4.3 Licensing Program Elements

Section 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. In Section 4.3.5, is the procedure for assuring the technical quality of licenses, 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* are included in Section 4.3.6.

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.

List of Acronyms/Abbreviations

AAPM	American Association of Physicists in Medicine
ACMUI	American Committee on the Medical Use of Isotopes
ACR	American College of Radiology
AEA	Atomic Energy Act
ARDL	Academic Research and Development License
ALARA	As Low As Reasonably Achievable
ALI	Annual Limit on Intake
ANSI	American National Standards Institute
AMP	Authorized Medical Physicist
ANP	Authorized Nuclear Pharmacist
AU	Authorized User
Bg	Background
Bq	Becquerel
CDE	Committed Dose Equivalent
CEDE	Committed Effective Dose Equivalent
CFR	Code of Federal Regulations
Ci	Curie
cm	centimeter
cm^2	square centimeter
Co-57	Cobalt-57
Co-60	Cobalt-60
COC	Certificate of Compliance
cpm	counts per minute
Department	Vermont Department of Health
DFP	Decommissioning Funding Plan
DIS	Decay-In-Storage

DOE	United States Department of Energy
DOELAP	Department of Energy Laboratory Accreditation Program
DOJ	United States Department of Justice
DOT	United States Department of Transportation
DP	Decommissioning Plan
dpm	disintegrations per minute
dpm/cm^2	disintegrations per minute per square centimeter
DU	Depleted Uranium
ECD	Electron Capture Device
EPA	United States Environmental Protection Agency
F-18	Fluorine-18
FA	Financial Assurance
FBI	United States Federal Bureau of Investigation
FDA	United States Food and Drug Administration
FE	Focus Element
FSME	Office of Federal and State Materials and Environmental Management Programs
ft	foot
GBq	Gigabecquerel
GC	Gas Chromatograph
G-M	Geiger-Mueller
GPS	Global Positioning System
GSR	Gamma Stereotactic Radiosurgery
Gy	Gray
HAZMAT	Hazardous Material
HDR	High Dose-Rate
Hr	Hour
HVL	Half Value Layer
I-125	Iodine-125

I-131	Iodine-131
ICRP	International Commission on Radiological Protection
IMC	Inspection Manual Chapter
IN	Nuclear Regulatory Commission Information Notice
IP	Inspection Procedure
Ir-192	Iridium-192
IRB	Institutional Review Board
L/C	License Condition
LDR	Low Dose-Rate
LLD	Lower Limit of Detection
LLEA	Local Law Enforcement Agency
LLW	Low-Level radioactive Waste
LVS	License Verification System
LSA	Low Specific Activity
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
MDA	Minimum Detectable Activity
MDC	Minimum Detectable Concentration
MeV	Million electron Volts
µCi	microCurie
mCi	milliCurie
mGy	milliGray
m	meter
MOU	Memorandum of Understanding
Mo-99	Molybdenum-99
mrem	millirem
mR	milliRoentgen
MSHA	Mine Safety and Health Administration
N/A	Not Applicable

NaI	Sodium Iodide
NCRP	National Council on Radiation Protection and Measurements
NIOSH	National Institute of Occupational Safety and Health
NIST	National Institute of Standards and Technology
NMED	Nuclear Materials Event Database
NMSS	Office of Nuclear Material Safety and Safeguards
NOV	Notice of Violation
NRC	United States Nuclear Regulatory Commission
NSTS	National Source Tracking System
NSTTR	National Source Tracking Transaction Report
NVLAP	National Voluntary Laboratory Accreditation Program
PG	United States Nuclear Regulatory Commission Policy and Guidance Directives
OSL	Optically Stimulated Luminescence Dosimeter
OSHA	United Stated Occupational Safety and Health Administration
QA	Quality Assurance
QC	Quality Control
OUO	Official Use Only
P-32	Phosphorous-32
PET	Positron Emission Tomography
PII	Personally Identifiable Information
Q	Quality factor
QA	Quality Assurance
R	Roentgen
RAI	Request for Additional Information
Ra-226	Radium-226
Ru-82	Rubidium-82
RMPP	Radioactive Materials Program Procedure
RSC	Radiation Safety Committee

RSO	Radiation Safety Officer
RSRM	Risk Significant Radioactive Material
SDE	Shallow Dose Equivalent
SI	International System of Units
SNM	Special Nuclear Material
SRI	Security Related Information
SSD	Sealed Source and Device [registration certificate]
SSDR	Sealed Source and Device Registry
Std	Standard
Sv	Sievert
TAR	Technical Assistance Request
TBq	TeraBecquerel
Tc-99m	Technetium-99m
T	Time
TEDE	Total Effective Dose Equivalent
TI	Transport Index
TLD	Thermo Luminescent Dosimeter
U.S.C	United States Code
VDH	Vermont Department of Health
VOSHA	Vermont Occupational Safety and Health Administration
WBL	Web Based Licensing
WD	Written Directive
Wk	Week
XRF	X-ray Fluorescence
Yr	Year

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

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 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 XXX

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TABLE XXX NUREG 1556 VOLUMES

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Commented [IW4R3]: We will get with final assembly of application.

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/ML0103/ML010370198.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/ML0103/ML010370258.pdf
9	Program-Specific Guidance About Medical Use Licenses https://www.nrc.gov/docs/ML0734/ML073400289.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/reading-rm/doc-collections/nuregs/staff/sr1556/v12/
13	Program-Specific Guidance About Commercial Radiopharmacy Licenses https://www.nrc.gov/docs/ML0731/ML073180179.pdf
14	Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses https://www.nrc.gov/docs/ML0037/ML003729920.pdf
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/ML0037/ML003776996.pdf
18	Program-Specific Guidance About Service Provider Licenses https://www.nrc.gov/docs/ML0037/ML003779351.pdf
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/ML0729/ML072900058.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. The table below 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 XXX: 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

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

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

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 – Not Applicable

4.3.4 Procedures for Conducting the Evaluation of a Regulatory Program for 11e.(2) Byproduct Material Including Uranium or Thorium Mining Facilities – Not Applicable

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

4.3.5 Procedures for Assuring the Technical Quality of Licenses

Vermont Department of Health Radioactive Materials Program staff will utilize RMPP 1.1 "Review of an Initial Application for License or an Amendment" to provide means by which the technical quality of licenses is assured. The elements included primary review, secondary review by two different qualified license reviewers, and a supervisory review. The primary and secondary review are documented using the Licensing Job Aid and the supervisory review is documented using the 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.