State of Vermont Department of Health

Radioactive Materials Program

Procedure 2.5, Revision 0

Enforcement, Escalated Enforcement, and Administrative Actions

Prepared By: _____ **Date:** _____

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Enforcement, Escalated Enforcement, and Administrative Actions

1.0 GENERAL INFORMATION

1.1 Purpose

The purpose of the Vermont Department of Health Radioactive Materials Program (RMP) is to support the overall safety mission of protecting the public health, safety, and environment through appropriate enforcement actions. Enforcement actions should be used to:

1.1.1 Deter noncompliance by emphasizing the importance of regulatory compliance;

1.1.2 Encourage prompt identification and comprehensive action following the occurrence of violations.

1.2 Applicability

Enforcement actions are dependent upon the circumstances of each individual case of violation. The implementation of specific enforcement actions requires the exercise of discretion after consideration of all available alternatives. However, under no circumstances, will licensees unable or unwilling to achieve and maintain adequate levels of safety be permitted to conduct licensed activities.

1.3 Statutory Authority

Statutory authority for promulgation and implementation of enforcement procedures is contained in Vermont law at 18 V.S.A. §§ 123-131.

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1.4 References

1.4.1 NUREG-1600, General Statement of Policy and Procedures for NRC Enforcement Action.

1.4.2 NRC Enforcement Manual.

1.4.3 NRC Enforcement Policy.

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1.4.4 Vermont Radioactive Materials Rule

1.5 Definitions

1.5.1 Administrative Action: Action implemented in addition to formal enforcement actions to supplement the enforcement program.

1.5.2 Aggregation of Violations: Group of violations that may be evaluated in the aggregate, providing the violations have the same underlying cause, resulting in a violation of a higher severity level. For example, a group of Severity Level IV violations may be evaluated in the aggregate and result in a Severity Level III violation, or a group of Minor Violations, if evaluated in the aggregate, may result in a Severity Level IV violation. Severity Level II and III violations are normally not aggregated except in the most egregious cases.

1.5.3 Assurance of Discontinuance (AOD): A written agreement between the (violator/respondent) and the Health Department, pursuant to 18 V.S.A. § 125, whereby the violator agrees to discontinue the action or inaction contributing to a public health risk or hazard and agrees not to commit a violation in the future. AOD's are filed in Superior Court and become an order of the court. 18 V.S.A. § 125 authorizes the Commissioner to enter into a written agreement with the violator, an Assurance of Discontinuance.

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1.5.4 Civil Enforcement: An action brought by the Health Department in Superior Court, pursuant to 18 V.S.A. § 130, due to a violation of Title 18 or any rules, permits, or orders issued by the Health Department or due to a public health hazard or public health risk.

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1.5.5 Deliberate Misconduct: an intentional act or omission that a person or entity knows:

1.5.5.1 Would cause a licensee or an applicant for a license, standard design certification, or standard design approval to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license, standard design certification, or standard design approval; or

1.5.5.2 Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, holder of a standard design approval, applicant for a license, standard design certification, or standard design approval, or contractor, or subcontractor.

1.5.6 Discretion: The Health Department's authority to either escalate or mitigate enforcement sanctions to ensure that the resultant enforcement action appropriately reflects the level of the Department's concern regarding the violation at issue and conveys the appropriate message to the licensee.

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1.5.7 Emergency Order: A written directive to modify, suspend, or revoke a license; to cease and desist from a given practice or activity when the

Health Department finds an emergency exists requiring immediate action; to impound byproduct, source, and special nuclear materials or to take other appropriate action. Orders may be issued as appropriate for Severity Level I, II, or III violations.

1.5.8 Enforcement Action: Actions in which violation or a public health hazard or public health risk has occurred or is occurring to enforce the provisions of statute, rules, permits or orders.

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1.5.9 Escalated Enforcement Action: An enforcement action for any Severity Level I, II, or III violations. Violations with willful aspects (i.e. careless disregard or deliberate misconduct) will typically be considered for escalated enforcement.

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Commented [OF9]: NRC comment 6

1.5.10 Hearings and Judicial Review: A proceeding in accordance with 18 V.S.A 1655 (a) for the issuance or modification of rules relating to control of byproduct, source, and special nuclear materials, for granting, suspending, revoking, or amending any license, or for determining compliance with, or granting exemptions from, rules and regulations.

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

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

1.5.13 Licensee Official: A first-line supervisor or above, a licensed individual, a radiation safety officer, or an authorized user of licensed material whether or not listed on the license.

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

1.5.15 Pre-decisional Enforcement Conference: A meeting between the Health Department and the licensee that may be called whenever the Department becomes aware of potential violation(s) which may warrant escalated enforcement action. The purpose of the conference is to allow the

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Department to obtain additional information necessary to determine the level of enforcement action needed. A pre-decisional enforcement conference is called prior to the issuance of an NOV.

1.5.16 Repetitive Violation: A violation that could have been prevented by a licensee's action to correct a previous violation occurring either (1) within the past two years of the inspection at issue, or (2) during the period between the last two inspections, whichever is longer.

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

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

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1.5.19 Severity Level: Categorization of violations of license requirements based on the seriousness of the violation. One of four levels of severity is assigned to a violation, ranging from Severity Level I, signifying the most significant, to Severity Level IV, the least.

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

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1.5.21 Willfulness: There are two types of willfulness:

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1.5.21.1 Deliberate Misconduct; an intentional act or omission that a person or entity knows (1) Would cause a licensee or an applicant for a license, standard design certification, or standard design approval to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license, standard design certification, or standard design approval; or (2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, holder of a standard design approval, applicant for a license, standard design certification, or standard design approval, or contractor, or subcontractor.

1.5.21.2 Careless Disregard; refers to situations in which an individual acts with reckless indifference to at least one of three things: (1) the existence of a requirement, (2) the

meaning of a requirement, or (3) the applicability of a requirement. Careless disregard occurs when an individual is unsure of the existence of a requirement, the meaning of a requirement, or the applicability of the requirement to the situation, but nevertheless, proceeds to engage in conduct that the individual knows may cause a violation. Although aware that the action might cause a violation, the individual proceeds without ascertaining whether a violation would occur.

2.0 RESPONSIBILITIES

2.1 Radiological Health Specialists

2.1.1 Conducts routine inspections and special inspections as defined in Section 1.5, in accordance with applicable procedures, rules, and instructions.

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2.1.2 Categorizes and documents any apparent violations of license conditions observed during the inspections.

2.1.3 Reports the violations to the RMPM.

2.1.4 Generally, Radiological Health Specialists perform both licensing and inspection functions.

2.2 Radioactive Materials Program Manager

2.2.1 Reviews all inspection reports or delegates this review to an appropriate designee.

2.2.2 Approves the issuance of any proposed NOVs.

2.2.3 Determines if the threat to health and safety described in any NOVs warrants the prompt issuance of an order

2.2.4 Determines whether a pre-decisional enforcement conference is warranted. A pre-decisional enforcement conference is conducted prior to issuing an NOV to allow the licensee an opportunity to demonstrate that corrective actions have been made or will be made in order to maintain compliance with Health Department regulations.

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2.2.5 Makes recommendations pertaining to the exercise of discretion in any proposed enforcement action.

2.2.6 Forwards, as appropriate, any escalated enforcement recommendations to the Radiation Control Program Director.

2.3 Radiation Control Program Director

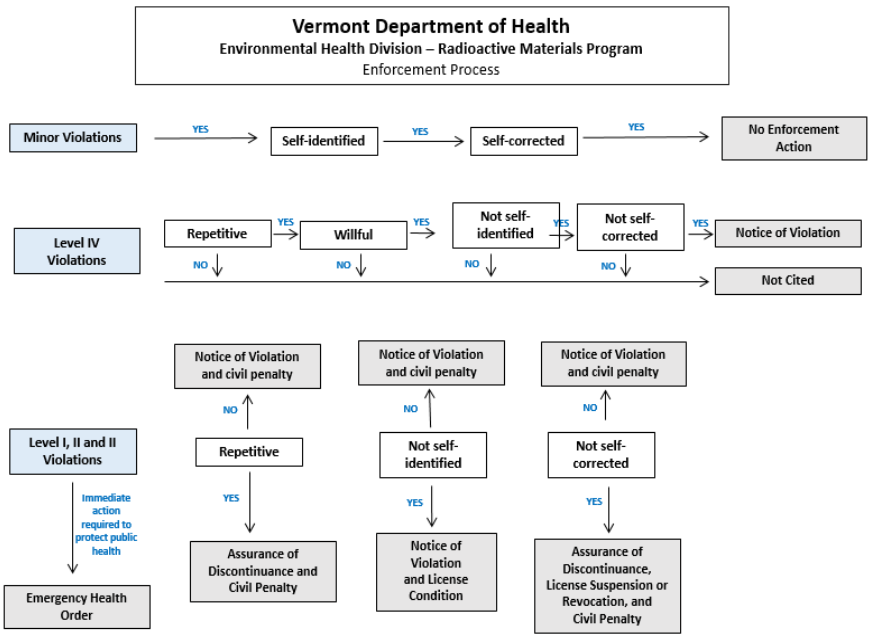
2.3.1 Reviews recommendations forwarded from the RMPM and, as appropriate, approving, modifying, or denying the recommendation for assessment and issuance of forfeiture, issuance of an order, or both.

2.3.2 For the actual issuance of an escalated enforcement action, responds as necessary, to a request for hearing by a licensee made in accordance with 18 VSA §1655.

2.3.3 In the event of licensee's failure to pay an imposed penalty, requests enforcement assistance from legal counsel.

3.0 ENFORCEMENT ACTIONS

This section describes the various ways the Health Department can disposition violations. The manner in which a violation is disposed is intended to reflect the seriousness of the violation and the circumstances involved. All available escalated enforcement actions should be reviewed by legal counsel for wording and format, provided a means of tracking the completion of enforcement actions, and assured to be a fair and impartial administration of regulatory law. The figure below and accompanying explanation provides an overall description of the Vermont Department of Health's enforcement process.



Enforcement Process

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Minor Violations: No Enforcement Action

Minor violations that are below the significance of Severity Level IV violations are typically not the subject of enforcement action and are not described in inspection reports. Nevertheless, minor violations must be corrected. Violations as indicated in Attachment 2.5-1 **Examples of Violations That May Be Cited on a Clear Inspection** if they are non-repetitive and non-willful and the licensee has self-implemented corrective actions. Minor violations are not the subject of formal enforcement action.

Non-Escalated Enforcement Process: Licensees and Non-Licensees Severity Level IV Violations

Violations as exemplified in Attachment 2.5-1 may be cited on a clear inspection. If the licensee failed to self-identify and/or correct the non-conformance, and/or the violation was willful, if the licensee failed to restore compliance in a reasonable amount of time after a violation was identified, then a Notice of Violation (NOV) is issued. Restoring compliance includes those actions taken to stop an ongoing violation from continuing and does not include those actions necessary to address root causes and prevent recurrence.

Escalated Enforcement Process: Severity Level I, II, and III violations with and without civil penalty

An NOV including Severity Level I, II, or III violations is considered escalated enforcement action. Escalated NOVs are normally issued subsequent to conferences or after a licensee has had an opportunity to respond to apparent violations in an inspection report.

The Health Department assesses significance by assigning a severity level to all violations, for example:

- Severity Level I violations are those that resulted in or could have resulted in serious safety or security consequences (e.g., violations that created the substantial potential for serious safety or security consequences or violations that created the substantial potential for serious safety or violations that involved systems failing when actually called on to mitigate a serious safety or security event).

- Severity Level II violations are those that resulted in or could have resulted in significant safety or security consequences (e.g., violations that created the potential for substantial safety or security consequences or violations that involved systems not being capable, for an extended period, of preventing or mitigating a serios or security event.

- Severity Level III violations are those that resulted in or could have resulted in moderate safety or security consequences (e.g., violations that created a potential for moderate safety or security consequences or violations that involved systems not being capable, for a relatively short period, of preventing or mitigating a serious safety or security event).

- Severity Level IV violations are those that are less serious, but are of more than minor concern, that resulted in no or relatively inappreciable potential safety or security consequences (e.g., violations that created the potential of more than minor safety or security consequences).

- Minor (non-cited) violations that are listed in Attachment 2.5-1 **Examples of Violations That May Be Cited on a Clear Inspection**, e.g., failure of the Radiation Safety Committee to meet as scheduled, or, licensee observed eating, drinking etc. in laboratories where un-sealed radioactive materials are stored but not being used.

3.1 Notice of Violation (NOV)

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3.1.1 An NOV is issued to a licensee and non-licensees (e.g., contractors) following an inspection, when items of noncompliance with regulations have been determined, or suspected. An NOV is a formal written notice

setting forth one or more apparent violations of a legally binding requirement, following an inspection. The NOV formally documents violations and is typically the only enforcement action taken unless the criteria for escalated enforcement are met.

3.1.2 The recipient of an NOV is normally required to provide a written response describing (1) the reasons for the violation or, if contested, the basis for disputing the violation; (2) the corrective steps that have been taken by the licensee or other persons and the results achieved; (3) the corrective steps planned to prevent reoccurrence; and (4) the date when full compliance will be achieved.

3.1.3 All or portions of the written response may be waived to the extent that relevant information has already been provided in writing or documented in the inspection report or inspection record.

3.1.4 A civil penalty may be issued in conjunction with an NOV.

3.1.5 An NOV shall be revised if the determination is later made that the violations were Severity Level I, II, or III, necessitating an escalated enforcement action.

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3.1.6 A follow-up inspection must be conducted within six months of receipt of a licensee's corrective action following an escalated enforcement action.

3.2 Pre-decisional Enforcement Conference

3.2.1 A pre-decisional enforcement conference is a conference held between the Radioactive Materials Program with a licensee for violation of Health Department regulations as determined by inspection and is convened prior to implementation of an escalated enforcement action if considered warranted by the Health Department. The purpose of this conference is to gather further information from the licensee and will assist the Department in determining the appropriate enforcement actions. In this situation, the licensee is informed that a potential violation of Department regulations has occurred, and the licensee is being granted an opportunity to discuss the findings and resolutions with the Department. This conference shall accomplish, at the least, a mutual understanding between the licensee and the Department, of:

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- Facts, root causes, and missed opportunities associated with the apparent violations;
- Any prior corrective actions taken or planned; and

- The significance of the issues and the need for lasting comprehensive corrective action.

3.2.2 The Health Department will normally provide an opportunity for an individual to address apparent violations before they take escalated enforcement action. Whether an individual will be provided an opportunity for a pre-decisional enforcement conference or an opportunity to address an apparent violation in writing will depend on the circumstances of the case; including the severity of the issue, the significance of the action the Department is contemplating, and whether the individual has already had an opportunity to address the issue.

3.2.3 If the Department concludes that it has sufficient information to make an informed enforcement decision involving a licensee, contractor, or vendor, a pre-decisional enforcement conference will not be held. If a pre-decisional enforcement conference is not held, the licensee may be given an opportunity to respond to a documented apparent violation (including its root causes and a description of planned or implemented corrective actions) before the Department takes enforcement action.

3.2.4 If a violation requires immediate action to protect public health and safety, an emergency order will be taken before the conference. In these cases, a conference may be held after the emergency order is taken.

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3.3 Civil Penalty

3.3.1 A monetary penalty is intended to deter future violations by both the involved licensee and other licensees conducting similar activities. It emphasizes the need for licensees to identify and report violations and to take prompt comprehensive corrective action.

3.3.2 Civil penalties may be levied pursuant to 18 V.S.A. § 130 for any violation of Title 18, or rules, permits, or orders issued pursuant to the title. In determining whether to levy a civil penalty, the Health Department may consider the following:

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- The imposition on the licensee of any escalated enforcement action within the last two years or last two inspections, whichever is longer;
- Any credit merited to the licensee for identification of violations or non-compliances;
- Any licensee corrective action taken or planned related to the identification; and,

- Whether, in view of all circumstances surrounding the violation, the exercise of discretion is warranted.

3.4 Orders

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3.4.1 Orders may be issued without prior opportunity for hearing when the Health Department finds that an emergency exists requiring immediate action. An order is a written Health Department directive that:

- Modifies, suspends, or revokes a license;
- Directs a licensee to cease and desist from a given practice or activity; or
- Delineates other action against the licensee as deemed appropriate by the Department.

3.4.2 Orders are effective immediately whenever it is determined that in interest of public health or safety it so requires, or when the order is in response to a violation involving willfulness.

3.4.3 Types of orders:

3.4.3.1 Assurance of Discontinuance (AOD): A written agreement between the licensee and the Health Department to discontinue the action or inaction contributing to a public health risk or hazard. AODs are filed in superior court and become an order of the court. 18 V.S.A § 125 authorizes the Commissioner to enter into a written agreement with the violator, an Assurance of Discontinuation. 18 V.S.A. § 104 authorizes the Commissioner to delegate any of his duties to members of the Department. In practice, the Commissioner does not delegate AOD authority.

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3.4.3.2 License Condition Orders: A license condition order requires change to licensee equipment, procedures, personnel, or management controls as deemed necessary. This requires the license to be amended, as appropriate to reflect the orders.

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3.4.3.3 Suspension Orders: A suspension order requires time-limited suspension of all or part of the licensed activity. Normally, a licensed activity is only suspended, or a suspension is prolonged, for failure to comply with requirements where such failure is willful or the corrective action taken or planned is inadequate. Suspension orders are used:

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- If the license holder submitted materially false or inaccurate information;
- If the license holder has violated any material requirement, restriction, or condition of any license, rule, statute, or order; or
- If there is a change in any condition that requires either a temporary or permanent restriction, limitation, or elimination of the licensed use. 18 V.S.A. § 123

3.4.3.4 Revocation Orders: A revocation (permanent) order revokes the license authorizing use of radioactive materials when:

- A licensee is unable or unwilling to comply with license requirements;
- A licensee refuses to correct a violation;
- A licensee does not respond when required by an issued NOV;
- A licensee refuses to pay an applicable fee under Health Department rules; or
- Any condition exists which would warrant refusal of a license on an original application.

3.4.3.5 Cease and Desist Orders: Cease and desist orders require a person to stop an unauthorized activity that has continued following notification by the Health Department that the activity is unauthorized.

3.4.3.6 Emergency Orders: Emergency orders are issued when immediate action is required to protect public health and safety and may be issued without notice or hearing. The order shall describe the existence of an emergency and the action required, including sequestration or impoundment of the radioactive source, to mitigate the emergency.

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3.4.3.7 Orders to Unlicensed Persons: Health orders, assurances of discontinuance, or injunctive relief pursuant to 18 V.S.A. §§ 126, 125, and 130, may be sought in cases where unlicensed persons, including vendors and contractors and their employees, are involved, when deliberate misconduct has been identified that

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potentially violates Health Department requirements, when incomplete or inaccurate information is deliberately submitted, or when the Department loses reasonable assurance that the regulated person will meet Department requirements if the unlicensed person continues involvement in activities covered by rule or license.

3.5 Administrative Actions

3.5.1 Confirmatory Action Letter (CAL)

3.5.1.1 A CAL, issued immediately following an inspection, is a letter confirming a licensee's verbal agreement to take the necessary actions to correct significant concerns regarding health and safety, security, or the environment.

3.5.1.2 Issuance of a CAL requires the concurrence of the Radioactive Materials Program Manager and Radiation Control Program Director.

3.5.1.3 Issuance of a CAL does not preclude the implementation of an escalated enforcement action, if deemed warranted by the Health Department.

3.5.2 Demand for Information: A written demand for information is issued to a licensee to enable the Department to determine whether an order or other escalated enforcement action is warranted.

3.5.3 Letters of Reprimand: Letters of Reprimand are letters addressed to individuals subject to the Department's jurisdiction, identifying a significant deficiency in their performance of licensed activities.

3.6 Enforcement Actions Involving Individuals

3.6.1 Any individual may be subject to Department enforcement action if the individual (1) deliberately causes or would have caused, if not detected, a licensee to be in violation of any regulation or order, any term, condition, or limitation of any license issued by the Department related to Department-licensed activities or (2) deliberately submits materially inaccurate or incomplete information to the Department, a licensee, an applicant for a license, or a contractor or subcontractor of a licensee or applicant for a license. The Department has authority pursuant to 18 V.S.A. §§ 125, 126, and 130 to take enforcement action against non-licensees. This includes contractors and subcontractors, holders of Department approvals (e.g., emergency and operating procedures and quality assurance program approvals) or applicants for any of them, and to employees of any of the foregoing, who knowingly provide components,

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equipment, or other goods or services that relate to a licensee's activities subject to Department regulation. The prohibitions and sanctions for any of these people who engage in deliberate misconduct or knowing submission of incomplete or inaccurate information are provided in the rule on deliberate misconduct.

3.6.2 When inspections determine that violations of Department requirements have occurred; enforcement action will be taken. Notices of Violation and orders will be used, as appropriate, for licensee failures to ensure that their contractors have programs that meet applicable requirements.

3.6.3 Notices of Violation will be issued for any violations of Vermont's Radioactive Materials Rule. Non-licensees in violation of the statute or rule shall be subject to civil penalties, impounding of materials, or injunctive relief as provided in 18 V.S.A. §§ 125, 126, and 130.

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3.7 Exercise of Discretion

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3.7.1 Notwithstanding the normal guidance contained in this policy, the Department may choose to exercise discretion and either escalate or mitigate enforcement actions within the Department's statutory authority to ensure that the resulting enforcement action takes into consideration all of the relevant circumstances of the particular case.

3.7.2 If licensee management is directly or indirectly involved in the violation, an increase in the amount of the penalty may be imposed. However, if licensee management is not involved in the violation, that information alone shall not be used to mitigate the penalty sought by the Department.

3.7.3 The Department exercises enforcement discretion to mitigate the penalty, but only if the Department is satisfied that such discretion will not adversely affect health and safety.

4.0 ENFORCEMENT PROCEDURE

4.1 Disposition of Inspection Findings

4.1.1 Determination of Severity Level: Determination of the severity level of a violation requires consideration to be given to the seriousness of the regulatory requirement violated and the deliberate and/or repetitive nature of the violation. In determining the severity level of a violation involving deliberate misconduct, consideration should be given to the position and responsibilities of the person(s) involved, the significance of the underlying violation, the intent of the violator(s), and any economic advantage gained. If the licensee refuses to correct a minor violation in a reasonable time such that it continues, then the resulting violation should

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be assigned to at least Severity Level IV. Upon conclusion of an inspection, staff inspection personnel shall review the preliminary findings and determine which of the following were observed:

- No Violations
- Any Severity Level IV Violations—without careless disregard
- Any Severity Level IV Violations—careless disregard and/or repetitive
- Any Severity Level III Violations – careless disregard and repetitive
- Any Severity Level II Violations – deliberate misconduct
- Any Severity Level I Violations – deliberate misconduct and repetitive

4.1.1.1 No Violations or Severity Level IV Violations without careless disregard: If inspection findings result in no violations, no Severity Level IV violations with careless disregard or violations that have been addressed by the licensee, then inspection personnel shall issue to the licensee, a Department Inspection Form 591M or a Department letter documenting the clean inspection. If inspection findings result in any Severity Level IV violations that are not addressed by the licensee and/or that have not been corrected, inspection personnel should issue to the licensee a Department letter and/or a Notice of Violation.

4.1.1.2 Severity Level IV Violations with careless disregard or where violations are repetitive: If inspection findings result in any Severity Level IV violations with careless disregard or where violations are repetitive, then inspection personnel shall upgrade the violation to Severity level III and issue a Notice of Violation to the licensee.

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4.1.1.3 Severity Level III violations: If inspection findings result in **any Severity Level III violations**, then inspection personnel shall refer the finding to the RMPM for review to determine what escalated enforcement action that is warranted.

4.1.1.4 Severity Level III, II or I Violations: If inspection findings result in any Severity Level III, Severity Level II, or Severity Level I violations, then inspection personnel shall, as soon as possible, refer the findings to the RMPM. The RMPM shall confer with the

Radiation Control Program Director for determining the extent of escalated enforcement action, and whether a pre-decisional enforcement conference is warranted.

4.2 Emergency Orders

If, during an inspection or during review of inspection findings, an emergency affecting public health and safety or affecting the environment is determined to exist, then the Department shall immediately issue an order to sequester or impound the licensed radiation source(s) as necessary to mitigate the emergency.

4.3 Escalated Enforcement

4.3.1 The Health Department considers violations categorized at Severity Level I, II, or III to be of significant regulatory concern.

4.3.2 If the application of the enforcement procedure of this RMPP does not result in an appropriate sanction, with the approval of the RMPM and in consultation with the Radiation Control Program Director, and the Department Legal Division has warranted, the Department may apply its full enforcement authority; this may include escalating civil penalties and/or issuing appropriate orders.

4.3.3 A follow-up inspection must be conducted within 6 months of receipt of a licensee's corrective action (s) following an escalated enforcement action.

5.0 ATTACHMENTS TO RMPP 2.5

2.5-1 **Examples of Violations That May Be Cited on a Clear Inspection**

2.5-2 **Examples of Severity Level I - Level IV Violations**

Attachment 2.5-1

Examples of Violations That May Be Cited on a Clear Inspection

1. Inventories not performed at the required frequency on one or two occasions that did not result in any consequences (e.g. lost material).

2. Licensee observed eating, drinking, etc. in laboratories where less than or equal to megabecquerel (microcurie) quantities of unsealed radioactive materials are stored, but not being used (a survey should be performed to confirm the absence of contamination).

3. Failure to calibrate survey instruments, alarm rate meters, or pocket dosimeters at the required frequency on one or two occasions.

4. Failure to use a dedicated check source before each use of a survey instrument, on one or two occasions.

5. Failure to perform routine surveys (e.g. radiation, contamination, airflow checks, or fume hood monitoring) at the required frequency on a few occasions.

6. Failures of the radiation safety committee to meet at the required frequency on one or two occasions.

7. Failure to have required attendees at all radiation safety committee meetings.

8. Rare failures to exchange personnel dosimetry at the required frequency, but with no loss of dosimetry data.

9. Failure to have properly prepared shipping papers.

10. Failure to include the emergency phone number, reportable quantity (RQ) designation, or SI units on shipping papers.

11. Occasional failure to meet all transportation requirements of 49 CFR.

12. Users of radioactive materials are adequately trained, but not as stated in the license tie-down conditions.

13. On rare occasions, dose calibrator tests are not performed as required.

14. Isolated cases of missed or late leak tests.

15. Failure to appropriately post areas where radioactive materials are stored or used.

Note: This list is not all-inclusive. Most Severity Level IV violations may be cited on Department Form 591M if they are not repetitive and are corrected within 30 days.

Attachment 2.5-2 Examples of Severity Level I - Level IV Violations

SL I violations (examples)

1. The loss of control over licensed activities, including chemical processes that are integral to the licensed or certified activity, resulting in serious injury or loss of life.

2. A system designed to prevent or mitigate a serious safety event is inoperable when required to perform its design function, and this results in serious injury or loss of life.

3. Failure to use a properly prepared written directive as required by 10 CFR 35.40, "Written Directives," or failure to develop, implement, or maintain procedures for administrations requiring a written directive as required by 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," results in serious injury or loss of life.

4. Failure to have or to follow written operating procedures as required by 10 CFR 36.53, "Operating and Emergency Procedures," results in a serious injury or loss of life.

SL II violations (examples)

1. The loss of control over licensed activities, including chemical processes that are integral to the licensed or certified activity, results in the substantial potential for a significant injury or loss of life, whether or not radioactive material is released.

2. A system designed to prevent or mitigate a serious safety event is inoperable when required to perform its design function.

3. A substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive, such as a failure of the licensee's procedures to address one or more of the elements in 10 CFR 35.40 or 10 CFR 35.41, or a failure to train personnel in those procedures, results in a medical event.

4. Failure to have or to follow written operating procedures as required by 10 CFR 36.53 results in a substantial potential (e.g., an event did not occur, but no barriers, neither procedural nor system, including interlocks, would have prevented it, and the event was not highly unlikely to occur) for a serious injury or death.

SL III violations (examples)

1. A system designed to prevent or mitigate a serious safety event has one of the following characteristics:

- It is unable to perform its intended function under certain conditions (e.g., a safety system is not operable unless the required backup power is available), or

- It is outside design specifications to the extent that a detailed evaluation would be required to determine its operability.

2. A programmatic failure occurs to implement written directives or procedures for administrations requiring a written directive, such as the following:

- A licensee's procedures fail to address one or more of the elements in 10 CFR 35.40 or 10 CFR 35.41,
- A licensee fails to train personnel in procedures for administrations requiring a written directive,
- A non-isolated failure occurs to use and follow written directives or procedures for administrations requiring a written directive; or
- A licensee fails to have procedures or requirements for written directives or fails to have procedures for administrations that require written directives.

3. Except as provided for in section 6.3.d.10 of the policy, a licensee fails to secure a portable gauge as required by 10 CFR 30.34(i).

4. A significant failure to implement the requirements of 10 CFR Part 34, "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations," during radiographic operations includes, but is not limited to, the following:

- During radiographic operations at a location other than a permanent radiographic installation, a licensee fails to have present a radiographer and at least one additional radiographer or qualified individual,
- A licensee fails, during radiographic operations, to use radiographic equipment, radiation survey instruments, or personnel monitoring devices as required by 10 CFR Part 34, or
- During radiographic operations, a failure to stop work occurs, after a pocket dosimeter is found to have gone off-scale or after an electronic dosimeter reads greater than 200 millirem (mrem), and before a determination is made of the individual's actual radiation exposure.

5. An unqualified person conducts licensed activities. The unqualified person is characterized by either of the following:

- lacking adequate qualifications, experience, or training to safely conduct activities, or
- lacking the required certification or training for positions such as radiographer; authorized user under 10 CFR Part 35, "Medical Use of Byproduct Material"; or irradiator operator under 10 CFR 36.51, "Training."

6. Licensed material is used on humans where such use is not authorized.

7. A licensee authorizes the release from its control of an individual who does not meet the release criteria in 10 CFR 35.75, "Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material."

8. An individual without supervision operates an irradiator when the individual has not been trained as required by 10 CFR 36.51.

9. A programmatic failure occurs to have and follow written operating procedures as required by 10 CFR 36.53.

10. A programmatic failure occurs to perform inspection and maintenance checks as required by 10 CFR 36.61, "Inspection and Maintenance."

11. A licensee fails to seek required Department approval before the implementation of a significant change in licensed activities that has radiological or programmatic significance, such as the following:

- a change in ownership,
- a change in the location where licensed activities are being conducted or where licensed material is being stored,
- an increase in the quantity or type of radioactive material being processed or used that has radiological significance, or
- a change in program status with regard to the RSO named on its license (e.g., licensee fails to have an RSO; licensee appoints an unqualified individual as RSO).

12. Failures occur involving decommissioning requirements, such as the following:

- a significant failure to meet decommissioning as required by regulation or license condition, or
- failure to meet required schedules without adequate justification.

SL IV violations (examples)

1. A licensee fails to use a properly prepared written directive as required by 10 CFR 35.40, or fails to develop, implement, or maintain procedures for administrations requiring a written directive as required by 10 CFR 35.41, whether or not a medical event occurs, provided that the failures are characterized by all of the following:

- are isolated,
- do not demonstrate programmatic weaknesses in implementation,
- have limited consequences if a medical event is involved.

2. A licensee fails to keep the records required by 10 CFR 35.2040, "Records of Written Directives," and 10 CFR 35.2041, "Records for Procedures for Administrations Requiring a Written Directive."

3. A licensee fails to implement procedures including, but not limited to, recordkeeping, surveys, and inventories.

4. A licensee fails to comply with the U.S. Department of Transportation requirement to provide hazardous material (HAZMAT) employee training as required by 10 CFR 71.5(a).

5. There is an isolated failure to have and to follow written operating procedures as required by 10 CFR 36.53.

6. A licensee fails to document the required certification or training for positions such as radiographer, authorized user under 10 CFR Part 35, or irradiator operator under 10 CFR 36.51.

7. A licensee fails to seek required Department approval before the implementation of a change in ownership that results in little or no adverse impact on radiological or programmatic activities or on the Department's ability to inspect licensed activities, such that the locations and types of activities are unaffected by the unauthorized license transfer.

8. A licensee fails to seek required Department approval prior to replacement of the RSO, where the RSO was evaluated as qualified.

9. A licensee fails to seek Department approval, when required, before changing the location where licensed activities are being conducted or where licensed material is being stored that has little or no radiological or programmatic significance, and all other safety and security requirements have been met.

10. A licensee fails to secure a portable gauge as required by 10 CFR 30.34(i), whenever the gauge is not under the control and constant surveillance of the licensee, where one level of physical control existed and there was no actual loss of material, and that failure is not repetitive.