



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

June 27, 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: 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 a reactive inspection conducted by the U.S. Nuclear Regulatory Commission at the U.S. Department of Commerce – National Institute of Standards and Technology (NIST) facility in Gaithersburg, Maryland on September 28, 2021, and October 12, 2021, through October 15, 2021, with continued in-office review through the exit interview conducted on June 15, 2022. The inspection was a review of activities conducted under NIST's license leading up to and in response to a September 22, 2021, personnel contamination event and to confirm compliance with the NRC rules, regulations, and the conditions of the license. Enclosure 1 provides the results of this inspection.

In addition to the inspection, an investigation of NIST was initiated on October 6, 2021, by the NRC Office of Investigations (OI) and completed on December 22, 2021. The purpose of the investigation was to determine whether a senior researcher (Source Custodian) at the Gaithersburg facility willfully delayed notification to the Gaithersburg Radiation Safety Division (GRSD) about a radium-223 (Ra-223) release and the resulting personnel contamination. A factual summary of the OI investigation is included as Enclosure 2 to this letter.

Based on the evidence gathered during the investigation, an apparent violation (AV) was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violation involved the failure to make certain that materials were used in accordance with the terms and conditions in License Condition 10 of Amendment 11 to License Number SNM-362. Specifically, it appears that you did not ensure that work was done in compliance with appropriate protocols, instructions, and safe handling practices in the statements, representations, and conditions of the NIST license renewal application dated June 29, 2007.

Enclosure 3 provides a description of the AV. Please be advised that the characterization of the AV described in Enclosure 3, as well as the number of AVs, may change as a result of further NRC 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 an opportunity to: (1) respond in writing to the apparent violations addressed in this inspection report within 30 days of the date of this letter, (2) request a predecisional enforcement conference (PEC), or (3) request alternative dispute resolution (ADR) mediation. If a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however the PEC will be closed to public observation since information related to an Office of Investigations report will be discussed and the report has not been made public. **If you decide to participate in a PEC or pursue ADR, please contact Christopher Cahill, Chief, Commercial, Industrial, Research and Development, and Academic Branch, NRC Region I, at 610-337-5108 or christopher.cahill@nrc.gov within 10 days of the date of this letter.** A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violation in NRC Investigation No. 1-2022-001; EA-22-009," and should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (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. Your response may reference or include previously docketed correspondence if the correspondence adequately addresses the required response. Your response should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, NRC Region I, 475 Allendale Road, Suite 102, King of Prussia, PA 19406. 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 or schedule a PEC.

If you choose to request a PEC, the conference will include an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in 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. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the Information Notice using Agencywide Documents Access and Management System (ADAMS) Accession No. ML061240509.

In lieu of a PEC, you may also request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation; a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them

reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC ADR program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC program as a neutral third party. Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

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 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>.

Please note that final NRC investigation documents, such as the OI report described above, may be made available to the public under the Freedom of Information Act (FOIA) and subject to redaction of information appropriate under the FOIA. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. Requests under the FOIA should be made in accordance with 10 CFR 9.23, "Requests for Records." Additional information is available on the NRC website at <http://www.nrc.gov/reading-rm/foia/foia-privacy.html>.

If you have any questions related to this matter, please contact Mr. Cahill at 610-337-5108 or Christopher.Cahill@nrc.gov.

Sincerely,

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

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

Enclosures:

1. NRC Inspection Report No. 07000398/2021003
2. Factual Summary of NRC OI Case No. 1-2022-001
3. Apparent Violation Identified Through NRC OI Case No. 1-2022-001

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

SUBJECT: U.S. DEPARTMENT OF COMMERCE, NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY – NRC INVESTIGATION REPORT I-2022-001; NRC INSPECTION REPORT NO. 07000398/2021003 DATED JUNE 27, 2022

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See Next Page

DOCUMENT NAME: <https://usnrc.sharepoint.com/teams/Region-I-DNMS1/Shared Documents/Division Director Correspondence/For DD Signature/NIST LIC Ch Letter EA-22-009 Final.docx>
ADAMS ACCESSION NUMBER: ML22115A166

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OFFICE	RI/ORA	RI/DRSS	RI/ORA	RI/ORA	OE
NAME	C Bickett via email	C Cahill via email	B Klukan via email	R McKinley via email	JPeralta
DATE	04/25/2022	04/26/2022	04/27/2022	04/27/2022	06/07/2022
OFFICE	OGC-NLO	NMSS	RI/DRSS		
NAME	R. Augustus	M.Burgess	BWelling		
DATE	06/09/2022	05/14/2022	6/27/22		

*Concurrence on previous page

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I-2022-001; NRC INSPECTION REPORT NO. 07000398/2021003 DATED
JUNE 27, 2022

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R McKinley, RI	
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G. Powell, RI	
Region I OE Files (with concurrences)	

ENCLOSURE 1

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 070-00398/2021003
Docket No. 070-00398
License No. SNM-362
EA No. EA-22-009
Licensee: U.S. Department of Commerce
National Institute of Standards and Technology
Address: 100 Bureau Drive, Stop 1731, Room C-125, Building 245
Gaithersburg, MD 20899-1731
Inspection Dates: 09/28/2021 – 06/15/2022
Exit Meeting 06/15/2022

Inspector: Jonathan B. Pfingsten
Digitally signed by Jonathan B. Pfingsten
Date: 2022.06.27
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Jonathan Pfingsten
Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Inspector: Michael C. Reichard
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Date: 2022.06.27
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Michael Reichard
Senior Health Physicist
Commercial, Industrial, Research and
Development, and Academic Branch
Division of Radiological Safety and Security

Inspector: Patrick-John E. Hann
Digitally signed by Patrick-John E. Hann
Date: 2022.06.24
15:09:52 -04'00'
Patrick Hann
Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Approved By:

Christopher
G. Cahill

Digitally signed by
Christopher G. Cahill
Date: 2022.06.27
08:11:16 -04'00'

Christopher Cahill, Chief
Commercial, Industrial, Research and
Development, and Academic Branch
Division of Radiological Safety and Security

EXECUTIVE SUMMARY

U.S. Department of Commerce
National Institute of Standards and Technology
NRC Inspection Report No. 070-00398/2021003

U.S. Department of Commerce, National Institute of Standards and Technology (NIST) is authorized under U.S. Nuclear Regulatory Commission (NRC) Materials License SNM-362 to possess and use byproduct, source, and special nuclear material at its facilities in Gaithersburg, Maryland, and offsite locations that are under NRC jurisdiction that are subject to the provisions committed to in License Amendment 11.

On September 22, 2021, the NIST Radiation Safety Division (RSD) and Radiation Safety Officer (RSO) were informed by a senior researcher (a non-governmental, contract employee (Source Custodian)) that, during routine production of Radium-223 (Ra-223) standards, a glass ampoule was dropped within a fume hood, resulting in a contamination event. Contrary to site procedures required by NIST's NRC license, the Source Custodian and his assistant did not stop work and immediately notify NIST's RSD. Rather, they continued working and then attempted to decontaminate the laboratory and product. Upon identifying that they were also contaminated, the Source Custodian and his assistant again failed to comply with the procedural requirement to notify the RSD, choosing instead to change into clean articles of clothing. On September 27, 2021, the RSO provided a courtesy notification to NRC Region I of the contamination event.

On September 28, 2021, the NRC began an onsite, reactive inspection of the contamination event and resulting personnel contaminations. The inspection continued onsite the week of October 10, 2021, in coordination with the previously scheduled routine inspection of the licensee. The scope of the reactive inspection was to examine the activities conducted under the license leading up to and in response to the contamination event and to confirm compliance with the NRC rules, regulations, and the conditions of the license.

Based on the inspection findings, the inspectors determined it is reasonable to conclude that no regulatory limits for occupational exposure were exceeded and determined that one apparent violation of NRC requirements occurred regarding the licensee's failure to follow appropriate procedures in response to a spill and contamination event as committed to in the license.

REPORT DETAILS

1. **Organization and Scope of the Program**

a. Inspection Scope

The inspection was a limited scope, reactive inspection focused on a contamination event that occurred during the production of Radium-223 (Ra-223) standards on September 22, 2021, at the U.S. Department of Commerce, National Institute of Standards and Technology's (NIST) (licensee) Gaithersburg, Maryland campus. The inspectors reviewed the license, application, and supporting documents related to the training of personnel, surveys, and other relevant procedures; surveys and dose estimates following the events; and the licensee's investigation and corrective action plans. The inspectors also interviewed personnel and observed licensee activities. The inspectors reviewed Inspection Procedures: 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing," 87125, "Materials Processor/Manufacturer Programs," and 87126, "Industrial/Academic/Research Programs," to assist them in analyzing the sequence of events leading to the incident, the conditions at the time of the incident, and identification of contributing and root causes.

During this inspection, the inspectors:

- Developed a clear understanding of the circumstances surrounding the events leading up to the contamination event and corrective actions taken by the licensee.
- Assessed the adequacy of the initial response to the contamination event, including the efforts to identify the source and cause of contamination and an assessment of the actions taken to prevent similar occurrences.
- Evaluated dose assessment methods and results including the actions taken pertaining to the identification of the event, initial dose assessment, effectiveness of the decontamination of affected staff, and the final dose estimates.
- Evaluated the adequacy and effectiveness of the NIST radiation safety program for any potential deficiencies that may have led to the Ra-223 spill, including compliance with applicable NRC requirements; radiation safety program oversight activities; and radiation safety procedures and equipment that was available and/or in use at the time of the incident.

b. Observations and Findings

The inspection team conducted multiple site visits to the NIST Gaithersburg, Maryland campus, toured the facilities and interviewed managers and staff regarding the circumstances surrounding the contamination event. The inspectors reviewed the NIST internal investigation report for the Ra-223 contamination event and reviewed the NIST report on the dose assessment for the contamination event. The inspectors also reviewed the NIST corrective action plans for the event.

The NIST license is a Type A broad scope program. Licensed activities are authorized by the NIST Ionizing Radiation Safety Committee (IRSC). The radiation safety program

is implemented by the staff of the Radiation Safety Division (RSD) which is part of the Office of Safety, Health, and Environment (OSHE) which is headed by the Chief Safety Officer. The RSD staff includes a Radiation Safety Officer (RSO), who is supported by various health physicists and health physics technicians. The radiation safety organization was found to be as described in the license.

Approximately 200 radiation workers perform activities with licensed materials in multiple buildings, although the majority work is conducted in Building 245 where the Radiation Physics Department is typically located. Work with licensed materials occurs daily.

2. Event Response – Ra-223 Contamination

a. Inspection Scope

The inspectors observed and interviewed NIST staff and reviewed relevant procedures and records to determine the contributing factors that led to the Ra-223 contamination event, the extent of the contamination, the NIST investigation of the contamination event, and planned corrective actions.

The inspectors reviewed NIST procedures for radiation safety personnel qualifications and training. The inspectors observed radioactive materials receipt, use, controls, inventory, and disposal.

Additionally, the inspectors observed surveys performed by NIST staff and reviewed records of surveys relevant to the Ra-223 contamination event.

b. Observations and Findings

On September 27, 2021, the RSO for NIST provided the NRC a courtesy notification of a contamination event in a laboratory in Building 245 at its Gaithersburg, Maryland site. The RSO said that the event, which involved non-government researchers working at NIST under a cooperative agreement, occurred on September 22, 2021. In response to this notification, NRC Region I staff initiated a reactive inspection at NIST.

Source Users are individuals who have been approved by their line management, the RSO, and the IRSC to use SNM-362 radioactive materials based on their education, experience, and training. Source Custodians are Source Users who have been approved by their line management, the RSO, and the IRSC to perform additional responsibilities for the control and accountability of licensed radioactive materials. The senior researcher (Source Custodian) had been working as a non-government employee at NIST since late 2014. He initially worked there under a cooperative agreement issued by NIST to a private company that produced radioactive reference standards and tested customer products to provide quality control and traceability (i.e., the NIST Radioisotope Measurement Assurance Program, NRMAP). In late 2018, NIST ended the agreement with the private company. The researcher formed his own company and entered into an agreement with NIST to perform the same work. The agreement allowed the researcher to use NIST's facilities and equipment for a fee while he provided the personnel and materials to run the NRMAP. Prior to working at NIST, the Source Custodian had worked for a radiopharmaceutical company and had been the Corporate RSO listed on their NRC license.

On September 22, 2021, the Source Custodian and his assistant, hired in late 2019, were preparing five ampoules of a Ra-223 solution. The samples were planned to be shipped that day with one ampoule being sent internationally. The Source Custodian indicated that he had believed the shipper would not be in the office the following day; therefore, he wanted to ensure the material would be sent that evening, due to the relatively short half-life of Ra-223 and the significant shipping time.

The Source Custodian was working with the material inside a fume hood. At approximately 11:30 a.m., he had filled all five ampoules and had flame-sealed four of them. He began to seal the final ampoule when it fell from its holder and landed at an angle on the fume hood working surface, which was lined with aluminum foil for spill containment purposes. The Source Custodian observed a release of liquid from the unsealed ampoule, primarily on the fume hood working surface and directed toward the back wall of the fume hood. The Source Custodian inspected the ampoule for any cracks or liquid on the exterior; he then weighed the ampoule, added a hydrochloric acid solution to account for the lost volume, and sealed the ampoule; the researchers then proceeded with the last stages of the production process.

The researchers subsequently performed separate tasks related to the decontamination of the laboratory space and the ampoules. The Source Custodian conducted surveys of the area and identified contamination on the surface of the fume hood, on the floor in front of the hood and on equipment inside the hood. The equipment was moved to another area of the laboratory designated for contaminated items. The Source Custodian proceeded to attempt to decontaminate the fume hood. The Source Custodian surveyed himself and identified contamination on his lab coat, clothing, and shoes; he removed those items and changed into new clothing. Additionally, the Source Custodian utilized the half-body personnel contamination monitor (PCM) and hand and foot monitor, identifying additional contamination on his backup shoes.

During this time, the assistant researcher was focused on wipe testing and decontaminating the sealed ampoules' exterior surfaces. The assistant researcher was having difficulties decontaminating the ampoules and utilizing the proportional counter. Throughout this process, the assistant researcher utilized the PCM and hand and foot monitoring stations multiple times and identified contamination on her clothing and shoes. The assistant researcher ultimately changed into scrubs and backup shoes.

Around 3:00 p.m., a member of NIST RSD entered the area where the wipe tests were being counted. The Source Custodian and assistant researcher notified the RSD health physicist of the equipment issues with the proportional counter but did not notify the RSD member of the spill and decontamination efforts at this time. The RSD member was able to assist with the restoration of the proportional counter and departed the area.

After the RSD member left the area, the researchers continued with their respective efforts to decontaminate the lab and ampoules. Lead sheets were laid on areas of the floor in front of the fume hood. The Source Custodian ultimately took over and was successful in decontaminating the ampoules.

The researchers placed their contaminated personal effects in a bag in a separate fume hood marked "decay in storage," posted the lab as contaminated, and left the building.

The Source Custodian went to the NIST RSD trailer at approximately 4:45 p.m. and reported that there had been a contamination incident and that it had been cleaned up. The researcher did not initially inform the RSD personnel that the incident had occurred hours earlier. The Source Custodian initially estimated the spilled material to be approximately 300 kBq of Ra-223.

The RSD supervisor and technician stated that upon arriving at the lab, they identified that the Source Custodian's hand and shoe were contaminated, and they identified widespread low-level contamination throughout the lab. They contacted the NIST RSO and sealed the lab until the following day when more RSD staff would be available to decontaminate it. The NIST RSO stated that the following day, after seeing how much of the lab was contaminated and identifying the bags of contaminated clothing and materials, he realized the extent of the actions the researchers had taken to decontaminate the area, product, and themselves. He retrieved data from the PCMs located outside of the Source Custodian's lab and identified that the Source Custodian and his assistant had received numerous alarms due to the contamination on their clothing and shoes during the period between approximately 12:00 p.m. and 4:00 p.m. The PCMs capture images of individuals who alarm the monitors, allowing RSD to confirm that the Source Custodian and his assistant had changed clothing multiple times due to receiving alarms.

The licensee confirmed that the approved procedure, which had been authored by the Source Custodian for these activities, includes direction that, in the event of a radioactive release, personnel must evacuate the room and immediately contact RSD. Additionally, the procedure requires that in the case of a personnel contamination, the RSD must be contacted as soon as possible. The researcher had been involved in three prior contamination events in 2016, 2017, and 2018 and in each of those incidents had properly notified RSD in accordance with the procedure. The researcher acknowledged that he delayed notifying RSD due to their previous incident responses of shutting down the lab. In each of the prior events he had reported to RSD, his lab had been shut down for extended periods of time and had, as a result, upset his customers.

The licensee ultimately estimated the activity of the spilled material as approximately 2-3MBq of Ra-223. The licensee conducted prospective dose evaluations associated with the event and sent the researchers' dosimetry to be evaluated. The final dose estimates below were calculated utilizing VARSKIN+. For the Source Custodian, the licensee assumed a point source geometry, exposure of 2.05 hours, and an activity of 76.60 kBq based off of gamma spectroscopy of the Source Custodian's contaminated PPE and personal clothing. For the assistant researcher, the licensee assumed a point source geometry, exposure of 1.65 hours, and an activity of 6.05 kBq based off of gamma spectroscopy of the assistant researcher's contaminated PPE and personal clothing.

- VARSKIN maximum shallow dose estimate for Source Custodian: 3089 mrem
- VARSKIN max shallow dose estimate for assistant researcher: 196.4 mrem
- Measured whole body shallow dose equivalent for monitoring period for Source Custodian: 16 mrem
- Measured whole body shallow dose equivalent for monitoring period for assistant researcher: 4 mrem
- Measured extremity dose for monitoring period for Source Custodian: 943 mrem

- Measured extremity dose for monitoring period for assistant researcher: 180 mrem

The inspectors determined licensee's dose estimates to be a conservative, yet reasonable method for calculating the estimated doses. The licensee's calculations most accurately represent an upper bound of dose, rather than the actual dose received. Given the uncertainties, the inspectors determined that the upper bound approach was reasonable.

The NRC initiated a reactive inspection on September 28, 2021. The inspection included tours of the facilities, interviews with RSD staff, and general information gathering. Independent surveys were performed by the inspectors in all locations inspected. Surveys were performed in restricted and non-restricted areas. All measurements were found to be within regulatory limits.

The inspection continued onsite the week of October 10, 2021. This included further tours of the facilities, additional interviews with NIST staff, and evaluation of extent of condition. Additionally, the inspectors reviewed the licensee's comprehensive root cause evaluation and determined that the licensee identified appropriate causes and corrective actions intended to address and prevent the repetition of those causes.

The following survey meters were utilized in the independent surveys:

- Ludlum Model 12 w/ 44-9 pancake, serial number 53261, calibration date 12/08/2020
- Ludlum Model 2224-1 w/ 43-2-2 alpha/beta probe, serial number 227239, calibration date 08/17/2021
- Ludlum Model 30 w/ 43-5 alpha probe, serial number 25016141, calibration date 01/20/2021
- NDS Products Model ND-2000, serial number 75162, calibration date 12/04/2020

The inspectors evaluated the safety culture of the NIST staff, particularly those researchers under similar work agreements. The questions centered around the researchers' willingness to inform licensee management of safety concerns and the proper response to events. The researchers interviewed were knowledgeable of proper incident response procedures; each indicated they were willing to report spills and incidents to RSD staff. No significant safety culture concerns were identified amongst the broader staff.

c. Conclusions

The NIST RSD staff response to the contamination event was thorough and comprehensive. The RSD took immediate actions upon notification to evaluate the extent of contamination and address concerns with safety and the performance of decontamination activities. The licensee performed a comprehensive root cause evaluation, identifying appropriate causes and corrective actions intended to address and prevent the repetition of those causes. Based on the dose calculations and measured doses received by the researchers, the inspectors determined it is reasonable to conclude that no regulatory limits for occupational exposure were exceeded. Further, no significant safety culture concerns were identified amongst the broader staff.

One apparent violation was identified that is being considered for potential escalated enforcement action, as detailed in Enclosure 3. The apparent violation involved the failure to make certain that materials were used in accordance with the terms and conditions in License Condition 10 of Amendment 11 to License Number SNM-362. Specifically, work was not done in compliance with appropriate protocols, instructions, and safe handling practices in the statements, representations, and conditions of the NIST license renewal application dated June 29, 2007.

3. Exit Meeting

Upon completion in-office review, a virtual exit meeting was held on June 15, 2022, with NIST senior management to present the inspection findings. The NRC discussed the content of the inspection report, described the NRC's enforcement process, and described the options that are available to the licensee.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Individual(s) present at formal entrance meeting on October 12, 2021

^ Individual(s) present for virtual exit meeting on June 15, 2022

#^Elizabeth Mackey, Director of OSHE and Chief Safety Officer

^James Adams, RSC Vice Chair

John Classen, Health Physicist

Benjamin Estes, Health Physicist

^James Kushmerick, Director of Physical Measurement Lab

#^Manuel Mejias, Radiation Safety Officer

#Janna Shupe, Assistant Radiation Safety Officer

Michael Spady, Supervisory Health Physicist

#^Alan Thompson, Radiation Safety Committee Chairman

^Henry Wixon, Chief Counsel for NIST

John Zometsky, Health Physicist

List of Items Opened, Closed, and Discussed

EA-22-009, Violation of License Condition 10 of Amendment 11 to License Number SNM-362 (Open)

LIST OF ACRONYMS USED

IRSC - Ionizing Radiation Safety Committee

kBq – kilobecquerels

MBq – Megabecquerels

NIST – U. S. Department of Commerce National Institute of Standards and Technology

NRC - Nuclear Regulatory Commission

NRMAP - NIST Radioisotope Measurement Assurance Program

OSHE - Office of Safety, Health, and Environment

PCM - personnel contamination monitors

Ra-223 – Radium-223

RSD - Radiation Safety Division

RSO - Radiation Safety Officer

uCi - microcuries

Partial List of Documents Reviewed

Authorized Use Permit SE-0010, Amendment 16: Preparation and Calibration of SRMs
Measurement Assurance Program for the Radiopharmaceutical Industry

Dosimetry results for researchers

GRSD Form 101, PCM Guidance

IRIS Event Report 21-IG-0057, “Researchers Contaminated When Spill Occurs During Source
Preparation”, dated September 30, 2021

IRIS Investigation of 21-IG-0057, dated March 25, 2022

IRSC Committee Meeting Investigation Update, dated December 2, 2021

NIST Radiation Safety Program Initial Training for Source Users & Supervised Users

NIST Radiation Safety Program Biennial Refresher Training for Source Users, Source Custodians, and Their Line Management (October 2020 Version)
PCM records from September 22, 2021, for the half-body and hand and foot (H&F) PCMs in the Bldg 245 H-wing second floor radiological suite
Radiological survey data from September 22, 2021, for the lab where the Ra-223 spill occurred
Safety and Compliance Communication, Stop Work Order, dated September 27, 2021
VARSKIN dose calculations

ENCLOSURE 2

Factual Summary of NRC Office of Investigations (OI) Case No. 1-2022-001

On October 6, 2021, the U.S. Nuclear Regulatory Commission (NRC), Office of Investigations (OI), Region I initiated an investigation to determine if a senior researcher (Source Custodian) designated as a source custodian at the U.S. Department of Commerce – National Institute of Standards and Technology (NIST) facility in Gaithersburg, Maryland willfully delayed notification of the Gaithersburg Radiation Safety Division (GRSD) about a radium-223 (Ra-223) release and resulting personnel contaminations. The investigation was completed on December 22, 2021.

The investigation identified that, on September 22, 2021, the Source Custodian was preparing five ampules of a Ra-223 solution that he intended to ship that evening. He was working with the material inside a fume hood, and at approximately 11:30 A.M., began to flame seal the final ampule when it fell from its holder and some of the material landed at the rear of the hood. Further, after completing the production process, the researcher surveyed the area and identified contamination on the floor in front of the fume hood. Testimony indicates that the researcher and his assistant also identified contamination on their lab coats and clothing. Further, testimony identified that by approximately 4:30 P.M., the researcher finished cleaning up the contamination and exited the lab. He went to the GRSD trailer and reported that an incident had occurred and that he had cleaned it up. However, testimony identifies that the researcher did not inform the GRSD personnel that the incident had occurred hours earlier or that anyone had been contaminated.

Additional testimony indicates that the Source Custodian acknowledged that he knew at the time when the spill occurred that he was supposed to immediately notify GRSD. The Source Custodian also confirmed that he received training from NIST on the responsibilities of a source custodian, which included training on immediately notifying the GRSD in the event of a spill. Moreover, testimony also indicates that the same Source Custodian had authored the safety evaluation for the work he had been performing and it contained directions that, in the event of a radioactive release, personnel must evacuate the room and immediately contact GRSD. The investigation also identified that the researcher had been involved in three prior contamination events (in 2016, 2017, and 2018) and in each of those incidents, he had properly notified GRSD in accordance with the procedure. The researcher explained that in response to the prior events, his lab had been shut down for extended periods of time and his material confiscated, which delayed product shipment to his customers. The researcher also explained that GRSD did not balance safety with operational needs and that he believed he could clean up the area as well or better than the GRSD staff.

Based on the evidence developed during the investigation, it appears that the Source Custodian deliberately delayed notification to GRSD and evacuation of the lab on September 22, 2021, following the release and contamination event to avoid disruption of his work activities.

ENCLOSURE 3

Apparent Violation Identified Through NRC OI Case No. 1-2022-001

APPARENT VIOLATION BEING CONSIDERED FOR ESCALATED ACTION

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.