



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713**

September 22, 2021

EA-21-113

Erin Kern, Director
Shore Readiness Division (N46)
Department of the Navy
2000 Navy Pentagon
Washington, DC 20350

**SUBJECT: THE DEPARTMENT OF THE NAVY NRC INSPECTION REPORT NO.
03029462/2021006 AND APPARENT VIOLATIONS**

Dear Ms. Kern:

On June 21 through June 24, 2021, the U.S Nuclear Regulatory Commission (NRC) conducted a routine team inspection of your activities performed under your NRC Master Materials License (MML). The inspection was an examination of your licensed activities as they relate to radiation safety, compliance with the Commission's regulations, and the conditions in your license. The enclosed inspection report presents the results of this inspection. The inspectors discussed the preliminary inspection findings with you at the conclusion of the on-site portion of the inspection on June 24, 2021. A final exit briefing was conducted (telephonically) with you and members of your staff on September 7, 2021.

Based on the results of this inspection, apparent violations (AVs) were identified, which are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The AVs involve the failure by an MML permittee to comply with 10 CFR 73.67(f) and also the failure by the Navy MML to notify the NRC Region I project manager immediately when the Navy Radiation Safety Committee (NRSC) identified a permittee violation of NRC regulations or MML or NRSC permit requirements that could result in escalated enforcement (i.e., Severity Levels I, II, and III) under the Policy as described in the letter of understanding (LOU) between the NRC and the Navy for the Navy MML. The circumstances surrounding these AVs, the significance of the issues, and the need for lasting and effective corrective actions were discussed with your staff during the exit meeting on September 7, 2021.

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. Please be advised that the number and characterization of the AVs

Enclosure 1 contains Sensitive Unclassified Non-Safeguards Information. Upon separation, this cover letter is DECONTROLLED.

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described in the enclosed inspection report may change as a result of further review. You will be advised by separate correspondence of the results of our deliberations on this matter.

Before the NRC makes its enforcement decision, we are providing you the opportunity to offer your perspective on this matter and provide any information you believe the NRC should take into consideration. You can elect to provide such information by either: (1) responding to the AVs addressed in this inspection report within 30 days of the date of this letter, (2) requesting a Pre-decisional Enforcement Conference (PEC), or (3) accepting the AVs as characterized in this letter and its enclosure. Please contact Christopher Cahill, Chief, Commercial, Industrial, R&D, and Academic Branch, NRC Region I, at 610-337-5108 or christopher.cahill@nrc.gov within **10 days** of the date of this letter to notify the NRC which of the above options you choose. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

If you choose to provide a written response you should provide the following information for each AV: (1) the reasons for the AV or, if contested, the basis for disputing the AV; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. You should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalties for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action", may be helpful.

The written response should be sent to the NRC within **30 days** of the date of this letter. The NRC recognizes that many licensees have been impacted by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19). Consequently, you may request an extension of time to submit the response by contacting Christopher Cahill at 610-337-5108 or christopher.cahill@nrc.gov. An extension request should explain the basis for the request and should specify the amount of additional time being requested. An extension request must be submitted no later than 20 days from the date of this letter. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. You should clearly mark the response as a "Response to Apparent Violations in NRC Inspection Report No. 03029462/2021001; EA-21-113," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to Blake Welling, Director, Division of Radiological Safety and Security, NRC Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406.

If you choose to request a PEC, the meeting will be held within 30 days of the date of this letter, although this timeframe may be extended due to impacts from COVID-19. The conference will afford you the opportunity to provide your perspective on this matter, including the significance, cause, and corrective actions, as well as any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the PEC may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The PEC would be open for public observation and the NRC would issue a press release to announce the time and date of the conference.

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In accordance with 10 CFR 2.390 of the NRC's Rules of Practice, a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

If you have any questions concerning this matter, please contact Steve Shaffer of my staff at steve.shaffer@nrc.gov.

Sincerely,

Blake D. Welling, Director
Division of Radiological Safety and Security

Enclosures:

1. NRC Inspection Report No. 03029462/2021006
2. NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action"

Docket No. 03029462

License No. 45-23645-01NA

cc w/Encls: Capt. Anthony Williams, Executive Secretary, NRSC
Erik J. Abkemeier, Director, Radiation Programs Division

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THE DEPARTMENT OF THE NAVY INSPECTION REPORT NO. 03029462/2021001 DATED SEPTEMBER 22, 2021

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NOTE: The following information is an updated excerpt from NRC Information Notice 96-28 issued in 1996.

NRC INFORMATION NOTICE 96-28

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO
DEVELOPMENT AND IMPLEMENTATION OF
CORRECTIVE ACTION

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VI.A of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as

Enclosure 2

required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence.

In some cases, such violations are documented on Form 591 (for materials licensees) which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional enforcement conference may be held to discuss those actions.

The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation.
Typically, such reviews include:
 - Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.
 - Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that

may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

- Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the current requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide an record that can be audited and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns and prevent recurrence of the violation.

It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, immediate corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?

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2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?
3. Have precursor events been considered and factored into the corrective actions?
4. In the event of loss of radioactive material, should security of radioactive material be enhanced?
5. Has your staff been adequately trained on the applicable requirements?
6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?
7. Has your staff been notified of the violation and of the applicable corrective action?
8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?
9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?
10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?
11. Is a system in place for keeping abreast of new or modified NRC requirements?
12. Does your staff appreciate the need to consider safety in approaching daily assignments?
13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?
14. Have work hours affected the employees' ability to safely perform the job?
15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?
16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?
17. Has management established a work environment that encourages employees to raise safety and compliance concerns?
18. Has management placed a premium on production over compliance and safety? Does

management demonstrate a commitment to compliance and safety?

19. Has management communicated its expectations for safety and compliance?
20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

Robert C. Pierson, Director
Division of Fuel Cycle Safety and Safeguards
Office of Nuclear Material Safety
and Safeguards

Donald A. Cool, Director
Division of Industrial and Medical Nuclear
Office of Nuclear Material Safety and
and Safeguards

Technical contacts: (Updated as of November 22, 2005)

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