processing of the renewal has been completed. This letter (Attachment 1.2-3) must be issued within 30 working days of the receipt.

3.1.4 If a timely application is not received by the expiration date, the licensee is informed that the license is considered to be expired. Any activity using licensed radioactive material shall cease and all licensed radioactive material shall be placed in storage or be disposed. The license will also be revised to become a possession only license. See sample letter as Attachment 1.2-1.

3.1.5 The Radiation Control Program Director must approve continued operation under the authority of any license for which the renewal application was submitted after the license's expiration date.

3.1.6 Processing of terminated licenses is covered in RMPP 1.3, *License Termination/Revocation*.

3.2 License Renewal

3.2.1 Radioactive Materials Program staff must review all license renewals in their entirety. One of the principal reasons for renewing a license in its entirety is to eliminate the confusion that can be caused by multiple amendments to the license and numerous tie-down conditions.

3.2.2 License renewal requests are conducted similarly to new license application (RMPP 1.1 *Review of Initial Application for License or an Amendment Request*). The time frame for conducting license renewals from RMPP 1.1 is 180 days.

3.2.3 The license renewal should contain all information that would be included in an initial license of the same program code(s) including tie-down license conditions that are based on any and all referenced license amendments.

3.2.4 Expedited renewals are conducted when a request is made by the licensee for new users or uses, such as a new medical modality (e.g., boron neutron capture therapy) or a new Radiation Safety Officer (RSO).

3.2.5 Expedited renewals are conducted on an as needed basis and should be completed in a timely manner depending on the scope of the request. They are granted only by the RCPD or RMPM in the absence of the RCPD.

4.0 RECORDS

4.1 Records to Be Maintained

The Application for license renewal plus attachments are maintained in the licensee's file as well as any deficiency letters, requests for additional information, and license transmittal letters generated.

4.2 Records Retention

4.1.1 Web Based Licensing is the primary electronic file repository.

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

5.0 ATTACHMENTS TO RMPP 1.2

1.2-1 Sample Letter for Expired License

1.2-2 Sample Renewal Letter for 90-day Notification

1.2-3 Sample Letter for Receipt of Renewal Application-Timely Filed

Vermont Department of Health Radioactive Materials Program

ATTACHMENT 1.2-1

License Expiration Letter

<DATE>

<LICENSEE NAME>

<CONTACT NAME TITLE>

<CITY, STATE, ZIP>

SUBJECT: **EXPIRED LICENSE**

Dear **<NAME>,**

Vermont Department of Health (Department) records show that Vermont Radioactive Materials License No. <**LICENSE NO.**> expired on **<DATE>**. A letter was sent on <**DATE**> (copy enclosed) informing you that your license would expire on <**DATE**>.

As of the date of this letter, no renewal application has been filed as per <**INSERT VDH REGULATION**>. The license has been amended by the Department of Health to be a possession-only license allowing only the storage of the licensed material pending its transfer to a person authorized to receive it by a license issued by the NRC or an Agreement State.

Any use of the licensed material is in violation of the Vermont radioactive material regulations. If you wish to resume use of the licensed material you may apply for a new Vermont Radioactive Material License.

Report to the Vermont Department of Health in writing of the steps taken to transfer all licensed material in your possession. Your report on VDH Form 314 Certificate of Disposition of Radioactive Materials must be received no later than <**INSERT DATE 30 days from date of letter**>.

If you have decided not to possess radioactive materials and to discontinue your program, immediately transfer all radioactive material formerly authorized by the license to an authorized recipient. You must verify that the recipient's license authorizes the receipt of the isotope(s), type, form, and quantity of radioactive material to be transferred.

Send copies of the transfer records, a separate written request for termination of the license and appropriate attachments (i.e., decommissioning surveys of the facility, leak tests, etc.) to the Department within 30 days of the date of this letter. Complete Department Form 314.

Send your response to the following address:

Vermont Department of Health

Radioactive Materials Program

108 Cherry Street PO Box 70

Burlington VT 05402-0070

Sincerely,

Radioactive Materials Program Manager

VDH: Send certified mail to ensure receipt.

Vermont Department of Health Radioactive Materials Program

ATTACHMENT 1.2-2

License Renewal Letter

[DATE]

{LICENSEE NAME}
{CONTACT NAME, TITLE}
{ADDRESS}
{CITY, STATE, ZIP CODE}

SUBJECT: NOTIFICATION TO RENEW VERMONT AGREEMENT STATE LICENSE

Dear **{SALUTATION, LAST NAME}:**

Your Vermont Radioactive Materials License No. **{LICENSE NO.}** expires on **{DATE}**.

If you wish to renew, please submit a new application with Department Form 313. It must include any and all information or documents previously submitted with the original application and any amendments. Please consult the Department if you wish to reference previously submitted information. Your license will be amended in its entirety utilizing the latest wording on the conditions of your license. These actions should help keep your license as complete and up-to-date as possible. If you do not wish to renew, you must complete VDH Form 314 Certificate of Disposition of Radioactive Materials. It is available at our web site: http://www.healthvermont.gov/environment/radiological.

Below is a link to the Nuclear Regulatory Commission Regulatory Guide (**NUREG-1556**) that you should use in preparing the application. All items in the guide must be addressed.

Please complete the application, retain a copy, and submit all renewal requests to the following address:

Vermont Department of Health
Radioactive Materials Program
108 Cherry Street PO Box 70
Burlington VT 05402-0070

If your application is submitted at least 30 days before the license expiration date, your license will remain in effect until the application has been finally determined by the Vermont Department of Health. You will be sent a Timely Renewal letter stating this.

If you have any questions concerning your license or the renewal process, please contact **{NAME}** at the Department at **{PHONE NUMBER}** or **{email address}.**

Sincerely,

{NAME}

Radioactive Materials Program Manager

Enclosure: Copy of License to be Renewed

Link to NUREG 1556 Series of Licensing Guidance:

https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/

Vermont Department of Health Radioactive Materials Program

ATTACHMENT 1.2-3

Letter for Receipt of Renewal Application-Timely Filed

<**DATE**>

<LICENSEE NAME>
<CONTACT NAME, TITLE>
<ADDRESS>
<CITY, STATE, ZIP>

Attention: <**CONTACT NAME**>
Radiation Safety Officer

SUBJECT: RENEWAL DEEMED TIMELY

Dear <**CONTACT NAME**>**:**

This acknowledges receipt of your application for renewal of Vermont Radioactive Material License No. **<NUMBER>**. Your license renewal request has been deemed timely filed and shall not expire until the application has been fully determined by this office.

If you have any questions concerning your license or the renewal process, please contact the Department at <**PHONE**> or <**EMAIL address**>.

Sincerely,

<NAME, SIGNATURE AND DATE>
Radiological Health Specialist

<NAME, SIGNATURE AND DATE >
Radioactive Materials Program Manager

State of Vermont Department of Health

Radioactive Materials Program
Procedure 1.3, Revision 0

License Termination/Revocation

Prepared By: _____ **Date:** _____

Reviewed By: _____ **Date:** _____

Approved By: _____ **Date:** _____

Effective Date:

Revision	Date	Description of Changes
0		

Radioactive Materials Program Procedure 1. 3, Revision 0

License Termination/Revocation

Table of Contents

Section

License Termination/Revocation

1.0 PURPOSE

1.1 Applicability

1.1.1 This procedure defines the process for terminating a license granted by the Vermont Department of Health (Department) to possess, use, store and, dispose of licensed radioactive material.

1.1.2 This procedure applies to the disposal of licensed material, decommissioning of the site and facilities, and surveys adequate to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E; .

1.2 References

1.2.1 Vermont Radioactive Materials Rule.

1.2.2 Title 10 Code of Federal Regulations, Part 20, Subpart E - Radiological Criteria for License Termination.

1.2.3 NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual" (MARSSIM).

1.2.4 NUREG-1757, "Consolidated Decommissioning Guidance" Volumes 1, 2 and 3 Revision 2.

1.2.5 The various RESRAD programs: (e.g., Dose Modeling Code (Soil Concentration Levels); RESRAD-Build, Dose Modeling Code (Buildings); RESRAD-OFFSITE).

1.2.6 The DandD Code for screening analyses for license termination and decommissioning. It automates the definition and development of the scenarios, exposure pathways, models, mathematical formulations, assumptions, and justifications of parameter selections documented in Volumes 1 and 3 of NUREG/CR-5512.

1.3 Files

The following records will be maintained by the Radioactive Materials Program, primarily in an electronic format, for each licensee:

1.3.1 Specific license.

1.3.2 License termination request document.

1.3.3 License termination letter.

1.3.5 Requests for Additional Information (RAI).

1.3.6 **VDH Form 314 Certificate of Disposition of Materials**

1.4 Definitions

1.4.1 ALARA. Acronym for “as low as is reasonably achievable,” which means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical, consistent with the purpose for which the licensed activity is undertaken, and taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to the benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest (see 10 CFR 20.1003).

1.4.2 Background Radiation: Radiation from cosmic sources, naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material and including global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents, such as Chernobyl, that contribute to background radiation and are not under the control of a licensee or registrant. Background radiation" does not include sources of radiation from radioactive materials regulated by the Department.

1.4.3 Certification Amount of Financial Assurance. See prescribed amount of financial assurance.

1.4.4 Certification of Financial Assurance. The document submitted to certify that financial assurance has been provided as required by regulation.

1.4.5 Characterization survey. A type of survey that includes facility or site sampling, monitoring, and analysis activities to determine the extent and nature of residual radioactivity. Characterization surveys provide the basis for acquiring necessary technical information to develop, analyze, and select appropriate cleanup techniques.

1.4.6 Cleanup. See decontamination.

1.4.7 Closeout Inspection. An inspection performed by NRC, or its contractor,

to determine if a licensee has adequately decommissioned its facility. Typically, a closeout inspection is performed after the licensee has demonstrated that its facility is suitable for release in accordance with NRC requirements.

1.4.8 Confirmatory Survey. A survey conducted by NRC, or its contractor, to verify the results of the licensee's final status survey. Typically, confirmatory surveys consist of measurements at a fraction of the locations previously surveyed by the licensee, to determine whether the licensee's results are valid and reproducible.

1.4.9 Critical Group: The group of individuals reasonably expected to receive the greatest exposure to radiation for any applicable set of circumstances.

1.4.10 DandD code. The Decontamination and Decommissioning (DandD) software package, developed by NRC, that addresses compliance with the dose criteria of 10 CFR 20, Subpart E. Specifically, DandD embodies NRC's guidance on screening dose assessments to allow licensees to perform simple estimates of the annual dose from residual radioactivity in soils and on building surfaces.

1.4.11 Decommission: To remove a facility or site safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license.

1.4.12 Decommission Funding Plan (DFP). A document that contains a site-specific cost estimate for decommissioning, describes the method for assuring funds for decommissioning, describes the means for adjusting both the cost estimate and funding level over the life of the facility, and contains the certification of financial assurance and the signed originals of the financial instruments provided as financial assurance.

1.4.13 Decommissioning Groups. For the purposes of this guidance document, the categories of decommissioning activities that depend on the type of operation and the residual radioactivity.

1.4.14 Decommissioning Plan (DP). A detailed description of the activities that the licensee intends to use to assess the radiological status of its facility, to remove radioactivity attributable to licensed operations at its facility to levels that permit release of the site in accordance with NRC's regulations and termination of the license, and to demonstrate that the facility meets NRC's requirements for release. A DP typically consists of several interrelated components, including (1) site characterization information; (2) a remediation plan that has several components, including a description of remediation tasks, a health and safety plan, and

a quality assurance plan; (3) site-specific cost estimates for the decommissioning; and (4) a final status survey plan (see 10 CFR 30.36(g)(4).

1.4.15 Decontamination. The removal of undesired residual radioactivity from facilities, soils, or equipment prior to the release of a site or facility and termination of a license. Also known as remediation, remedial action, and cleanup.

1.4.16 Derived Concentration Guideline Levels (DCGLs). Radionuclide-specific concentration limits used by the licensee during decommissioning to achieve the regulatory dose standard that permits the release of the property and termination of the license. The DCGL applicable to the average concentration over a survey unit is called the DCGLW. The DCGL applicable to limited areas of elevated concentrations within a survey unit is called the DCGLEMC.

1.4.17 Distinguishable from Background: The detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site, or in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

1.4.18 Dose (or radiation dose). A generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other paragraphs of 10 CFR 20.1003 (see 10 CFR 20.1003). In this NUREG report, dose generally refers to total effective dose equivalent (TEDE).

1.4.19 Effluent. Material discharged into the environment from licensed operations.

1.4.20 Environmental Monitoring. The process of sampling and analyzing environmental media in and around a facility (1) to confirm compliance with performance objectives and (2) to detect radioactive material entering the environment to facilitate timely remedial action.

1.4.21 Exposure Pathway. The route by which radioactivity travels through the environment to eventually cause radiation exposure to a person or group. Exposure Scenario. A description of the future land uses, human activities, and behavior of the natural system as related to a future human receptor's interaction with (and therefore exposure to) residual radioactivity. In particular, the exposure scenario describes where humans may be exposed to residual radioactivity in the environment, what exposure group habits determine exposure, and how residual radioactivity moves through

the environment.

1.4.22 External Dose. That portion of the dose equivalent received from radiation sources outside the body (see 10 CFR 20.1003).

1.4.23 Final Status Survey (FSS). Measurements and sampling to describe the radiological conditions of a site or facility, following completion of decontamination activities (if any) and in preparation for release of the site or facility.

1.4.24 Final Status Survey Plan (FSSP). The description of the final status survey design.

1.4.25 Final Status Survey Report (FSSR). The results of the final status survey conducted by a licensee to demonstrate the radiological status of its facility. The FSSR is submitted to NRC for review and approval.

1.4.26 Financial Assurance. A guarantee or other financial arrangement provided by a licensee that funds for decommissioning will be available when needed. This is in addition to the licensee's regulatory obligation to decommission its facilities.

1.4.27 Financial Assurance Mechanism. Financial instruments used to provide financial assurance for decommissioning.

1.4.28 Ground Water. Water contained in pores or fractures in either the unsaturated or saturated zones below ground level.

1.4.29 Hydraulic Conductivity. The volume of water that will move through a medium in a unit of time under a unit hydraulic gradient through a unit area measured perpendicular to the direction of flow.

1.4.30 Hydrology. Study of the properties, distribution, and circulation of water on the surface of the land, in the soil and underlying rocks, and in the atmosphere.

1.4.31 Impact. The positive or negative effect of an action (past, present, or future) on the natural environment (land use, air quality, water resources, geological resources, ecological resources, aesthetic and scenic resources) and the human environment (infrastructure, economics, social, and cultural).

1.4.32 Impacted Areas. The areas with some reasonable potential for residual radioactivity in excess of natural background or fallout levels (see 10 CFR 50.2).

1.4.33 Inactive Outdoor Area. The outdoor portion of a site not used for licensed activities or materials for 24 months or more.

1.4.34 Infiltration. The process of water entering the soil at the ground surface. Infiltration becomes percolation when water has moved below the depth at which it can be removed (to return to the atmosphere) by evaporation or transpiration.

1.4.35 Institutional Controls. Measures to control access to a site and minimize disturbances to engineered measures established by the licensee to control the residual radioactivity.

1.4.36 Institutional controls include administrative mechanisms (e.g., land use restrictions) and may include, but are not limited to, physical controls (e.g., signs, markers, landscaping, and fences).

1.4.37 Karst. A type of topography that is formed over limestone, dolomite, or gypsum by dissolution, characterized by sinkholes, caves, and underground drainage.

1.4.38 Leak Test. A test for leakage of radioactivity from sealed radioactive sources. These tests are made when the sealed source is received and on a regular schedule thereafter. The frequency is usually specified in the sealed source and device registration certificate and/or license.

1.4.39 License Termination Rule (LTR). The License Termination Rule refers to the final rule on "Radiological Criteria for License Termination," published by NRC as Subpart E to 10 CFR 20 on July 21, 1997 (62 FR 39058).

1.4.40 Licensee. A person who possesses a license, or a person who possesses licensable material, who the Health Department could require to obtain a license.

1.4.41 License Review: The processing of any licensing action (i.e., new application, amendment, renewal, termination) and serves two capacities – primary review and secondary review.

1.4.42 License Reviewer: A Radiologic Health Specialist or other Radioactive Materials Program staff member qualified to review, process, and document a specific category of licensing action. A license reviewer shall not perform a review for any category of license for which they are not qualified.

1.4.43 License Revocation: A license is revoked during its effective validity

period for cause, usually for failure to comply with licensing requirements and applicable regulations. NOTE: The Department must take formal action in order to revoke a license under 18 V.S.A. § 1655, 18 V.S.A. §§ 126 & 127, 10 CFR 30.61, 10 CFR 40.71, and 10 CFR 70.81.

1.4.44 License Expiration: When the licensee has allowed the license to expire, did not respond after being informed that the license had expired, and/or did not request that the license be renewed, then the Department will issue a possession-only license.

1.4.45 MARSSIM. The Multi-Agency Radiation Site Survey and Investigation Manual (NUREG–1575) is a multi-agency consensus manual that provides information on planning, conducting, evaluating, and documenting building surface and surface soil final status radiological surveys for demonstrating compliance with dose- or risk-based regulations or standards.

1.4.46 Model. A simplified representation of an object or natural phenomenon. The model can be in many possible forms, such as a set of equations or a physical, miniature version of an object or system constructed to allow estimates of the behavior of the actual object or phenomenon when the values of certain variables are changed. Important environmental models include those estimating the transport, dispersion, and fate of chemicals in the environment.

1.4.47 Monitoring. Monitoring (radiation monitoring, radiation protection monitoring) is the measurement of radiation levels, concentrations, surface area concentrations, or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses (see 10 CFR 20.1003).

1.4.48 mrem/y (millirem per year). One one-thousandth (0.001) of a rem per year. (See also sievert.).

1.4.49 Naturally Occurring Radioactive Material (NORM). The natural radioactivity in rocks, soils, air and water. NORM generally refers to materials in which the radionuclide concentrations have not been enhanced by or as a result of human practices. NORM does not include uranium or thorium in source material.

1.4.50 Non-impacted Areas. The areas with no reasonable potential for residual radioactivity in excess of natural background or fallout levels.

1.4.51 Pathway. See exposure pathway.

1.4.52 Performance-Based Approach. Regulatory decision-making that relies upon measurable or calculable outcomes (i.e., performance results) to be met, but provides more flexibility to the licensee as to the means of meeting those outcomes.

1.4.53 Permeability. The ability of a material to transmit fluid through its pores when subjected to a difference in head (pressure gradient). Permeability depends on the substance transmitted (oil, air, water, and so forth) and on the size and shape of the pores, joints, and fractures in the medium and the manner in which they are interconnected.

1.4.54 Porosity. The ratio of openings, or voids, to the total volume of a soil or rock expressed as a decimal fraction or as a percentage.

1.4.55 Potentiometric Surface. The two-dimensional surface that describes the elevation of the water table. In an unconfined aquifer, the potentiometric surface is at the top of the water level. In a confined aquifer, the potentiometric surface is above the top of the water level because the water is under confining pressure.

1.4.56 Prescribed Amount of Financial Assurance. An amount of financial assurance based on the authorized possession limits of the VDH license, as specified in 10 CFR 30.35(d), 40.36(b), or 70.25(d).

1.4.57 Principal Activities. 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 (see 10 CFR 30.4).

1.4.58 Probabilistic. Refers to computer codes or analyses that use a random sampling method to select parameter values from a distribution. Results of the calculations are also in the form of a distribution of values. The results of the calculation do not typically include the probability of the scenario occurring.

1.4.59 Reasonable Alternatives. Those alternatives that are practical or feasible from a technical and economic standpoint.

1.4.60 Reasonably foreseeable land use. Land use scenarios that are likely within 100 years, considering advice from land use planners and stakeholders on land use plans and trends.

1.4.61 rem. The special unit of any of the quantities expressed as dose equivalent.

The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert) (see 10 CFR 20.1004).

1.4.62 Remedial Action. See decontamination.

1.4.63 Remediation. See decontamination.

1.4.64 Residual Radioactivity: Radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental release of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 10 CFR 20.2001**.**

1.4.65 RESRAD Code. A computer code developed by the U.S. Department of Energy and designed to estimate radiation doses and risks from RESidual RADioactive materials in soils.

1.4.66 RESRAD-BUILD Code. A computer code developed by the U.S. Department of Energy and designed to estimate radiation doses and risks from RESidual RADioactive materials in BUILDings.

1.4.67 Restricted Area. Any area to which access is limited by a licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials (see 10 CFR 20.1003).

1.4.68 Risk. Defined by the “risk triplet” of a scenario (a combination of events and/or conditions that could occur) or set of scenarios, the probability that the scenario could occur, and the consequence (e.g., dose to an individual) if the scenario were to occur.

1.4.69 Risk-Based Approach. Regulatory decision making that is based solely on the numerical results of a risk assessment. (Note that the Commission does not endorse a risk-based regulatory approach.)

1.4.70 Risk-Informed Approach. Regulatory decision making that represents a philosophy whereby risk insights are considered together with other factors to establish requirements that better focus licensee and regulatory

attention on design and operational issues commensurate with their importance to public health and safety.

1.4.71 Risk Insights. Results and findings that come from risk assessments.

1.4.72 Robust engineered barrier. A man-made structure that is designed to mitigate the effect of natural processes or human uses that may initiate or accelerate release of residual radioactivity through environmental pathways. The structure is designed so that the radiological criteria for license termination (10 CFR 20, Subpart E) can be met. Robust engineered barriers are designed to be more substantial, reliable, and sustainable for the time period needed without reliance on active ongoing maintenance.

1.4.73 Saturated Zone. That part of the earth's crust beneath the regional water table in which all voids, large and small, are ideally filled with water under pressure greater than atmospheric.

1.4.74 Scoping Survey. A type of survey that is conducted to identify (1) radionuclide contaminants, (2) relative radionuclide ratios, and (3) general levels and extent of residual radioactivity.

1.4.75 Screening Approach/Methodology/Process. The use of (1) predetermined building surface concentration and surface soil concentration values, or (2) a predetermined methodology (e.g., use of the DandD code) that meets the radiological decommissioning criteria without further analysis, to simplify decommissioning in cases where low levels of residual radioactivity are achievable.

1.4.76 Sealed Source. Any special nuclear material or byproduct material encased in a capsule designed to prevent leakage or escape of the material.

1.4.77 sievert (Sv). The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 sievert = 100 rem) (see 10 CFR 20.1004).

1.4.78 Site. The area of land, along with structures and other facilities, as described in the original Department license application, plus any property outside the originally licensed boundary added for the purpose of receiving, possessing, or using radioactive material at any time during the

term of the license, as well as any property where radioactive material was used or possessed that has been released prior to license termination.

1.4.79 Site Characterization. Studies that enable the licensee to sufficiently describe the conditions of the site, separate building, or outdoor area to evaluate the acceptability of the decommissioning plan.

1.4.80 Site Characterization Survey. See characterization survey.

1.4.81 Site-Specific Dose Analysis. Any dose analysis that is done other than by using the default screening tools.

1.4.82 Smear. A radiation survey technique which is used to determine levels of removable surface contamination. A medium (typically filter paper) is rubbed over a surface (typically of area 100 cm^2), followed by a quantification of the activity on the medium. Also known as a swipe.

1.4.83 Source Material. Uranium or thorium, or any combination of uranium and thorium, in any physical or chemical form, or ores that contain by weight one-twentieth of one percent (0.05 percent) or more of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material (see 10 CFR 20.1003).

1.4.84 Source Term. A conceptual representation of the residual radioactivity at a site or facility.

1.4.85 Special Nuclear Material. (1) Plutonium, uranium-233 (U-233), uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission, pursuant to the provisions of Section 51 of the Atomic Energy Act, determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing but does not include source material (see 10 CFR 20.1003).

1.4.86 Specific Licenses. Licenses issued to a named person who has filed an application for the license under the provisions of 10 CFR Parts 30, 32 through 36, 39, 40, 61, and 70. Examples of specific licenses are industrial radiography, medical use, irradiators, and well logging.

1.4.87 Survey. An evaluation of the radiological conditions and potential hazards

incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present (see 10 CFR 20.1003).

1.4.88 Survey Unit. A geographical area consisting of structures or land areas of specified size and shape at a site for which a separate decision will be made as to whether or not the unit attains the site-specific reference-based cleanup standard for the designated pollution parameter. Survey units are generally formed by grouping contiguous site areas with similar use histories and having the same contamination potential (classification). Survey units are established to facilitate the survey process and the statistical analysis of survey data.

1.4.89 Technologically Enhanced Naturally Occurring Radioactive Material (TENORM). Naturally occurring radioactive material with radionuclide concentrations increased by or as a result of past or present human practices. TENORM does not include background radioactive material or the natural radioactivity of rocks and soils. TENORM does not include uranium or thorium in source material.

1.4.90 Timeliness. Specific time periods stated in NRC regulations for decommissioning unused portions of operating nuclear materials facilities and for decommissioning the entire site upon termination of operations.

1.4.91 Total Effective Dose Equivalent (TEDE). The sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (CEDE) (for internal exposures) (see 10 CFR 20.1003).

1.4.92 Transmissivity. The rate of flow of water through a vertical strip of aquifer which is one unit wide and which extends the full saturated depth of the aquifer.

1.4.93 Unrestricted Area. An area, access to which is neither limited nor controlled by the licensee (see 10 CFR 20.1003).

1.4.94 Unsaturated Zone. The subsurface zone in which the geological material contains both water and air in pore spaces. The top of the unsaturated zone typically is at the land surface, otherwise known as the vadose zone.

1.4.95 Vadose Zone. See unsaturated zone.

1.4.96 Voluntary termination: a licensee has requested that a license be terminated.

2.0 RESPONSIBILITIES

2.1 Radiological Health Specialist

2.1.1 Identifies licenses that have expired or are about to expire and notifies licensee and the Radioactive Materials Program Manager (RMPM) within 30 days of the license expiration date.

2.1.2 Issues acknowledgment letters for receipt of termination requests within 30 days of receipt of the request for termination.

2.1.3 Maintains computer-based and other licensing files.

2.1.4 Begins to process requests for license termination or expired licenses as assigned within a 15-day period, upon the notification of the license expiration date.

2.1.5 When required, performs closeout surveys to verify that the licensee survey data is accurate and supports the finding that the license can be terminated when a licensee is decommissioning their facility.

2.2 Radioactive Materials Program Manager (RMPM)

2.2.1 Assigns a request for license termination or an expired license to a Radiological Health Specialist (RHS) for processing. The RMPM will instruct the RHS in the required scope of the termination or expired license process, i.e., whether the licensee is required to submit a Decommissioning Plan.

2.2.2 In concert with the Department of Health Legal Division, initiates a petition for revocation of the license or other sanction, when deemed necessary to protect the public health and the environment.

2.3 Radiation Control Program Director

2.3.1 Reviews, concurs or does not concur, with the petition for revocation of the license or other sanctions after consultation with the Environmental Health Division Director and Department legal advisors.

2.3.2 Reviews, approves, and signs terminated license letters.

2.3.3 Approves the implementation of a revocation action and signs the final order.

3.0 PROCEDURE

3.1 General Provisions

3.1.1 The criteria for termination of a license are listed in 10 CFR 30.36, 40.42, and 70.38 as well as the Vermont Radioactive Materials Rule.

3.2 Request for Termination

3.2.1 Within 15 working days following the receipt of the request for license termination, the notice is placed in the licensee file and the reviewer should prepare a termination letter and inform the licensee that the Radioactive Materials Program may request additional information.

3.2.2 Following the receipt of a request for termination, a determination of the potential for residual radioactive contamination of the facility shall be made. The license and inspection history shall be reviewed to determine the potential risk of residual radioactive contamination.

3.2.3 The highest risk would be licensees that utilize significant quantities of unsealed radioactive material with half-lives greater than 120 days such as, but not limited to, nuclear pharmacies; waste disposal processing and repackaging services; manufacturing and distribution; nuclear laundries; academic or medical Type A Broad; and research and development, Type A Broad licenses. The lowest risk would be licensees that utilize radioactive materials only in the form of sealed sources. Unless there has been a significant leak of a sealed source, the probability of residual contamination is essentially zero. (NOTE: However, there have been a number of cases of residual contamination resulting from melting sealed sources contained in measuring gauges.)

3.2.4 For licenses that authorize both sealed and unsealed sources of radioactive material, the highest risk use shall dictate the decommissioning process.

3.3 License Termination - Sealed Sources

3.3.1 Determine which decommissioning group applies and follow the guidance in NUREG-1757 Volume 1.

3.4 License Termination - Unsealed Sources

3.4.1 Determine which decommissioning group applies and follow the guidance in NUREG-1757 Volume 1.

3.5 Expired License

3.5.1 Licensee Contacted.

3.5.1.1 Within fifteen (15) working days following the expiration date of a license without the receipt of a request for license termination or license renewal, the licensee shall be contacted by telephone or in person and informed that the license has expired. The licensee shall be informed, in writing, that any activity using radioactive material under the license shall cease, the licensed material shall be placed in storage or disposed of, and an application for license termination shall be submitted within 30 days.

3.5.1.2 If the licensee intends to continue licensed operations and states that the failure to submit an application for license renewal was an oversight, the licensee shall be informed that operations shall cease and that an application for license renewal should be submitted as soon as possible. The licensee shall be informed that operation without a current *valid* license constitutes noncompliance and that appropriate enforcement action will result.

3.5.1.3 The licensee shall be informed that only the RMPM may authorize continued use of radioactive material without a current license.

3.5.1.4 The notice to cease licensed activities shall be recorded and transmitted to the licensee by registered mail, return receipt requested (Attachment 1.2-1 **Sample Letter for Expired License** of RMPP 1.2 *Renewal of Licenses*). This notification to the licensee transmits the requirements for the proper disposition of radioactive materials with a **VDH Form 314** (Attachment 1.3-1) attached.

3.5.2 Licensee Not Contacted.

3.5.2.1 Returned, undeliverable mail to licensees must trigger an immediate follow-up. The follow-up must include a telephone call, email, or site visit to the licensee to verify the licensee's physical address.

3.5.2.2 If the licensee cannot be contacted either by telephone, visit to the

address on the license, or all other reasonable efforts, the authorized place of use shall be inspected and surveyed. All possible means must be taken to establish the facts associated with the loss of contact, including interviews of related parties like landlords, neighboring parties, or vendors. A survey for radiation and radioactive materials must also be conducted of premises left abandoned. If no radioactive materials are found and the survey indicates the facility is free of radioactive contamination, necessary legal action must proceed in order to revoke the license.

3.5.2.3 If residual contamination is discovered, the facility shall be restricted from unauthorized access and decontaminated to acceptable levels and the license revoked in accordance with 18 V.S.A. § 1653 (b) (7) (B). All legal efforts to require this of the licensee shall be exhausted before taking other actions. Consult with Department of Health Legal about these and all other steps.

3.5.2.4 If there was an emergency, the Department could use a Health Order (or Emergency Health Order) 18 V.S.A. § 126 (or § 127) to mitigate or force the mitigation of the hazard. If the Department incurred any cost as a result of this action, it has the authority to seek the recovery of costs under our civil enforcement statute. 18 V.S.A. § 130 (b) (5).

4.0 RECORDS

4.1 Records to be Maintained

4.1.1 Terminated License File.

4.1.2 Licensee Correspondence Requesting Termination.

4.1.3 Transfer the decommissioning records discussed in 10 CFR 30.35, 30.36, and 30.51; 40.36, 40.42, and 40.61; 70.25, 70.38, and 70.51; or 72.80, as appropriate, or affirm that they are not required to retain or transfer the records.

4.1.4 License Termination Letter.

4.1.5 **VDH Form 314 Certificate of Disposition of Radioactive Materials.**

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 ATTACHMENT TO RMPP 1.3

1.3-1 **VDH Form 314, Certificate of Disposition of Radioactive Materials**

Vermont Department of Health
Radioactive Materials Program
(802) 865-7730
Form 314

Certificate of Disposition of Radioactive Materials

Completion of this form is required to request termination of a Radioactive Material License as outlined in 10 CFR 30.36, 40.42, & 70.38.

Instructions – Complete all items. Retain one copy and submit original to Vermont Department of Health, Radioactive Materials Program, 108 Cherry Street P.O. Box 70 – Drawer 30, Burlington VT. 05402-0070.

CONTACT INFORMATION	
Item 1: Licensee Name and Mailing Address of Applicant	**Item 2: Vermont Radioactive Material License Number and expiration date**
Email Address: _____	**Item 3: Contact-Name** **Contact Telephone Number:**

LICENSE STATUS

☐ This license has expired. (Date) ☐ This license has not yet expired; please terminate it.

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with 10 CFR 30.36, 40.42 and 70.38

The licensee, or any individual executing this certificate on behalf of the licensee, certifies that:

☐ **Item 4** All use of radioactive material authorized under the above referenced license has been terminated.

☐ **Item 5** All radioactive materials have been removed such that any remaining residual radioactivity is within the limits of 10 CFR Part 20, Subpart E, and is as low as reasonably achievable (ALARA).

☐ **Item 6** All activities authorized by this license have ceased, and all radioactive material previously procured and/or possessed under the authorization granted by the above referenced license has been transferred and/or disposed of as follows. (Check all that apply)

A. ☐ Transferred to: Name Address

_____ _____

_____ _____

Who is (are) authorized to possess such material under License Number: _____

B. ☐ Disposal as radioactive waste:

1. Directly by the licensee: ☐
2. By licensed disposal site: ☐ License No.: _____
3. By licensed waste contractor: ☐ License No.: _____

C. ☐ Decayed, surveyed and disposed of as non-radioactive waste.

D. ☐ No radioactive material has ever been procured and/or possessed by the licensee under the authorization granted by the above referenced license.

☐ **Item 7**

1. A radiation survey was conducted by the licensee. The survey confirms:
   a. ☐ The absence of licensed radioactive material
   b. ☐ That any remaining residual radioactivity is within the limits of 10 CFR 20, Subpart E and is ALARA.
2. A copy of the radiation survey results:
   a. ☐ Is attached; or
   b. ☐ Is not attached (Provide explanation); or
   c. ☐ Was forwarded to the Department on: _____
3. A radiation survey is not required as only sealed sources were ever possessed under this license, and
   a. ☐ The results of the latest leak test are attached; and/or
   b. ☐ No leaking sources have ever been identified.

☐ Records required to be maintained for the license termination requested are available at the following location(s):

Name: _____

Address _____

Contact Telephone Number _____

(Copies of these records are kept in the licensee's file, maintained by the Vermont Department of Health)

Additional remarks (Attach additional pages if necessary.)

_____

_____

CERTIFICATION (To be completed by an individual authorized to make binding commitments on behalf of the applicant.)

Item 8. The undersigned, on behalf of the licensee, hereby certifies that licensable quantities of radioactive material under the jurisdiction of the Vermont Department of Health are not possessed by the licensee. It is therefore requested that the above referenced radioactive material license be terminated.

WARNING: THE STATEMENTS CONTAINED OR REFERENCED HEREIN ARE MADE SUBJECT TO THE PROVISIONS OF 32 V.S.A.§ 631(8) (*Relating to Penalties for Unsworn False Statements to Government Authorities*)

SIGNATURE – (Applicant or Authorized Individual) **Date signed**

_____ _____

Authorized Individual Contact Telephone Number: _____

Authorized Individual E-mail address: _____

Print Name and Title of Above Signatory: _____

CERTIFICATE OF DISPOSTION OF MATERIALS

PLEASE READ THESE INSTRUCTIONS BEFORE COMPLETING VDH FORM 314

Subpart E of 10 CFR 20 contains the radiological criteria for license termination/decommissioning of facilities licensed under 10 CFR Parts 30, 40, and 70.

INSTRUCTIONS

Item 1: Provide the Licensee name and mailing address, including e-mail address.

Item 2: Provide the Vermont Radioactive Materials License Number and expiration date.

Item 3: Provide the contact name and telephone number for the individual responsible for the information contained on VDH Form 314.

Item 4: Indicate that all licensed activities have been terminated.

Item 5: "Residual radioactivity" as defined in 10 CFR 20.1003, means radioactivity in 'areas' (structures, materials, soils, etc.) remaining as a result of activities (licensed and unlicensed) under the licensee's control from sources used by the licensee, excluding background radiation. ALARA is defined in 10 CFR 20.1003.

Item 6 A: Licensees should describe the specific radioactive material transfer actions. If radioactive wastes were generated in terminating this license, the licensee should describe the disposal actions taken, including the disposition of low-level radioactive waste, mixed waste, greater-than-Class-C waste, and sealed sources.

Item 6 B: For disposal of radioactive materials, licensees should describe the specific method or procedure (e.g., decay-in-storage). Indicate if the material was decayed, surveyed and disposed of as non-radioactive waste. For those cases when radioactive materials are disposed of by a licensed disposal site or by a waste contractor, the licensee should specify the name, address, and telephone number of the licensed disposal site operator or waste contractor.

Item 6 C: Indicate if radioactive material was never procured and/or possessed by the licensee under the authorization granted by the above reference license

Item 7: Provide the radiation and contamination survey results, if applicable.

Item 8: Provide the name and location of the individual who is responsible for maintaining the information for the licensee.

References:
NUREG-1757 Volume 2 "Consolidated Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria"

NUREG-1757, Volume 3, "Consolidated Decommissioning Guidance: Decommissioning Process for Materials Licensees"

State of Vermont Department of Health

Radioactive Materials Program

Procedure 4.1, Revision 0

Renewal Notices, Receipt and Tracking of Licensing Actions

Prepared By: _____ **Date:** _____

Reviewed By: _____ **Date:** _____

Approved By: _____ **Date:** _____

Effective Date: _____

Revision	Date	Description of Changes
0		

Radioactive Materials Program Procedure 4.1, Revision 0

Renewal Notices, Receipt and Tracking of Licensing Actions

Table of Contents

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, store, 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.

1.4.4 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 Web-Based Licensing (WBL) in consultation with the 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 deemed 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 telephone 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 WBL.

Note: If the information needed is not extensive, the request may be communicated by telephone 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 telephone 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 WBL.

3.5.2 On a weekly basis, 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 by a licensee or applicant, 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 WBL.

3.5.5 The license reviewer will prepare an abandonment letter for signature of the RCPD and send it 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 discuss any issues of concern with the initial license reviewer and make the necessary corrections.

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 is assigned 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 actions into WBL.

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