Radioactive Materials Control Program Procedure 4.1, Revision 0

Enforcement

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1.0 Introduction

1.1 Purpose

The State of Indiana's Radioactive Materials Control Program (RMCP) Enforcement Policy supports the State's mission to ensure adequate protection of public health and safety and protect the environment. Adequate protection is presumptively assured by compliance with RMCP requirements. Compliance with RMCP requirements, including regulations, technical specifications, license conditions, and orders, provides reasonably assurance to the State of Indiana and the public that safety and security are being maintained. The application of this Policy ensures that associated enforcement actions properly reflect the safety or security significance of such violations. Consistent with the objective, the Enforcement Policy endeavors to do the following:

A. Deter noncompliance by emphasizing the importance of compliance with RMCP requirements.
B. Encourage prompt identification and prompt comprehensive correction of violations of RMCP requirements.

1.2 Applicability

The RMCP Enforcement Policy applies to all RMCP licensees and applicants, to various categories of non-licensees, and to individual employees of licensed and non-licensed entities involved in RMCP-regulated activities. These include, but are not limited to the following:

a. Organizations and individuals holding RMPC licenses
b. License applicants
c. Contractors and subcontractors to RMPC licensees
d. Vendors supplying safety-related components to RMCP licensees
e. Employees of any of the above

Not all RMCP requirements apply to all of the categories listed above; however, the Department will use the Enforcement Policy, as appropriate, to address violations of RMCP requirements.

It is RMCP policy to hold licensees and applicants responsible for the acts of their employees, contractors, or vendors and their employees, and the RMCP may cite the licensee or applicant for violations committed by its employees, contractors, or vendors and their employees.

The RMCP may use the term "licensee" in this Policy to generally refer not only to licensees, but also applicants.

1.3 Authority

The RMCP derives its authority to license and regulate the use of radioactive materials within the State of Indiana from §10-19-13. The RMCP's enforcement program is governed by the regulations outlined in IAC 290 3.

1.4 References

- NUREG-1600, General Statement of Policy and Procedures for NRC Enforcement Action
- NRC Enforcement Manual
- NRC Enforcement Policy
- RMCP Enforcement Manual
- Indiana Radioactive Materials Rules

2.0 Adequate Protection Standard

Adequate protection of public health and safety and protection of the environment are the RMCP's fundamental regulatory objectives. Compliance with RMCP requirements plays a critical role in giving the RMCP and the public confidence that safety and security are being maintained. While adequate protection is presumptively assured by compliance with RMCP requirements, circumstances may arise where new information reveals that an unforeseen hazard or security issue or security event exists or that a substantially greater protection exists for a known hazard to occur. In such situations, the RMCP has the statutory authority to require actions by the licensees, their employees and contractors above and beyond existing regulations to maintain the level of protection necessary to avoid undue risk to public health and safety, and to ensure security of materials.

The RMCP also has the authority to exercise discretion to permit continued operations – despite the existence of a noncompliance – where the noncompliance is not significant from a risk perspective and does not, in the particular circumstances, pose an undue risk to public health and safety. When noncompliance with RMCP requirements occurs, the RMCP must evaluate the degree of risk posed by that noncompliance to determine whether immediate action is required. If the RMCP determines that the noncompliance itself is of such safety significance that adequate protection is no longer provided, or that the noncompliance was caused by a failure of licensee control so significant that it calls into questions the licensee's ability to ensure adequate protection, the RMCP may demand immediate action, up to and including a shutdown or suspension of licensed activities. Based on the RMCP's evaluation of noncompliance, the appropriate action could include refraining from taking any action, taking specific enforcement action including the use of civil penalties, issuing Orders, or providing input to other regulatory actions or assessments, such as increased RMCP oversight of a licensee's activities. Since some requirements are more important to safety than others, the RMCP

endeavors to use a risk-informed approach when applying RMCP resources to the oversight of licensed activities, including enforcement activities.

3.0 Responsibilities

3.1 Health Physicist (HP)

The HP conducts routine inspections and special inspections in accordance with applicable procedures, rules, and instructions. Once the inspection is complete, the HP will categorize and document any apparent violation of the RMCP rules, orders, or license conditions observed during the inspection. The HP will provide the complete inspection report, with any cited violations, to the S/HP or RCPD for review.

3.2 Senior Health Physicist (S/HP)

The S/HP will review all inspection reports or delegate this review to another qualified HP. The S/HP will also conduct routine inspections and special inspections in accordance with appliable procedures, rules, and instructions. If the S/HP is the principal inspector during an inspection, the S/HP will submit their inspection reports to another S/HP or the RCPD for review. Once the inspection report is finalized, the S/HP will provide any violations to the RMPD for review.

3.3 Radiation Control Program Director (RCPD)

The RCPD, or their designee, will finalize all inspection reports. If violations have been reported, the RCPD will determine the next steps as outlined below:

a. If the inspection report indicates no violation or SL IV violations that have been addressed by the licensee and adequate corrective actions have been implemented, the RCPD will issue an Indiana Inspection Form 591M or a Department letter documenting a closed inspection.
b. If the proposed violation is SL IV and the licensee has not addressed and/or corrected the violation, the RCPD may issue the Notice of Violation, as designated by the State Fire Marshal.
c. If the proposed violation is greater than SL IV, the RCPD will present a case for the violation and a recommendation of enforcement to the Radioactive Control Program Enforcement Committee (RCPEC).

Once the RCPEC has determined the appropriate violation and enforcement actions, the RCPD will work with the IDHS General Council to conduct pre-decisional conferences, and issue the violation(s), as appropriate.

3.4 Radioactive Control Program Enforcement Committee (RCPEC)

The RCPEC consists of the Executive Director of IDHS, IDHS Chief of Staff, Indiana State Fire Marshal, IDHS General Council, and IDHS Hazmat Senior Management. RCPM staff will provide technical assistance to the RCPEC.

The RCPD will present all proposed violations greater than SL IV to the RCPEC for review. The RCPEC will determine the appropriate severity level, enforcement action, civil penalty, and/or order; however, the Indiana State Fire Marshal has the ultimate authority to approve or issue all enforcement actions.

4.0 RMCP Enforcement Process

The RMCP's enforcement process has the following basic steps.

a. First, violations must be identified.
b. Next, the RMCP must assess the severity or significance of the violations.
c. Finally, the RMCP must disposition the violation.

Throughout the process, an organization or individual subject to a RMCP enforcement action has multiple opportunities to provide input.

4.1 Identification of Violations

The enforcement process begins with the identification of violations, either through RMCP inspection or investigation, a licensee report or substantiation of an allegation.

All violations are subject to consideration for civil enforcement action; some violations may also be considered for criminal prosecution by the Office of the Attorney General. After a potential violation is identified, it is assessed in accordance with this policy. The RMCP's enforcement assessment process is fact driven, performance based, and when appropriate and possible, risk informed. The RMCP reviews each case being considered for enforcement action on its own merits to ensure that the severity of a violation is characterized at the level appropriate to the safety and security significance of the particular violation.

4.2 Assessment of Violations

After a violation is identified, the RMCP assesses its severity or significance (both actual and potential). Under traditional enforcement, the severity level (SL) assigned to the violation generally reflects the assessment of the significance of a violation.

4.2.1 Factors Affecting Assessment of Violations

In determining the appropriate enforcement response to a violation, the RMCP considers the four specific factors discussed below. Whenever possible, the RMCP uses risk information in assessing the safety or security significance of violations and assigning severity levels. A higher severity level may be warranted for violations that have greater risk, safety, or security significance, while a lower severity level may be appropriate for issues that have lower risk, safety, or security significance. Duration of the violation is also an appropriate consideration in assessing the significance of the violation.

a. Whether the violation resulted in safety or security consequences. In evaluation actual consequences, the RMCP considers issues such as whether the violation resulted in the onsite or offsite releases of radiation or radiation exposures exceeding 290 IAC 3-2-2 (10 CFR Part 20) regulatory limits, loss of significant safety barriers, loss of control of radioactive materials or radiological emergency, or whether the security system did not function as required and, as a result of the failure, a significant event or an event that resulted in an act of radiological sabotage occurred.

b. Whether the violation had potential safety or security consequences. In evaluating potential consequences, the RMCP considers whether the violation created a credible accident, security failure, or exposure scenario that could potentially have significant actual consequences.

c. Whether the violation impacted the ability of the RMCP to perform its regulatory oversight function. The RMCP considers the safety and security implications of noncompliance that may affect the RMCP's ability to carry out its statutory mission. These types of violations include failure to provide complete and accurate information; failures to receive prior RMCP approval for changes in licensed activities, when required; and failure to comply with reporting requirements, etc. Even inadvertent reporting failures are important because many of the surveillance, quality control and auditing systems on which both the RMCP and its licensees rely to monitor compliance with safety standards are based primarily on complete, accurate, and timely recordkeeping and reporting. The existence of a regulatory process violation does not automatically mean that the issue is significant to safety or security. In determining the significance of a violation, the RMCP will consider appropriate factors for the particular regulatory process violation. These factors may include the significance of the underlying issue, whether the failure actually impeded or influenced regulatory action, the level of individuals involved in the failure and the

reason why the failure occurred given their position and training, and whether the failure invalidates the licensing basis.

The severity level of a violation involving the failure to make a required report to the RMCP will depend on the significance of and the circumstances surrounding the matter that should have been reported. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances. The RMCP will not normally cite a licensee for a failure to report a condition or event unless the licensee was aware of the condition or event that it failed to report. On the other hand, the Department will normally cite a licensee for a failure to report a condition or event if the licensee knew of the information to be reported and did not recognize that it was required to make a report.

d. Whether the violation involved willfulness. Willful violations are of particular concern because the RMCP's regulatory program is based on licensees and their contractors, employees, and agents acting with integrity and communicating with candor. The RMCP cannot tolerate willful violations. Therefore, a violation may be considered more significant than the underlying noncompliance if it includes indications of willfulness. Violations with willful aspects will typically be considered for escalated enforcement. The term "willfulness" as used in this policy refers to conduct involving either a careless disregard for requirements or a deliberate violation of requirements or falsification of information. In determining the significance of a violation involving willfulness, the RMCP will consider such factors as the position, training, experience level, and responsibilities of the person involved in the violation, the significance of any underlying violations, the intent of the violator, and the economic or other advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in the significance assessment will depend on the circumstances of the violation. However, if a licensee refuses to correct a minor violation within a reasonable time such that it willfully continues, the violation should be considered more than minor. Licensees are expected to take significant remedial action in responding to willful violations commensurate with the circumstances, such that the action reflects the seriousness of the violation, thereby creating a deterrent effect within the licensee's organization.

4.2.2 Traditional Enforcement

Under its traditional enforcement process, the RMCP assesses significance by assigning a severity level to all violation by those subject to the RMCP's

enforcement authority as defined in Section 1.2, "Applicability of the Enforcement Policy." Recognizing that the regulation of radiological activities in many cases does not lend itself to a mechanistic treatment, judgement and discretion must be exercised in determining the severity levels of the violations and the appropriate enforcement sanctions. This judgement and discretion include the decision to issue an NOV, or to propose or impose a civil penalty and the amount of this penalty, after considering the general principles of this statement of policy and the significance of the violations, as well as the surrounding circumstances.

Severity level designations reflect different degrees of significance depending on the activity area in which the severity level is designated.

- Severity level I (SL 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 involved systems failing when called on to prevent or mitigate a serious safety or security event).
- Severity level II (SL II) violation 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 serious safety or security event).
- Severity level III (SL 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 (SL IV) violation 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., violation that created the potential of more than minor safety or security consequences).
- Minor Violations are those that are less significant than a SL IV violation. Minor violations do not warrant enforcement actions; however, minor violations must be corrected. If the licensee has already identified the violation and corrective actions have been implemented, and the RMCP feels the corrective actions are adequate, minor violations can be documented as observations.

Examples of violations and the corresponding severity level can be found in the "NRC Enforcement Policy"

4.2.3 Escalated Enforcement Violations

If the RMCP determines that a violation, or group of violations, exceed a Severity Level IV, the RMCP may consider escalated enforcement action. This escalation will be determined based on several factors including but not limited to severity, security, frequency, and willfulness. Violations that may result in escalated enforcement include but are not limited to moderate or significant safety or security consequences,

If escalated enforcement is recommended, the RMCP and facility will proceed as outlined in 2.4.

If a violation requires immediate action to protect public health and safety or the environment, the RCPD, in consultation with Office of General Counsel, may process and issue a cease-and-desist order.

4.3 Disposition

4.3.1 Notice of Violations

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

4.3.2 Civil Penalty

A civil penalty is a monetary penalty that the RMPC may impose for violations of any RMCP rule adopted under Indiana Code 10-19-12, or Order issued by the RMCP. Based on the circumstance of a specific case, the RMCP may increase a civil penalty where application of the guidance in this Policy would normally result in a zero penalty or a base civil penalty, to ensure that the proposed civil penalty reflects the safety significance of the case. The RMCP will generally impose graduated civil penalties taking into account the gravity of the violation as the primary consideration and the ability to pay as a secondary consideration. Thus, operations involving greater radiological material inventories, significantly higher consequences

resulting from a release or exposure to radioactive material and consequences to the public and workers receive higher civil penalties. Regarding the secondary factor of the ability of various classes of licensees to pay the civil penalties, it is not the RMCP's intention that the economic impact of a civil penalty be so severe that it adversely affects a licensee's ability to safely conduct license activities or puts a licensee out of business (Orders, rather than civil penalties, are used when the RCMP's intent is to suspend or terminate licensed activities).

Civil penalties are considered for all SL I, II, and III violations. The civil penalty assessment process described in this section should be followed to determine the appropriateness of a civil penalty for any escalated enforcement action.

The RMCP may exercise discretion and assess a separate violation and attendant civil penalty up to the statutory limit for each day the violation continues. The RMCP may exercise this discretion when a licensee was aware of a violation of at least moderate significance (i.e., at least a SL III) and had a clear opportunity to prevent, identify, and correct the violation but failed to do so.

In evaluating whether daily civil penalties are appropriate, the RMCP will consider such factors as whether the violation resulted in actual consequences to public health and safety, the safety significance of the violation, whether the violation was repetitive because of inadequate corrective action, the degree of management culpability in allowing the violation to continue or in not precluding it, the responsiveness of the licensee once the violation and its significance were identified and understood, whether the continuing violation was willful, and the duration of the violation. These evaluation factors are not necessarily of equal significance; therefore, for each case, the RMCP will weigh the relative importance of each contributing factor, as well as any extenuating circumstances, to determine whether it is appropriate to use daily civil penalties.

The RMCP will consider civil penalties for violations associated with loss of regulated material. The loss of RMCP-regulated material is a significant regulatory and security concern because of the potential unauthorized possession or use of the material and because of the potential for overexposure to members of the public from its misuse. Such violations may include but are not limited to the loss, abandonment, improper transfer, or improper disposal of a device, source, or other form of regulated material.

For cases involving the willful failure to either file for reciprocity or obtain a RMCP specific license, the RMCP will consider a civil penalty to deter noncompliance for economic benefit. In cases where there is any indication that the violation was committed for economic gain, the RMCP may exercise discretion and impose a civil penalty.

4.3.3 Orders

An Order is a written RMCP directive to modify, suspend, or revoke a license; to cease and desist from a given practice or activity; or to take such other action as may be proper. Orders may be made immediately effective, without prior opportunity for a hearing, whenever the RMCP determines that the public health, safety, interest, or security so requires, or if the violation or conduct causing the violation is willful.

4.4 Participation in the Enforcement Process

Before making a final enforcement decision in cases where the RMCP is considering taking escalated enforcement action, the RMCP will typically offer the organization or individual subject to the enforcement action a conference with the RMCP to present facts relevant to the assessment and disposition of the apparent violation. The RMCP may also request a conference if additional information is needed to make a determination relevant to the assessment and disposition of the apparent violations.

4.4.1 Pre-decisional Enforcement Conference

A pre-decisional enforcement conference (PEC) is a conference held with a licensee for violation assessed using traditional enforcement. The purpose of the PEC is to obtain information from the licensee to assist the RMCP in determining whether an enforcement action is necessary and, if so, the appropriate enforcement action. The PEC focuses on areas such as (1) a common understanding of the facts, root causes, and missed opportunities associated with the apparent violation and (2) a common understanding of the corrective actions taken or planned. If held, a PEC is normally the final step in the RMCP's fact-finding process before making an enforcement decision.

When the RMCP determines that there is a violation for which escalated enforcement action appears warranted, the Department normally offers the licensee the opportunity to attend a PEC or provide a written response to the apparent violation, or both, before the RMCP makes an enforcement decision. If the RMCP concludes that it has sufficient information to make an informed enforcement decision involving a licensee, the RMCP will notify the licensee that the PEC does not appear to be necessary, and unless the

licensee specifically requests a PEC, one will not be held. The RMCP may specifically request a PEC if it needs additional information before making a final enforcement decision. If the RMCP does not request a PEC or if the licensee does not accept the RMCP's offer to attend a PEC, the licensee may choose to respond in writing to a documented apparent violation before the RMCP takes enforcement action. To the extent practicable, the RMCP will consider the licensee's response before taking enforcement action.

4.4.2 Alternative Dispute Resolution

This Agreement shall be construed in accordance with the laws of the State of Indiana. Any dispute, controversy, or claim arising out of or relating in any way to this Agreement including without limitation any dispute concerning the construction, validity, interpretation, enforceability, or breach of the Agreement, shall require the parties to first meet within thirty (30) days of a party's request to discuss and remedy the dispute. If the parties are not able to resolve the dispute litigation may then be conducted following the normal procedure.

5.0 Enforcement Actions Involving Individuals

Any individual may be subject to RMCP 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, or any term, condition, or limitation of any license issued by the State of Indiana related to RMCP-licensed activities or (2) deliberately submits materially inaccurate or incomplete information to the RMCP, a licensee, an applicant or a licensee, or a contractor or subcontractor of a licensee or applicant for a license.

The Department will normally take enforcement actions against non-licensed individuals only in cases involving deliberate misconduct by the non-licensed individual, in cases involving a lack of reasonable assurance and in cases in which an individual violates any requirement directly imposed on him or her.

The RMCP considers enforcement actions against individuals to be significant actions that will be closely evaluated and judiciously applied. Typically, the RMCP will take an enforcement action involving an individual, either licensed or non-licensed, only when the violation has actual or potential safety or security significance. Generally, before taking enforcement action against an individual, the RMP will seek to gather information to determine whether an Order or other enforcement action should be issued. The Department may gather such information by conducting a PEC, or by requesting a written response from the individual. If the violation was deliberate, the individual may also be provided the opportunity to address the apparent violations during the Alternative Dispute Resolution process. The exact nature of the opportunity to address the apparent violation will depend on the circumstances of the case, including the significance of the issue, the enforcement sanction that the RMCP is

contemplating, and whether the individual has already had an opportunity to respond to the apparent violation.

Since it is RMCP policy to hold licensees responsible for the acts of their employees and contractors, in most cases, the RMCP will cite the licensee for violations committed by their employees and contractors. Violations with a significance that would typically warrant escalated enforcement action against the licensee may warrant an enforcement action against the individual. Typically, the RMCP will not take enforcement action against the employee or contractor if failures of licensee management are responsible for the individual's improper actions. In deciding whether to issue enforcement actions both to a licensee and a non-licensed individual, the RMCP will make decisions on a case-by-case basis.

5.1 Considerations in Determining Enforcement Actions Involving Individuals

The RMCP recognizes that decisions regarding enforcement actions against individuals will have to be made on a case-by-case basis. The RMCP may propose an enforcement action or refrain from taking an enforcement action after considering all the relevant circumstances of each case.

The primary factors considered by the RMCP in considering whether to take action or what action to take are (1) the significance of the underlying violation or technical issue and (2) the individual's position within the organization.

Other factors include, but are not limited to, whether the violation was the result of deliberate misconduct, the benefit to the wrongdoer, the degree of management responsibility or culpability, and the attitude of the wrongdoer.