



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE RD, SUITE 102
KING OF PRUSSIA, PA 19406-1415

October 5, 2022

EA-22-009

Dr. Elizabeth A. Mackey
Chief Safety Officer
Director, Office of Safety, Health,
and Environment
U.S. Department of Commerce
National Institute of Standards
and Technology
100 Bureau Drive
Gaithersburg, MD 20899

SUBJECT: NOTICE OF VIOLATION – U.S. DEPARTMENT OF COMMERCE, NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY – NRC INVESTIGATION REPORT I-2022-001; NRC INSPECTION REPORT NO. 07000398/2021003

Dear Dr. Mackey:

This letter refers to the inspection and investigation conducted by the U.S. Nuclear Regulatory Commission (NRC) at the U.S. Department of Commerce – National Institute of Standards and Technology (NIST) facility in Gaithersburg, Maryland (Investigation Report I-2022-001; Inspection Report 07000398/2021003). The inspection was conducted from September 28, 2021, through October 1, 2021, and October 12, 2021, through October 15, 2021, with continued in-office review through June 15, 2022. The purpose of the inspection was to review activities conducted under NIST's license leading up to and in response to a September 22, 2021, radium-223 (Ra-223) release and resulting personnel contamination event. The inspection was also conducted to confirm compliance with the NRC rules, regulations, and the conditions of the license. In addition to the inspection, an investigation of NIST by the NRC Office of Investigations was initiated on October 6, 2021, and completed on December 22, 2021. The purpose of the investigation was to determine whether a senior researcher designated as a Source Custodian under a contract with NIST willfully delayed notification to the Gaithersburg Radiation Safety Division (GRSD) about the Ra-223 release and the resulting personnel contamination.

Based on the information developed during the inspection and investigation, as well as the information that you provided during an August 10, 2022, pre-decisional enforcement conference (PEC) with NRC staff, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding it were described in detail in the subject inspection report and the investigation summary that were provided in our letter dated June 27, 2022 (ML22115A166).¹

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

The violation involves the failure to make certain that materials were used in accordance with the terms and conditions of NIST's NRC License Number SNM-362, in that, the contract Source Custodian did not ensure work was done in compliance with appropriate instructions. Namely, during the preparation of Ra-223 standards on September 22, 2021, there was a release of radioactivity. However, the Source Custodian did not evacuate the laboratory room closing the door behind, prevent entry by other personnel, and immediately contact GRSD, in accordance with NIST procedures. Rather, the Source Custodian attempted to decontaminate himself, the equipment, and laboratory facilities to avoid disruption to his work activities. Based on the investigation, the NRC determined that the apparent violation was the result of deliberate misconduct by the Source Custodian. Section 1.2 of the NRC Enforcement Policy states that licensees are responsible for the acts of their employees and the NRC may cite licensees for violations committed by their employees.

In a letter dated June 27, 2022, we provided the inspection report and we offered you the opportunity to address the apparent violation identified in the report by either attending a PEC or by providing a written response before we made our final enforcement decision. Subsequently, the August PEC was conducted with members of your staff to discuss the apparent violation, its significance, the root causes, and your corrective actions.

During the conference, you described that NIST conducted an incident investigation of the event and completed corrective actions based on the results of this investigation. The completed corrective actions include: (1) Evaluating lead pigs used in the flame sealing process for any potential issues that could cause spills; (2) implementing a new procedure requiring inspection of equipment at the start of every experiment and prohibiting the use of noncompliant equipment; (3) revising procedures with enhanced guidance for the use of paper liners during flame sealing; (4) enhancing Source User initial and refresher training regarding the requirement to obtain approval for deviating from operating procedures; (5) revising procedure to include technical management as part of the radiation safety department (RSD) field audit team periodically overseeing Source User activities; (6) enhancing Supervised User training to explicitly discuss incident response requirements, including notification of the RSD; (7) activating a feature on personnel contamination monitors (PCMs) to initiate an automatic email to alert RSD to alarms; and, (8) implementing enhanced retraining of individuals involved in procedural failures and recurring issues.

Additionally, you described recommendations from the investigation team that NIST has also implemented. These completed recommendations include: (1) updating Source User and RSD initial and refresher training materials to reference this event and to include reporting protocols for receiving a PCM alarm and reviewed other training materials for similar improvements; (2) implementing a procedure requiring new lab users to receive formal review of radiation safety equipment use and revising Source User initial and refresher training to clarify the responsibility of the RSD to engage with Users on radiation safety equipment; (3) continuing engagement with NIST Security to obtain PCM photos and videos when needed to investigate incidents; (4) implementing a revised emergency procedure clarifying that "uncontrolled leakage" includes incidences of spilled ampoule contents; (5) issuing a policy clarifying the roles and responsibilities for the safety "buddy system;" and, (6) placing posters of incident reporting requirements by laboratory telephones and in hallways. Finally, you noted that NIST initially suspended the senior researcher pending retraining and subsequently terminated the individual's contract.

The deliberate failure by the former Source Custodian to evacuate a laboratory room and immediately notify NIST's GRSD following a release of radioactivity delayed the ability of radiation safety staff to provide a timely response to the contamination event and address both the laboratory and the individuals working therein to prevent potential further spread of the contamination. Further, the deliberate nature of the violation is of particular concern to the NRC because the NRC's regulatory program is based on licensees and their contractors acting with integrity, especially those with substantial responsibilities for the safe use of radioactive material around other individuals. Therefore, this violation is categorized in accordance with the NRC Enforcement Policy as a Severity Level III (SL III) violation. The NRC Enforcement Policy can be found on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$16,000 is considered for a SL III violation. Because the violation was willful, the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC determined that identification credit was warranted because NIST identified the violation and notified the NRC. The NRC determined that corrective action credit was warranted for NIST's actions taken to address the violation, as described above.

Therefore, to encourage prompt identification and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SL III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 07000398/2021003, Investigation Report No. I-2022-001, and this letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in 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>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

Dr. E. Mackey

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If you have any questions concerning this matter, please contact Mr. Chris Cahill of my staff at 610-337-5108 or Christopher.Cahill@nrc.gov.

Sincerely,

David C. Lew
Regional Administrator

Docket No. 70-398
License No. SNM-362

Enclosure:
Notice of Violation

cc w/encl:
M. Mejias, Radiation Safety Officer

SUBJECT: NOTICE OF VIOLATION – U.S. DEPARTMENT OF COMMERCE, NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY – NRC INVESTIGATION REPORT I-2022-001; NRC INSPECTION REPORT NO. 07000398/2021003: DATED OCTOBER 5, 2022.

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ML22230B483

DOCUMENT NAME: S:\Enf-allg\Enforcement\Proposed-Actions\Region1\NIST NOV EA-22-009.docx

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DATE					9/30/22	10/05/22

ENCLOSURE

NOTICE OF VIOLATION

National Institute of Standards and Technology
Gaithersburg, Maryland

Docket No.: 07000398
License No.: SNM-362
EA-22-009

During an NRC inspection conducted between September 28, 2021, and June 15, 2021, and an NRC investigation conducted between October 6, 2021, and December 22, 2021, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

License Condition 10 of Amendment 11 to License Number SNM-362 states, in part, that the authorized use for materials is in accordance with statements, representations, and conditions of the licensee's renewal application dated June 29, 2007. The renewal application dated June 29, 2007, states, in part, that Source Custodians shall maintain control over source utilization and ensure work is done in compliance with appropriate protocols, instructions, and safe handling practices.

Safety Evaluation SE-0010, "Preparation and Calibration of SRMs Measurement Assurance Program for the Radiopharmaceutical Industry," is the work instruction for preparation and calibration of short-lived radioactive standards in support of the NIST Radioactivity Measurements Assurance Program (NRMAP). The section "Emergency Procedures" states, in part, that if there is a release of radioactivity; evacuate the room closing the door behind, prevent entry by other personnel to the lab, and immediately contact Gaithersburg Radiation Safety Division (GRSD).

Contrary to the above, on September 22, 2021, the licensee did not use materials in accordance with statements, representations, and conditions of the licensee's renewal application dated June 29, 2007, in that, a Source Custodian did not ensure work was done in compliance with appropriate instructions. Specifically, during the preparation of short-lived radioactive standards in support of the NRMAP, there was a release of radioactivity, but the Source Custodian did not evacuate the room closing the door behind, prevent entry by other personnel to the lab, and immediately contact GRSD. Rather, the Source Custodian attempted to decontaminate himself, the equipment, and lab facilities in order to avoid disruption to his work activities by GRSD.

This is a Severity Level III violation (Enforcement Policy Section 6.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 07000398/2021003, Investigation Report No. I-2022-001, and the letter forwarding this Notice of Violation. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, (EA-22-009)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region I, 475 Allendale Road, Suite 102, King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in 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>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 5th day of October, 2022.