



UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-

July 25, 2018

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

License No. SNM-362
Docket # 70-398
TAC No. L32643

Mr. David Lew
Regional Administrator, NRC Region I
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Reply to a Notice of Violation

Dear Mr. Lew,

The National Institute of Standards and Technology (NIST) intends to conduct its radiation safety programs with high standards of safety and compliance to avoid radiation exposure to employees and the public. NIST fully understands the importance of promptly correcting the deficiencies identified in the radiation safety program in the form of cited violations and root causes of licensee events 52900 and 52916. Several corrective actions have been implemented and full compliance is expected by September 28, 2018.

This letter and attached report address the request for a written statement or explanation in response to the Notice of Violation issued to the U.S. Department of Commerce National Institute of Standards and Technology on June 22, 2018 (received June 25, 2018). Pursuant to the provisions of 10 CFR 2.201, *Notice of violation*, NIST as a licensee under the SNM-362 license is providing the taken and planned corrective actions in response to the issues identified as violations of 10 CFR 20 requirements and License Condition 10.

The attached report provides for each violation (a) the description of the cited violation; (b) the reason for the violation; (c) the corrective steps that have been taken and the results achieved; (d) the corrective steps that will be taken to avoid further violations; and (e) the date when full compliance will be achieved.

Thank you for your attention to this letter and attached report. If you have further questions about this report, please contact the NIST Gaithersburg Radiation Safety Officer, Mr. Manuel Mejias at 301-975-5800 or manny.mejias@nist.gov.

Sincerely,

Stephen W. Banovic (Acting)
Chief Safety Officer
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899-1730
301-975-8822, Stephen.banovic@nist.gov

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Enclosures:

Reply to a Notice of Violation Report

Appendix A Licensee Event 52916 Corrective Action Plan

Appendix B License Event 52900 Corrective Action Plan

cc: J.M. Trapp, Director, Division of Nuclear Materials Safety, USNRC Region I
D.M. Janda, Chief, Medical and Licensing Assistance Branch, USNRC Region I
T.D. Naquin, Project Manager, USNRC NMSS/FCSE/FMB
W.G. Copan, NIST Director
J.K. Olthoff, NIST Associate Director for Laboratory Programs
D. Brockett, NIST Associate Director for Management Resources
H.N. Wixon, NIST Chief Counsel
A.K. Thompson, NIST IRSC Chair
M. Mejias, NIST Radiation Safety Officer

Reply to Notice of Violation Report

July 25, 2018

On June 25, 2018, NIST received NRC Inspection Report No. 07000398/2017001, which included a Notice of Violation addressing four violations of NRC requirements. These were identified during the inspection activities between September 13, 2017, and May 8, 2018. The Notice of Violation identified violations of 10 CFR 20.1101(b), 10 CFR 20.1501, and License Condition 10 of the SNM-362 license. The inspection was limited to a review of two events reported to NRC on August 14 and August 19, 2017, involving a lost sealed source and an unplanned contamination event, respectively. The Notice of Violation communicated a requirement for NIST to submit a written statement or explanation to address each violation.

This report addresses the required response by providing for each violation (a) the description of the cited violation; (b) the reason for the violation; (c) the corrective steps that have been taken and the results achieved; (d) the corrective steps that will be taken to avoid further violations; and (e) the date when full compliance will be achieved.

VIOLATION #1

1a. Description of Violation #1

“10 CFR 20.1101(b) requires, in part, the licensee use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses that are as low as reasonably achievable (ALARA).

Contrary to the above, on August 17, 2017, the licensee did not use procedures, based on sound radiation protection principles, to achieve occupational doses that were as low as reasonably achievable. Specifically, a radiation worker handled radioactive material without donning proper protective clothing (in this case a protective glove) and failed to perform a survey of the work area prior to handling radioactive material without a protective glove, which resulted in the worker receiving a committed effective dose to the bone surface of 3.68 rem. The dose was avoidable had the licensee used procedures based upon sound radiation protection principles and therefore not ALARA.”

1b. Reason for Violation #1

An incident investigation, including root cause analysis (RCA), was performed at the request of the NIST Ionizing Radiation Safety Committee (IRSC) by internal and external subject matter experts. The investigation identified the following root causes: inadequate procedures to prevent rupture of the ampoule, inadequate procedures for detecting contamination, not following procedures for responding and communicating events, procedures did not adequately specify personal protective equipment (PPE) and monitor

use, and contamination events not investigated according to procedure. Information on the contributing factors is found in the attached NIST IRSC Investigation of the August 2017 Am-241 Event.

1c. Corrective steps that have been taken and the results achieved for Violation #1

- i. A Safety Evaluation that includes procedures for safe storage of radioactive sources was approved by the IRSC on 6/29/2018.
- ii. A risk-based evaluation of the existing requirements for personnel contamination monitoring was completed on 7/1/2018.
- iii. The leak testing procedure, RSI 4-5, was modified on 6/14/2018 to explicitly state the conditions requiring PPE.
- iv. The standard operating procedure for health physics training and qualifications (RSI 1-2) was revised on 7/10/2018 to add explicit oversight requirements and management of change in duties and/or personnel.

For additional information concerning the event, refer to NRC event notification 52916.

1d. Corrective steps that will be taken for Violation #1 to avoid further violations

- i. The Gaithersburg Radiation Safety Division (GRSD) will revise standard operating procedures RSI B 1-1 "Radiation Safety ALARA Action Levels", E 4-1 "Radiation Facility Surveys and Audits", D 4-5 "Sealed Source Leak Testing", B 6-4 "Counting Statistics and Reporting Criteria" and all the G 7 – X series for instrumentation. The procedures will include a more stringent threshold for GRSD follow-up of potential contamination as well as further notification requirements for informing GRSD line management, OUs line management, Radiation Facility Owners, and Source Users and Custodians.
- ii. GRSD will modify the Source Users training standard operating procedure, RSI 1-4B, to more explicitly capture the importance of prompt notification of contamination alarms and cover the capabilities and limitations of contamination monitors.
- iii. GRSD will revise Source User training slides/material to capture the modifications to RSI B 1-4B.
- iv. GRSD will modify the standard operating procedure for responding to radiological incidents (RSI 1-3) to include guidance on incident investigation; including the importance of timeliness for investigating contamination monitor alarms.
- v. GRSD in coordination with the IRSC will revise Safety Evaluations and procedures that do not effectively cover the subject of personnel contamination monitoring.
- vi. GRSD will develop a procedure to cover identification and reporting of contamination events.
- vii. GRSD will modify the training standard operating procedure, RSI B 1-4B, to more explicitly provide contamination control guidance for activities not covered under Safety Evaluations (e.g. leak testing).

- viii. GRSD will revise standard operating procedures, RSI 1-3 and RSI B 1-4B, to have requirements to occasionally have Source Users participate in exercises and drills.
- ix. The RSO will ensure that training is delivered to health physics personnel on all revised procedures.

1e. Date when full compliance will be achieved for Violation #1

The planned corrective actions stated above in response to Violation #1 are expected to be completed no later than September 28, 2018. The attached document "Licensee Event 52916 Corrective Action Plan" provides milestones for actions between now and September 28, 2018.

VIOLATION #2

2a. Description of Violation #2

"10 CFR 20.1501 requires, in part, that:

- (a) Each licensee shall make, or cause to be made, surveys that –
 - (1) May be necessary for the licensee to comply with the regulations in this part, and
 - (2) Are reasonable under the circumstances to evaluate –
 - (i) The magnitude and extent of radiation levels; and
 - (ii) Concentrations or quantities of residual radioactivity; and
 - (iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

Contrary to the above, as of August 16, 2017, the licensee failed to make, or cause to be made, surveys necessary to assure compliance with the occupational dose limits in 10 CFR Part 20.1201 and were reasonable to evaluate the magnitude and extent of radiation levels; the concentrations or quantities of residual radioactivity; the potential radiological hazards of the radiation levels and residual radioactivity detected; and the potential radiological hazards of the long-term storage of high specific activity alpha solutions in glass ampoules. Specifically, as of August 16, 2017, licensee personnel detected unexpected and anomalous contamination in and near a source storage room in Building 245 and did not sufficiently evaluate the magnitude of residual alpha contamination present to adequately characterize the radiological hazard of the residual contamination present."

2b. Reason for Violation #2

An incident investigation, including RCA, was performed at the request of the NIST IRSC by internal and external subject matter experts. The investigation identified the following root causes: inadequate procedures to prevent rupture of the ampoule; inadequate procedures for detecting contaminations; not following procedures for responding and communicating events; procedures did not adequately specify PPE and monitor use; and

contamination events to be investigated according to procedure. Information on the contributing factors is found in the attached NIST IRSC Investigation of the August 2017 Am-241 Event.

2c. Corrective steps that have been taken and the results achieved for Violation #2

- i. A Safety Evaluation that includes procedures for safe storage of radioactive sources was approved by the IRSC on 6/29/2018.
- ii. A risk-based evaluation of the existing requirements for personnel contamination monitoring was completed on 7/1/2018.
- iii. The leak testing procedure, RSI 4-5, was modified on 6/14/2018 to explicitly state the conditions requiring PPE.
- iv. The standard operating procedure for health physics training and qualifications (RSI 1-2) was revised on 7/10/2018 to add explicit oversight requirements and management of change in duties and/or personnel.

2d. Corrective steps that will be taken for Violation #2 to avoid further violations

- i. The Gaithersburg Radiation Safety Division (GRSD) will revise standard operating procedures RSI B 1-1 "Radiation Safety ALARA Action Levels", E 4-1 "Radiation Facility Surveys and Audits", D 4-5 "Sealed Source Leak Testing", B 6-4 "Counting Statistics and Reporting Criteria" and all the G 7 – X series for instrumentation. The procedures will include a more stringent threshold for GRSD follow-up of potential contamination as well as further notification requirements for informing GRSD line management, OUs line management, Radiation Facility Owners, and Source Users and Custodians.
- ii. GRSD will modify the Source Users training standard operating procedure, RSI 1-4B, to more explicitly capture the importance of prompt notification of contamination alarms and cover the capabilities and limitations of contamination monitors.
- iii. GRSD will revise Source User training slides/material to capture the modifications to RSI B 1-4B.
- iv. GRSD will modify the standard operating procedure for responding to radiological incidents (RSI 1-3), to include guidance on incident investigation; including the importance of timeliness for investigating contamination monitor alarms.
- v. GRSD will revise Safety Evaluations and procedures that do not effectively cover the subject of personnel contamination monitoring.
- vi. GRSD will develop a procedure to cover identification and reporting of contamination events.
- vii. GRSD will modify the training standard operating procedure, RSI B 1-4B, to more explicitly provide contamination control guidance for activities not covered under Safety Evaluations (e.g. leak testing).

- viii. GRSD will revise standard operating procedures, RSI 1-3 and RSI B 1-4B, to have requirements to occasionally have Source Users participation in exercises and drills.
- ix. The RSO will ensure that training is delivered to health physics personnel on all revised procedures.

2e. Date when full compliance will be achieved for Violation #2

The planned corrective actions stated above in response to Violation #2 are expected to be completed by September 28, 2018. The attached document "Licensee Event 52916 Corrective Action Plan" provides milestones for actions between now and September 28, 2018.

VIOLATION #3

3a. Description of Violation #3

"License Condition 10 of NRC License No. SNM-362 requires, in part, that licensed material be used in accordance with statements, representations, and conditions of the licensee's renewal application dated March 23, 2011. Section 10.3, page 18, of the application dated March 23, 2011, requires that a Source Custodian perform an annual physical inventory of all sealed sources that are under their responsibility that are required to be leak tested.

Contrary to the above, a Source Custodian did not perform an annual physical inventory of a sealed source that was under the custodian's responsibility that was required to be leak tested. Specifically, since 2005 when a Source Custodian was assigned responsibility for a Cf-252 sealed source designated as RS# 75-0086, no physical inventory of the source was performed because the custodian did not visually verify nor confirm with a radiation measurement that the source was in its shielded drum."

3b. Reason for Violation #3

An incident investigation, including RCA, was performed at the request of the NIST IRSC by internal subject matter experts. The investigation identified the following root causes: inadequate on-the-job training for Source Custodians; lack of a formal procedure for changes in custodianship; failure of Source Custodian to follow existing procedures; outdated inventory information; and insufficient effort to place infrequently used materials into storage. Information on the contributing factors is found on the attached NIST IRSC Investigation of August 2017 lost Cf-252 source.

3c. Corrective steps that have been taken and the results achieved for Violation #3

- i. GRSD revised standard operating procedure RSI A1-11 on 7/10/2018 by developing a NIST/GRSD form to ensure that Source Custodianship transfers are done in a manner

that would provide all the necessary information about the source(s) to the new Source Custodian.

- ii. GRSD revised standard operating procedure RSI E4-1 (Radiation Facility Surveys and Audits) to include specific guidance on monitoring the upkeep of RAM facilities on 7/23/2018.
- iii. GRSD revised standard operating procedure RSI 1-4B (covers Source User and Source Custodian training requirements) on 6/8/2018 to include detailed guidance on inventory management and management of changes.
- iv. GRSD conducted Source Custodian refresher training sessions to include detailed guidance on inventory management and management of changes. Sessions completed on 5/30/2018.
- v. GRSD modified standard operating procedure RSI 4-5 (sealed source leak testing) to explicitly state the requirement to contact Source Custodians ahead of leak tests and arrange for laboratory visits and to discuss any new or changed procedures. Procedure variance signed 7/10/2018.
- vi. GRSD revised standard operating procedure RSI B 1-3 (emergency response) to include specific guidance on responding to loss of material. The revision also updated other NRC reporting requirements. Procedure variance approved 5/31/2018.
- vii. GRSD revised standard operating procedure RSI 4-18 (inventory spot check) to include a review of metrics to monitor the effectiveness of RAM inventory practices. Procedure change approved 7/18/2018.
- viii. The form provided to Source Custodians to perform inventory reconciliation was modified to explicitly indicate the method of verification: visual inspection, radiation measurements, mass measurements, and/or security/tamper seal. Form change approved in August 2017.
- ix. GRSD and the IRSC approved a new Safety Evaluation to address the safety requirements of sources in storage, titled "Inactive Radioactive Material." The new document was approved on 6/29/2018.
- x. Source Custodians confirmed, via the 2018 annual inventory source reconciliation, that sources that are not foreseen to be used were placed into storage or inactive status in the database. Inventory reconciliation was completed on 6/29/2018.
- xi. The Radiation Physics Division provided GRSD with a source list and accompanying waste manifests for unwanted sources deemed no longer having scientific value.
- xii. A GRSD health physicist was realigned/reassigned to oversee quality assurance (QA) of GRSD activities, including spot checks to verify adequacy of source storage and labeling. The realignment was effective October 2017.

For additional information concerning the event, refer to NRC event notification 52900.

3d. Corrective steps that will be taken for Violation #3 to avoid further violations

While no other actions are deemed necessary to avoid further violations, GRSD is working with the Office of Information Systems Management, the Office of Health Safety and Environment, and Source Custodians from the Radiation Physics Division to develop a new web-based database system which will allow Source Users (and Custodians) to have real-time and accurate data in support of radioactive material control and accountability activities. This project is underway and initial deployment is expected in early 2019.

3e. Date when full compliance will be achieved for Violation #3

The corrective steps that have been taken are deemed adequate to achieve full compliance.

VIOLATION #4

4a. Description of Violation #4

“License Condition 10 of NRC License No. SNM-362 requires, in part, that licensed material be used in accordance with statements, representations, and conditions of the licensee’s renewal application dated March 23, 2011. Section 10.7, page 28, of the application dated March 23, 2011, requires the following:

- Each sealed source containing more than 100 microcuries of beta and/or gamma emitting material or more than 10 microcuries of alpha emitting material, other than H-3, with a half-life greater than 30 days and in any form other than gas, shall be tested for leakage and/or contamination semiannually, unless otherwise specified by the source’s respective SSD registration certificate.
- The sample must be taken from the sealed source or appropriate accessible surfaces of the container or from the device where the sealed source is mounted or stored in which one might expect contamination to accumulate.

Contrary to the above, a Cf-252 source (22 uCi of Cf-252, 5.3 mCi of Cf-250, and 8.5 uCi of Cm-248) designated as RS# 75-0086, was tested for leakage and/or contamination in March and September of 2015 and 2016, and the sample was not taken from the sealed source or appropriate accessible surfaces of the container where the sealed source is stored in which one might expect contamination to accumulate. Specifically, the employee who collected the leak test sample indicated that the smear(s) were collected on the top surface of the shielded drum and just beneath the plug; considering the source had not been removed from the shield since 2005, these were not surfaces where one would expect contamination to accumulate.”

4b. Reason for Violation #4

An incident investigation, including RCA, was performed at the request of the NIST IRSC by internal subject matter experts. The investigation identified the following root causes,

including: inadequate on-the-job training for Source Custodians; lack of a formal procedure for changes in custodianship; failure of Source Custodian to follow existing procedures; outdated inventory information and; insufficient effort to place infrequently used materials into storage. Additional information on the contributing factors is found on the attached NIST IRSC Investigation of August 2017 lost Cf-252 source.

4c. Corrective steps that have been taken and the results achieved for Violation #4

- i. GRSD revised standard operating procedure RSI A1-11 on 7/10/2018 to include the development of a NIST/GRSD form to ensure that Source Custodianship transfers are done in a manner that would provide all the necessary information about the source(s) to the new Source Custodian.
- ii. GRSD revised standard operating procedure RSI 1-4B (covers Source User and Source Custodian training requirements) on 6/8/2018 to include detailed guidance on inventory management and management of changes.
- iii. GRSD conducted a Source Custodian refresher training session to include detailed guidance on inventory management and management of changes. Sessions completed on 5/30/2018.
- iv. GRSD modified standard operating procedure RSI 4-5 (sealed source leak testing) to explicitly state the requirement to contact Source Custodians ahead of leak tests and arrange for laboratory visits and to discuss any new or changed procedures. Procedure variance signed 7/10/2018.
- v. GRSD revised standard operating procedure RSI B 1-3 (emergency response) to include specific guidance on responding to loss of material. The revision also updated other NRC reporting requirements. Procedure variance approved 5/31/2018.
- vi. GRSD revised standard operating procedure RSI 4-18 (inventory spot check) to include a review of metrics to monitor the effectiveness of RAM inventory practices. Procedure change approved 7/18/2018.
- vii. The form provided to Source Custodians to perform inventory reconciliation was modified to explicitly indicate the method of verification: visual inspection, radiation measurements, mass measurements, and/or security/tamper seal. Form change approved in August 2017.
- viii. GRSD and the IRSC approved a new Safety Evaluation to address the safety requirements of sources in storage, titled "Inactive Radioactive Material". The new document was approved on 6/29/2018.
- ix. Source Custodians confirmed, via the 2018 annual inventory source reconciliation, that sources that are not foreseen to be used were placed into storage or inactive status in the database. Inventory reconciliation was completed on 6/29/2018.
- x. The Radiation Physics Division provided GRSD with a source list and accompanying waste manifests for unwanted sources deemed no longer having scientific value.

- xi. A GRSD health physicist was realigned/reassigned to oversee QA of GRSD activities, including spot checks to verify adequacy of source storage and labeling. The realignment was effective October 2017.

For additional information concerning the event, refer to NRC event notification 52900.

4d. Corrective steps that will be taken for Violation #4 to avoid further violations

While no other actions are deemed necessary to avoid further violations, GRSD and the IRSC will remain vigilant to make sure compliance with license conditions is maintained.

4e. Date when full compliance will be achieved for Violation #4

The corrective steps that have been taken are deemed adequate to achieve full compliance.

Corrective Action Plan (CAP)

Licensee Event 52916



| Root Cause | Description | Finding/Recommendation | Concur Status | Concur Status Basis | Comments | Corrective or Preventive Action(s) | Projected Completion Date | Actual Closure Date |
|---|---|--|---------------|---------------------|---|---|---------------------------|---------------------|
| Event 1. Breach of Ampoule | | | | | | | | |
| Existing procedures were inadequate to prevent rupture. | <ul style="list-style-type: none"> NIST 364 does not require a safety evaluation for sources in storage. Safety Evaluation process does not apply to sources in storage. OU hazard assessments are activity based and do not assess storage. | Develop a procedure to ensure safety of sources (in use and in storage) to include evaluation of: <ol style="list-style-type: none"> Material stability with respect to: <ul style="list-style-type: none"> Off-gassing (radiological, chemical) Reactivity (chemical, physical) Radiolysis of matrix constituents and specifically of water by isotopes and their progeny Adequacy of container, taking into consideration ageing of container Adequacy of storage location: room, location within room; shielding; potential for adverse effects on nearby sources; Need for separation from other sources based on risk to other sources in the area Determine and specify controls needed to handle co-located sources. Consider segregating sources based on hazard class. | C | N/A | GRSD, in collaboration with the SUs, is working on the modification of existing Safety Evaluations to prevent pressure build up conditions. | The Gaithersburg Radiation Safety Division (GRSD) will create a Safety Evaluation that includes procedures for safe storage of radioactive sources. | 6/29/2018 | 6/29/2018 |

Corrective Action Plan (CAP)

Licensee Event 52916



| Root Cause | Description | Finding/Recommendation | Concur Status | Concur Status Basis | Comments | Corrective or Preventive Action(s) | Projected Completion Date | Actual Closure Date |
|---|---|---|---------------|---------------------|----------|---|---------------------------|---------------------|
| Event 2. Contamination Event | | | | | | | | |
| Procedures were inadequate for detecting contamination. | <p>Contributing Factors:</p> <p>Inadequate contamination monitoring equipment.</p> <p>Inadequate Counting procedure</p> <p>Inadequate procedure for leak testing: threshold for response to potential contamination conditions.</p> | <p>Revise procedures to require use of monitors or survey instruments appropriate for sources in the use area. Monitoring equipment used must be based on sources present and risks presented. Reevaluation of adequacy of monitoring equipment should occur when conditions change, including when types of RAM in the room change, and equipment changed if necessary based on this evaluation.</p> <p>Revise smear counting procedure to compare readings to appropriate detection levels. Procedural thresholds for investigation must be revised to ensure timely investigation and control of potentially contaminated areas. Include appropriate notification of GRSD supervisors and RAM facility and Source Custodians. Revise leak test procedure accordingly.</p> <p>Note: Consider use of critical or decision levels rather than MDA. Consider whether values above the detection level but below the ALARA action level should be reported to stakeholders and/or investigated.</p> | C | N/A | N/A | GRSD will revise standard operating procedures RSI B 1-1 "Radiation Safety ALARA Action Levels", E 4-1 "Radiation Facility Surveys and Audits", D 4-5 "Sealed Source Leak Testing", B 6-4 "Counting Statistics and Reporting Criteria" and all the G 7 – X series for instrumentation. The procedures will include a more stringent threshold for GRSD follow-up of potential contamination as well as further notification requirements for informing GRSD line management, OUs line management, Radiation Facility Owners, and Source Users and Custodians. | 9/28/2018 | |

Corrective Action Plan (CAP)

Licensee Event 52916



| Root Cause | Description | Finding/Recommendation | Concur Status | Concur Status Basis | Comments | Corrective or Preventive Action(s) | Projected Completion Date | Actual Closure Date |
|--|---|---|---------------|---------------------|---|--|---------------------------|---------------------|
| Procedures for responding to and communicating contamination events were not followed. | <p>Contributing Factors:</p> <p>Inadequate response to personnel contamination events.</p> <p>Failure to report monitor alarms.</p> <p>Inadequate knowledge of contamination monitors by users.</p> | <p>Reinforce the responsibility and importance of all personnel reporting alarms promptly to GRSD during biannual training.</p> <p>Ensure procedures for responding to personnel contamination events are followed and investigations of events conducted in a timely manner.</p> <p>Reinforce procedures for investigation of contamination monitor alarms.</p> <p>Consider reviewing H & F monitors usage logs to determine rate of unreported events and develop a protocol for addressing unreported events.</p> <p>Provide training on capabilities and limitations of contamination monitors. Consider posting this information directly on the monitors.</p> | C | N/A | GRSD line management will reinforce the procedures for investigating contamination monitor alarms and responding to contamination events. | <p>GRSD will modify the Source Users training standard operating procedure, RSI B 1-4B, to more explicitly capture the importance of prompt notification of contamination alarms and cover the capabilities and limitations of contamination monitors. GRSD will revise Source User training slides/material to capture the modifications to RSI B 1-4B.</p> <p>GRSD will modify the standard operating procedure for responding to radiological incidents (RSI 1-3), to include guidance on incident investigation; including the importance of timeliness for investigating contamination monitor alarms.</p> <p>GRSD shall develop a procedure to cover identification and reporting requirements to address unreported events.</p> | 9/28/2018 | |

Corrective Action Plan (CAP)

Licensee Event 52916



| Root Cause | Description | Finding/Recommendation | Concur Status | Concur Status Basis | Comments | Corrective or Preventive Action(s) | Projected Completion Date | Actual Closure Date |
|------------|--|---|---------------|---------------------|--------------------------------------|---|--|---------------------|
| N/A | Contributing Factor: Inadequate procedure for exiting RAM facilities. | Perform a risk-based evaluation of requirements for H & F monitor use upon leaving RAM facilities, based on sources present and stability, potential for leaks, breaches. | C | N/A | This will be a multi-stage response. | GRSD will perform a risk-based evaluation of the existing requirements for personnel contamination monitoring. GRSD will revise Safety Evaluations and procedures that do not effectively cover the subject of personnel contamination monitoring. | 5/31/2018 7/1/2018 9/28/2018 | 7/1/2018 |

Corrective Action Plan (CAP)

Licensee Event 52916



| Root Cause | Description | Finding/Recommendation | Concur Status | Concur Status Basis | Comments | Corrective or Preventive Action(s) | Projected Completion Date | Actual Closure Date |
|------------|---|---|---------------|---------------------|--|---|-----------------------------------|---------------------|
| N/A | <p>Contributing Factors: Lack of PPE during routine handling and use of sources in C11, including during conduct of inventory.</p> <p>Lack of protective equipment use during leak testing.</p> | <p>PPE requirements for routine handling should take into consideration all sources stored in that location.</p> <p>Modify the leak-testing procedure to explicitly state the conditions requiring the use of gloves and other PPE. Provide guidance specifying when gloves can be reused or must be changed. *</p> <p><i>*Consider consulting RPD in developing guidance for glove reuse based on the type of research being performed in that area, the potential for cross-contamination, and programmatic impact of such cross-contamination.</i></p> | C | N/A | Periodic management oversight of staff will reinforce this activity. | <p>GRSD will modify the standard operating procedure for leak testing, RSI 4-5, to explicitly state the conditions requiring PPE.</p> <p>GRSD will modify the training standard operating procedure, RSI B 1-4B, to more explicitly provide contamination control guidance for activities not covered under Safety Evaluations (e.g. leak testing).</p> | <p>5/28/2018</p> <p>9/28/2018</p> | 6/14/2018 |

Corrective Action Plan (CAP)

Licensee Event 52916



| Root Cause | Description | Finding/Recommendation | Concur Status | Concur Status Basis | Comments | Corrective or Preventive Action(s) | Projected Completion Date | Actual Closure Date |
|------------|---|--|---------------|---------------------|---|--|---------------------------|---------------------|
| N/A | <p>Contributing Factor: Inadequate supervision and follow-up by several previous supervisors when user observed not using PPE.</p> <p>Inadequate Survey</p> | <p>GRSD management must ensure that all personnel are held accountable for compliance with applicable procedures. Supervisors must ensure adequate oversight and adherence to procedures. *</p> <p><i>*This corrective action was already underway with the technician and the technician's first level supervisor.</i></p> <p>Reinforce training on use of alpha survey equipment, including proper functioning of equipment.</p> | C | N/A | GRSD line management performance plans were changed to require documented observations of work of staff members. The QAM duties additionally include oversight of various tasks on a quarterly basis. | GRSD will revise the standard operating procedure for health physics training and qualifications (RSI 1-2) to add explicit oversight requirements and management of change in duties and/or personnel. | 6/29/2018 | 7/10/2018 |

Corrective Action Plan (CAP)

Licensee Event 52916



| Root Cause | Description | Finding/Recommendation | Concur Status | Concur Status Basis | Comments | Corrective or Preventive Action(s) | Projected Completion Date | Actual Closure Date |
|--|--|---|---------------|---------------------|---|--|----------------------------|---------------------|
| Event 3. Exposure Event | | | | | | | | |
| Procedures did not adequately specify PPE and monitor use. | Contributing Factor: Inadequate contamination monitoring equipment. | Revise procedures to specify PPE (types and when required) and require that monitoring equipment used must be based on sources present and risks presented. Ensure that appropriate monitors are available for use and located near work performed to minimize potential for personnel exposure. | C | N/A | Additional alpha monitoring instruments were acquired to improve availability and detection capabilities to minimize the potential for the spread of contamination. | GRSD will modify the standard operating procedure for leak testing, RSI 4-5, to explicitly state the conditions requiring PPE. GRSD will modify the training standard operating procedure, RSI B 1-4B, to more explicitly provide contamination control guidance for activities not covered under Safety Evaluations (e.g. leak testing). | 5/28/2018 9/28/2018 | 6/14/2018 |

Corrective Action Plan (CAP)

Licensee Event 52916



| Root Cause | Description | Finding/Recommendation | Concur Status | Concur Status Basis | Comments | Corrective or Preventive Action(s) | Projected Completion Date | Actual Closure Date |
|--|-----------------------------|---|---------------|---------------------|---|---|---------------------------|---------------------|
| Contamination events were not investigated according to procedure. | N/A | Ensure that indicators of contamination events are investigated adequately and in a timely manner, according to procedure. | C | N/A | RSI B 1-3 does not currently provide requirements and guidance on incident investigation. | GRSD will modify the standard operating procedure for responding to radiological incidents (RSI 1-3), to include guidance on incident investigation; including the importance of timeliness for investigating contamination monitor alarms. | 9/28/2018 | |
| N/A | Exogenous factors: workload | Consider conducting collaborative drills to practice for radiation safety incidents, after which RPD and GRSD collaborate to identify ways to improve the response. | C | N/A | N/A | GRSD will revise standard operating procedures, RSI 1-3 and RSI B 1-4B, to have requirements to occasionally have Source Users participation in exercises and drills. | 9/28/2018 | |

Corrective Action Plan (CAP)

Licensee Event 52900

| Recommendation | Concur Status | Concur Status Basis | Comments | Corrective or Preventive Action(s) | Projected Completion Date | Actual Closure Date |
|---|---------------|---|---|---|---------------------------|---------------------|
| Recommendation 1: A procedure should be implemented to ensure that when a source is transferred to a new SC, information about the source's physical description/source storage conditions, including photographs of sealed sources and of non-routine storage conditions, is conveyed to the new SC along with it. GRSD should be included in any relevant information exchange, including having the SC present at the initial leak checks. | C | N/A | Meetings were held with GRSD personnel and Source Users to discuss changes to practices and procedures. | GRSD will revise standard operating procedure RSI A1-11 to include the development of a NIST/GRSD form to ensure that Source Custodianship transfers are done in a manner that would provide all the necessary information about the source(s) to the new Source Custodian. | 6/29/2018 | 7/10/2018 |
| Recommendation 2: Ensure that work areas and storage spaces are maintained in a clean, organized manner. | PC | GRSD does not control the space used by various OUs. The OUs must be responsible for ensuring their facilities are maintained in a clean, organized manner. | GRSD will work with OU management and place additional effort on housekeeping of radiation facilities during audits and inspections. A letter from the RSO and IRSC Chair was drafted and will be sent to OU line managers (with cc to Directors) informing them of prevalent housekeeping issues in RAM facilities. | GRSD will revise standard operating procedure RSI E4-1 (Radiation Facility Surveys and Audits) to include specific guidance on monitoring the upkeep of RAM facilities. | 6/29/2018 | 7/10/2018 |

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|---|---------------|---------------------|--|---|---------------------------|---------------------|
| Recommendation 3: Management should periodically emphasize inventory management procedures. Initial and refresher training should be revised to reemphasize adequate inventory management practice. | C | N/A | Annual inventory reconciliation activities were rescheduled to Spring to avoid increased workload for SCs. Changing the schedule to the Spring time was proposed during an all-hands meeting with divisions 682 and 152 in 2017. | GRSD will revise standard operating procedure RSI 1-4B (covers Source User and Source custodian training requirements) to include detailed guidance on inventory management and management of changes. | 5/4/2018 | 6/15/2018 |
| | | | A training session specifically for SCs will be done prior to the next reconciliation. | GRSD will conduct a Source Custodians refresher training session to include detailed guidance on inventory management and management of changes. | 5/30/2018 | 5/30/2018 |
| Recommendation 4: SCs should always be notified for all leak tests, or when any new procedure is being pursued. | C | N/A | The Gaithersburg radioactive materials suborder (to be deployed) includes roles and responsibilities of Source Custodians regarding leak tests. | GRSD will modify standard operating procedure RSI 4-5 (sealed source leak testing) to explicitly state the requirement to contact Source Custodians ahead of leak tests and arrange for laboratory visits and to discuss any new or changed procedures. | 5/30/2018 | 7/10/2018 |

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| Recommendation 5: GRSD should review incident response procedures and modify as necessary to assure that responses are ongoing and address all conditions. | C | N/A | The review of RSI B 1-3 will look for opportunities to improve guidance on response to other conditions. | GRSD will revise standard operating procedure RSI B 1-3 (emergency response) to include specific guidance on responding to loss of material. The revision will also update other NRC reporting requirements. | 5/30/2018 | 5/31/2018 |
| Recommendation 6: GRSD should continue to perform inventory spot checks requiring visual source verification where feasible and develop metrics to determine the effectiveness of radioactive material inventory practices. | C | N/A | The spot check procedure is an integral activity of inventory and program management. As such, it will be a continued activity. | GRSD will revise standard operating procedure RSI 4-18 (inventory spot check) to include a review of metrics to monitor the effectiveness of RAM inventory practices. | 5/30/2018 | Closed pending NCNR approval. |
| Recommendation 7: Add the source verification method used to the inventory response forms (already done by GRSD). | C | N/A | The documentation of the method of source accountability verification will also be useful to the spot check program. | The form provided to Source Custodians to perform inventory reconciliation was modified to explicitly indicate the method of verification: visual inspection, radiation measurements, mass measurements, and/or security/tamper seal. | N/A | 8/2017 |

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| Recommendation 8: GRSD and PML management should examine relationships within and between their organizations to better facilitate open and timely communications. | PC | This recommendation will require ongoing effort from both divisions. | GRSD and the Radiation Physics Division management have established a weekly meeting to generate more effective communication between the groups. The Chiefs of divisions 152 and 682 have established a quarterly meeting to discuss issues and collaboration with the PML director. | N/A | N/A | N/A |

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| Recommendation 9: GRSD should develop a robust, user-friendly database, accessible to users to ensure accurate data is maintained in a timely manner for each source (new database in preparation). | C | N/A | <p>The new database will address the main inventory management limitations in the existing database, such as allowing for multiple radionuclides to be registered under a source.</p> <p>As an interim action, hard-copy records are being reconciled with the assistance of Source Custodians to make the data in the current database as up-to-date and accurate as possible.</p> | GRSD will lead the effort to develop a new database system which will allow Source Users (and Custodians) to have real-time and accurate data in support of radioactive material control and accountability activities. | March 2019 | |

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| Recommendation 10: OUs should ensure that sources that are not in use are placed into storage, thus obviating the need for increased resources in performing frequent leak checks. | C | N/A | GRSD will verify that all sources "in use" are covered under a safety evaluation and hazard assessment. GRSD will also verify that all inactive sources are registered as being in storage. | GRSD will create a Safety Evaluation for sources in storage. This will include instructions for evaluating each source under a hazard assessment. | 6/29/2018 | 6/29/2018 |
| | | | The Source Custodians will also have the ability to indicate that a source is to be wasted. | Source Custodians will confirm, via the annual inventory source reconciliation, that sources that are not foreseen to be used are placed into storage or inactive status in the database. | 6/29/2018 | 6/29/2018 |

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| Additional Recommendation: An effort should be made to identify any sources that have no scientific value and dispose of them. This will reduce the effort in maintaining, leak checking, and verifying the large source inventory. | C | N/A | <p>The Radiation Physics Division has established a committee to compile a list of unwanted sources and to declare those sources as waste prior to completion of the next inventory reconciliation.</p> <p>A similar effort was done in CY 2015 and resulted in disposal of 255 sources significantly reducing risk and liability, plus operational burden.</p> | RPD will provide GRSD with a source list and accompanying waste manifests for unwanted sources deemed no longer having scientific value. This will be done as part of the annual inventory reconciliation. | 6/29/2018 | 6/29/2018 |
| The NIST Ionizing Radiation Safety Committee will conduct a root cause analysis and identify corrective actions. | C | N/A | N/A | The NIST Ionizing Radiation Safety Committee conducted a root cause investigation and identified recommendations for NIST. GRSD is leading the development and implementation of corrective actions. | 2/8/2018 | 2/26/2018 |

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| A quality assurance program will be developed within GRSD. This program will have a dedicated element to inventory management activities, including spot checks to verify adequacy of source storage and labeling. | C | N/A | N/A | A GRSD health physicist was realigned/reassigned to oversee QA of GRSD activities, including spot checks to verify adequacy of source storage and labeling. | N/A | 10/2017 |