UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

February 22, 2016

EA-15-165

Dr. Renee A. Reijo Pera, PhD
Vice-President for Research
Montana State University
1160 Research Drive
Bozeman, MT 59718-6856

SUBJECT: NRC SPECIAL INSPECTION REPORT 030-00871/2014-001 AND INVESTIGATION REPORT 04-2014-042

Dear Dr. Pera:

This letter refers to the special inspection and investigation conducted at your facility in Bozeman, Montana. The purpose of the inspection was to review the circumstances related to Montana State University's report of a lost, specifically licensed, gas chromatograph (GC) containing a nickel-63 (Ni-63) sealed source. Montana State University notified the U.S. Nuclear Regulatory Commission (NRC) Headquarters Operations Center on August 2, 2014, and submitted a written report to the NRC on September 16, 2014. The on-site portion of the special inspection was conducted October 7-9, 2014, with in-office review through January 7, 2016. The NRC's Office of Investigations (OI) initiated an investigation on August 21, 2014. The inspector discussed the preliminary inspection findings with Mr. Justin Cook of your staff at the conclusion of the on-site portion of the inspection. A final exit briefing was conducted telephonically with you and members of your staff on January 7, 2016. The enclosed report presents the results of this inspection (Enclosure 1). The results of the investigation are discussed in the Factual Summary of the NRC Investigation (Enclosure 2).

The inspector examined activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations. Within these areas, the inspection consisted of an examination of selected records, observations of activities, and interviews with personnel. The focus of the inspection was to review the circumstances surrounding the lost Ni-63 sealed source.

Based on the information developed during the inspection and investigation, five apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations involve the failure to: (1) maintain control over licensed material as required by 10 CFR 20.1802; (2) conduct leak tests of sealed sources; (3) conduct a complete physical inventory; (4) provide complete and accurate information as required by 10 CFR 30.9(a); and (5) provide required Department of Transportation training to individuals who transported licensed material outside of the site of usage. Based on the results of the OI investigation, the NRC is concerned that willfulness might be associated with the apparent violation of 10 CFR 30.9(a).

Because you identified the violations, your facility has not been the subject of escalated enforcement actions within the last 2 years, and based on our understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. The final decision will be based on you confirming on the license docket that the corrective actions previously described to the NRC staff have been or are being taken.

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 pre-decisional enforcement conference (PEC); or (3) request Alternative Dispute Resolution (ADR). 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 Brooke G. Smith at 817-200-1456 and in writing, within 10 days from the issue date of this letter to notify us of your intentions. 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 Violations in NRC Inspection Report 030-00871/2014-001; EA-15-165" 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. Additionally, your response should be sent to the NRC's Document Control Center, with a copy mailed to Mr. Mark R. Shaffer, Region IV, 1600 E. Lamar Blvd., Arlington, Texas 76011, within 30 days of the date of this letter. If an adequate response is not received within the time specified and 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 afford you the opportunity 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 conference 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 would be considered in assessing any civil penalty for the apparent violations. The guidance in the NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the Information Notice on the NRC Web site at http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf .

In lieu of a PEC, you may 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. Mediation is 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's program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr/post-investigation.html. The Institute on Conflict Resolution (Cornell) has agreed to facilitate the NRC's program as a neutral third party. Please contact Cornell at 877-733-9145 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report 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.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter and its enclosures 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). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, security-related, or safeguards information so that it can be made available to the Public without redaction.

If you have any questions concerning this matter, please contact Brooke G. Smith at (817) 200-1456.

Sincerely,

/RA/

Mark R. Shaffer, Director
Division of Nuclear Materials Safety

Docket No. 030-00871
License No. 25-00326-06

Enclosures:
1. NRC Inspection Report 030-00871/2014-001
2. Factual Summary of OI Investigation Report (4-2014-042)

cc: Director, Montana Radiation Control Program

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Division of Nuclear Materials Safety

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cc: Director, Montana Radiation Control Program

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Letter to Dr. Renee A. Reijo Pera from Mark R. Shaffer dated 22 February 2016

SUBJECT: NRC INSPECTION REPORT 030-00871/2014-001 AND INVESTIGATION REPORT 04-2014-042

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U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.:	030-00871
License No.:	25-00326-06
Report No.:	2014-001
EA No.:	EA-15-165
Licensee:	Montana State University
Location Inspected:	1160 Research Drive, Bozeman, Montana
Inspection Date:	October 7, 2014 – January 7, 2016
Inspector:	Michelle M. Hammond, M.Sc., Health Physicist Nuclear Materials Safety Branch B
Approved By:	Brooke G. Smith, Acting Chief Nuclear Materials Safety Branch A

EXECUTIVE SUMMARY

Montana State University
NRC Inspection Report No. 030-00871/2014-001

This report describes the circumstances surrounding an event involving the loss of a 13.73 millicurie (mCi) nickel-63 (Ni-63) sealed source contained in a gas chromatograph at Montana State University (MSU) campus located in Bozeman, Montana. The event was reported to the U.S. Nuclear Regulatory Commission's (NRC) Headquarters Operations Center (HOC) on August 2, 2014, and documented in a Licensee Event Report submitted on September 16, 2014. The NRC performed a site inspection, an investigation, and in-office review of all information obtained.

Program Overview

MSU is authorized for the possession and use of radioactive material under NRC Broadscope Type A License Number 25-00326-06. The licensed activities include research and development as defined in 10 CFR 30.4, academic instructional purposes, use of sealed and unsealed sources at locations on and off campus, use of sealed sources in analytical instruments, use of unsealed sources in laboratory research, and use of a gamma irradiator for irradiation of small animals and cells. (Section 1)

Licensee Response to Event

On August 2, 2014, MSU notified the NRC HOC regarding the loss of a 13.73 mCi Ni-63 sealed source enclosed in a gas chromatograph. The licensee's report to the NRC dated September 16, 2014, described an extensive search for a gas chromatograph containing the Ni-63 source. The findings of the licensee's internal investigation, probable cause analysis of the event, and any potential for public exposures above the public dose limits were included in the report and a subsequent report received on October 7, 2014. In addition, the licensee provided a detailed description of the corrective actions implemented as part of the measures to prevent recurrence. (Section 2)

Contributing Causes

The licensee concluded that contributing causes of the event included: (1) the former Radiation Safety Officer (RSO) failed to follow procedures and perform physical inventories of sealed sources authorized under MSU's license; and (2) the RSO did not consistently follow the university's prescribed procedures for material accountability. The inspector agreed with licensee's assessment of the contributing causes to the event. (Section 2)

Inspection Findings

In January 2014, as part of a reorganization, the Radiation Safety Office, which was part of Safety Research Management, moved to the Office of Research Compliance (ORC). During the transition, MSU management became concerned about the adequacy of the radiation safety program and instructed the RSO to perform a program audit including an inventory of all sealed sources authorized under the MSU license. On July 3, 2014, an inventory was conducted by the RSO and a 13.73 mCi Ni-63 sealed source was discovered to be missing. However, the RSO did not disclose this information to the ORC until July 10, 2014. A report of a missing source Ni-63 was made to the NRC HOC on August 2, 2014 (NMED Item No. 140417). In August 2014, the licensee hired an external consultant to perform a full audit of the radiation safety program.

The audit results noted that an additional Ni-63 source (approximately 14 mCi) was misplaced and another sealed source (1.74 mCi of Ni-63) was found to be leaking. The second missing Ni-63 source was later confirmed to have been transferred to another academic institute and the leaking source was reported to the NRC HOC. The audit revealed that the RSO had failed to conduct leak tests or complete a physical inventory of all the sealed sources authorized under the MSU license. Furthermore, the records kept by the RSO indicated that leak tests had been performed on the two Ni-63 sources when they had not been performed and that a physical inventory of all sealed sources possessed under the MSU license had been performed when it had not been performed on two sources. In August 2014, the licensee took disciplinary action against the former RSO for failing to maintain complete and accurate records of inventories to account for licensed material at the 1160 Research Drive location. This was identified as an apparent violation of 10 CFR 30.9. (Section 3)

During the inspection, the NRC inspector confirmed the information provided by the licensee in its report of the missing Ni-63 sources and it was determined that as of July 3, 2014, the licensee failed to control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that was not in storage. This was identified as an apparent violation of 10 CFR 20.1802. (Section 3)

In addition, during the inspection it was determined that licensed material consisting of waste from various research laboratories had been transported by the licensee outside of the site of usage without the required Department of Transportation hazmat employee training. This was identified as an apparent violation of 10 CFR 71.5(a). (Section 3)

Corrective Actions

In a letter dated January 15, 2015, MSU documented the corrective actions that it had taken (ML15015A687). These corrective actions included:

- From August 2, 2014 through January 15, 2015, the licensee reviewed documents associated with the radiation safety program, including leak test and physical inventory records, and conducted a physical search of multiple locations on the campus in an attempt to locate all of its licensed devices and material authorized under the NRC license.

- The licensee interviewed personnel who may have known about or removed any of the devices or material from service to try to determine whereabouts of the missing Ni-63 sealed sources.

- In August 2014, the licensee hired an external consultant to conduct an audit of the MSU Radiation Safety Program. In September 2014, MSU informed NRC that they were in the process of implementing the recommendations from the consultant and staff was still searching for the missing Ni-63 sealed source in the gas chromatograph. During the audit, an additional Ni-63 sealed source contained in a gas chromatograph was also determined to be lost and another source was found to be leaking. During the onsite inspection, it was confirmed that the additional source that was determined to be lost was actually in another location, and the leaking source was properly contained, labeled, and transferred for waste disposal.

- On October 3, 2014, the licensee appointed a new RSO that will report to the Director of the Office of Research Compliance to ensure the day-to-day compliance with regulations and requirements for the use and storage of radioactive materials at its facilities.

- The licensee updated procedures and provided training to the staff, focusing on material accountability, radiation safety practices, transportation, university policies, and security.

Report Details

1 Program Overview (87114)

1.1 Inspection Scope

The inspector reviewed the license application, supporting documents, and other records provided by the licensee. In addition, the inspector review the Licensee Event Report (LER) submitted on September 16, 2014, detailing the report of the missing 13.73 mCi Ni-63 sealed source contained in a gas chromatograph that was originally reported to the NRC's HOC on August 2, 2014. Collectively, these documents describe the licensee's radiation safety program and actions taken in response to the event and the licensee's subsequent investigations and reviews.

1.2 Observations and Findings

MSU is authorized for the possession and use of radioactive material under NRC Broad scope Type A License Number 25-00326-06. The licensed activities include: research and development as defined in 10 CFR 30.4, use of radioactive material for academic instructional purposes, use of sealed and unsealed sources at the main campus on Research Drive in Bozeman, Montana, use of sealed sources in analytical instruments, use of unsealed sources in laboratory research, and use of a gamma irradiator for irradiation of small animals and cells. MSU also has authorization for use and storage of licensed materials within the boundaries of Yellowstone National Park, Montana, Barrow Arctic Science Consortium in Barrow, Alaska, and temporary job sites anywhere in the United States where the NRC maintains jurisdiction.

2 Licensee's Event Report (87103)

On August 2, 2014, MSU reported a missing specifically licensed gas chromatograph containing a 13.73 mCi Ni-63 sealed source to the NRC HOC and submitted an LER on September 16, 2014. The report was submitted in accordance with the requirements of 10 CFR 20.2201. The 13.73 mCi Ni-63 sealed source was contained in a gas chromatograph/electron capture detector (GC/ECD Varian model 3400, serial #13762) that was in storage at the licensee's main campus in Bozeman, Montana. The manufacturer and model numbers on the initial and updated reports from the licensee were for the devices (GC/ECD) not the sources. The inspector included the source model numbers in accordance with the sealed source and device (SS&D) registry (#CA-8253-D-801-B (device) and #CA0406S214S (sources).

2.1 Licensee's Response to the Event

MSU management was not aware that the gas chromatograph containing a 13.73 mCi Ni-63 sealed source was missing until July 10, 2014. In January 2014, as part of a reorganization, the Radiation Safety Office, which was part of Safety Research Management, moved to the Office of Research Compliance (ORC). During the transition, MSU management became concerned about the adequacy of the radiation safety program and instructed the RSO to perform a program audit including an inventory of all sealed sources authorized under the MSU license. On July 3, 2014, an inventory was conducted by the RSO and the 13.73 mCi Ni-63 sealed source was discovered to be missing. However, the RSO did not disclose this information to the ORC until July 10, 2014.

A report of a missing source Ni-63 was made to the NRC HOC on August 2, 2014 (NMED Item No. 140417).

In August 2014, the licensee hired an external consultant to perform a full audit of the radiation safety program. The audit results noted that an additional gas chromatograph containing a Ni-63 sealed source (approximately 14 mCi) was misplaced and another sealed source (1.74 mCi of Ni-63) was found to be leaking. The second missing Ni-63 source was later confirmed to have been transferred to another academic institute and the leaking source was reported to the NRC HOC.

As part of the audit, MSU management reviewed previous records and noted that leak test records showed results for the missing source and proposed that inventories appeared to be duplicated and/or falsified. The audit revealed that the RSO had failed to conduct leak tests or complete a physical inventory of all the sealed sources authorized under the MSU license. The records kept by the RSO indicated that leak tests had been performed on the two Ni-63 sources when they had not been performed and that a physical inventory of all sealed sources possessed under the MSU license had been performed when it had not been performed on two sources. In August 2014, the licensee took disciplinary action against the former RSO for failing to maintain complete and accurate records of inventories to account for licensed material at the 1160 Research Drive location.

During the inspection, the inspector reviewed the licensee's leak test records from 2008 through 2014 and confirmed that the licensee had failed to test the two Ni-63 sealed sources enclosed in gas chromatographs for leakage and/or contamination at intervals not to exceed 6 months, or at other intervals as specified by a certificate of registration referred to in 10 CFR 32.210. The inspector also reviewed the licensee's physical inventory records from 2008 through 2014 and confirmed that the licensee had failed to conduct a physical inventory every 6 months or at other intervals approved by the NRC of the two Ni-63 sealed sources enclosed in gas chromatographs.

It was also confirmed during the inspection that the RSO failed to maintain complete and accurate information with regard to leak test documentation. Although the previous RSO documented performance of leak tests and a physical inventory with the correct serial number on the record, the individual failed to conduct an adequate physical inventory by not physically observing or conducting the leak tests on the two missing gas chromatographs containing Ni-63 sealed sources during previous inventories. As a result, the records that the former RSO had developed to document these leak tests and physical inventories was inaccurate in all material respects.

In summary, the licensee failed to test sealed sources for leakage and/or contamination, failed to conduct a complete physical inventory, and failed to maintain complete and accurate information with regard to the physical inventory and leak test documentation.

2.2. Licensee's Contributing Causes of the Event

According to MSU's internal assessment, the causes for the loss of the gas chromatograph containing a 13.73 mCi Ni-63 sealed source were: 1) the former RSO did not follow procedures when performing the physical inventories; 2) the licensee failed to train all of the authorized users on material accountability and security of devices that contained licensed material; and 3) the RSO failed to inform management that sources could not be located during leak testing procedures. The former management structure lacked

accountability and oversight and the former Safety Manager was the primary advisor to the Director of Research on all compliance issues and responsible for reporting weaknesses in the radiation safety program. MSU restructured its management in this area and currently has a new Director of the Office of Research Compliance to ensure compliance with all regulatory requirements and hired a new RSO. The inspector agreed with the licensee's assessment of the contributing causes of the event.

3 Inspection Findings

3.1 Inspection Scope

A reactive inspection was conducted October 7-9, 2014 on the main campus of MSU in Bozeman with in-office review continued through January 7, 2016. The inspection included a follow-up to MSU's report of a missing Ni-63 source to the NRC Operations Center on August 2, 2014, and follow-up written report regarding an additional missing source and a leaking source received on September 16, 2014. The inspector interviewed cognizant individuals associated with the event and reviewed the license application, supporting documents, and other records provided by the licensee. Collectively, these documents described the actions taken as a result of the event and the licensee's radiation safety program. The inspector reviewed the licensee's possession, accountability, and transportation of licensed material, including the process used to conduct physical inventories of the material. Additionally, a comprehensive review of all physical inventories were completed by the licensee's consultant and reviewed by the inspector.

3.2 Observations and Findings

MSU was in the process of disposing of all unwanted or unused radioactive sources. The RSO determined that the gas chromatograph containing the 13.73 mCi Ni-63 sealed source was no longer in Chemistry/Biochemistry Room 28. A note and picture of the gas chromatograph was sent to all personnel in the Land Resources/Environmental Science and Chemistry/Biochemistry departments. In addition, a search of all chemistry laboratories was conducted by the previous RSO. The previous RSO and staff searched various locations of use on the campus. Two other gas chromatographs were picked up by the previous RSO and taken to his secure laboratory for removal of their Ni-63 sealed sources in order to prevent this type of incident from happening again. During the search for the missing gas chromatograph, another gas chromatograph was found in a laboratory that had not been registered with the previous RSO. The previous RSO requested that all principle investigators (PIs) report all radiation producing equipment to him. The previous RSO met with all PIs to verify there were no unreported radiation producing devices on campus. The previous RSO also placed notices on all gas chromatographs specifying that the RSO must be contacted prior to relocating devices.

An updated report submitted to the NRC on September 16, 2014 (ML14260A554) stated that during an inventory performed by an independent consultant, Stan Wilson, Behavioral-Based Improvement Solutions, another gas chromatograph containing a Ni-63 sealed source was identified as missing from its last known location (GC/ECD Agilent model 6890, serial # U4156) at the McCall Builiding, Room 25. This device contained a ~13.95 mCi Ni-63 sealed source. Additionally, this report included a notification that a 1.74 mCi Ni-63 sealed source (Eckert & Zeilger, IPL (formerly New England Nuclear) NER-9048 S/N 37515-01) was leak tested and revealed the presence of contamination in excess of 0.005 microcuries.

The inspector reviewed documentation provided for the ~13.95 mCi Ni-63 sealed source reported in September 2014 (GC/ECD (SN10212088)) and confirmed that it had been transferred to another department before ultimately being sent to Property Management to be surplussed. Acquisition documentation stated that the disposal date was August 1, 2011, and the disposal method was "Salvaged/Cannibalized." The inspector confirmed that the leaking source was properly packaged and stored until disposal.

In a letter dated January 15, 2015 (ML15076A311), the newly appointed RSO stated that they were suspending the search for the gas chromatograph containing a 13.73 mCi Ni-63 sealed source that remained "missing," which by all accounts was most likely thrown away in regular trash while parts of the GC/ECD were surplussed by the Property Management Department.

During the October 2014 inspection, the inspector confirmed that the leaking source did not lead to contamination of the licensee's facilities and was adequately packaged, stored, and prepared for disposal. The inspector also reviewed transfer documentation and interviewed staff regarding the gas chromatograph containing ~13.95 mCi Ni-63 sealed source that was reported missing in September 2014 but its whereabouts was later determined by the licensee. This information was reviewed and found to be adquate. The inspector also observed the ongoing effort to locate the 13.73 miCi Ni-63 sealed source.

As the inspection progressed, the inspector identified another apparent violation involving the transportation of licensed material consisting of waste from various research laboratories by the licensee outside of the site of usage without the required Department of Transportation hazmat employee training.

3.3 Apparent Violations

3.3.1 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

As of July 3, 2014, the licensee failed to control and maintain constant surveillance of its licensed material resulting in the loss of licensed material (Varian/Agilent Gas Chromatograph model number 6890, containing 13.73 millicuries of Ni-63, model number NER-004 serial number U4156 as of January 2015) located in Bozeman, Montana. The failure to control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area was identified as an apparent violation of 10 CFR 20.1802. (030-00871/14-01)

3.3.2 Condition 14 A. of NRC license No. 25-00326-06, Amendment No. 61, states that sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210.

Between 2008 and 2014, the licensee failed to test sealed sources for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified by certificate of registration referred to in 10 CFR 32.210. Specifically, the failure to leak test Ni-63 sources at intervals not to exceed 36 months as specified by their certificates of registration was identified as an apparent violation of License Condition 14 A. (030-00871/14-02)

3.3.3 License Condition 25 of NRC license No. 25-00326-06, Amendment No. 61, states, in part, that the licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.

Between 2008 and 2014, the licensee failed to conduct a physical inventory every 6 months or at other intervals approved by the U.S. Nuclear Regulatory Commission to account for all sources and/or devices received and possessed under the license. The failure to conduct an inventory of two of its Ni-63 sealed sources enclosed in gas chromatographs every 6 months or at other intervals approved by the NRC was identified as an apparent violation of License Condition 25. (030-00871/14-02)

3.3.4 10 CFR 30.9(a) states, in part, that information provided to the Commission by a licensee or information required by license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

License Condition 14 F. of License No. 25-00326-06, Amendment No. 61, states, in part, that records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.

License Condition 25 of License No. 25-00326-06, Amendment No. 61, states, in part, that records of inventories shall be maintained for 5 years from the date of the each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

As of July 3, 2014, the licensee did not maintain complete and accurate information with regard to leak test and inventory documentation as required by 10 CFR 30.9(a) and as required by license conditions 14.F and 25. Specifically, records indicated that leak tests had been performed on two sources when they had not been performed. In addition, records indicated that a physical inventory of all sources possessed under the license had been performed when it had not been performed on two Ni-63 sources. This information is material because it demonstrates the licensee's control of licensed material. This was identified as an apparent violation of 10 CFR 30.9(a) and License Conditions 14 F. and 25. (030-00871/14-04)

3.3.5 10 CFR 71.5(a) requires, in part, that each licensee who transports licensed material outside of the site of usage shall comply with the applicable DOT regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397.

Title 49 CFR 172.704(c) requires, in part, that a hazmat employee receive initial hazmat training.

At various dates from August to September 2014, an employee transported radioactive waste on a public highway to an offsite location. The licensed material, consisting of waste from various research laboratories, was transported a licensee employee outside of the site of usage without the required Department of Transportation hazmat employee training. This was identified as an apparent violation of 10 CFR 71.5(a). (030-00871/14-05)

3.4 Corrective Actions

Corrective Actions implemented by the licensee included:

- Hiring an external consultant to complete a comprehensive and periodic audits of the Radiation Safety Program;
- Reviewing the consultant's report with observations and recommendations; implementing the recommendations from the consultant;
- Appointing a new RSO that will report to the Director to the Office of Research Compliance to ensure the day-to-day compliance with regulations and requirements for the use and storage of radioactive materials at its facilities;
- Updating procedures and providing training to the staff, focusing on material accountability, radiation safety practices, transportation, university policies, and security; and
- Increasing management oversight of the radiation safety program.

4.0 Conclusions

The licensee failed to control and maintain constant surveillance of licensed material that was in a controlled or unrestricted area and that was not in storage. The licensee failed to test sealed sources for leakage and/or contamination, failed to conduct a complete physical inventory, and failed to maintain complete and accurate information with regard to leak test and physical inventory documentation. A licensee employee transported licensed material outside of the site of usage without the required hazmat training. The inspector attributed the cause of the apparent violations to the licensee's failure to provide adequate oversight of the radiation protection program.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Leslie Taylor, University Legal Counsel
Dr. Renee Reijo Pera, Vice President for Research
Justin Cook, Director, Office of Research Compliance
Dr. Nick Childs, Current Radiation Safety Officer
Dr. Jim Berardinelli, Chairman, Radiation Safety Committee
Kirk Lubick, BioSafety Officer
Chris Hofer, Previous Radiation Safety Officer
Eric Boyd, Member, Radiation Safety Committee
Mark Quinn, Member, Radiation Safety Committee

INSPECTION PROCEDURES USED

IP 87126	Industrial/Academic/Research Programs
IP 87103	Inspection of Material Licensees Involved in an Incident or Bankruptcy

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-00871/2014-01	APV	An apparent violation involving the loss and control of licensed material.
030-00871/2014-02	APV	An apparent violation involving failure to conduct leak tests.
030-00871/2014-03	APV	An apparent violation involving failure to conduct a physical inventory.
030-00871/2014-04	APV	An apparent violation involving failure to maintain complete and accurate information.
030-00871/2014-05	APV	An apparent violation involving the failure to transport licensed material outside of the site of usage without the completed required HAZMAT training

Closed

None

Discussed

None

LIST OF ACRONYMS USED

APV	Apparent Violation
CFR	Code of Federal Regulations
GC/ECD	Gas Chromatograph/Electron Capture Device
MSU	Montana State University
NRC	Nuclear Regulatory Commission
OI	Office of Investigation
ORC	Office of Research Compliance
RSO	Radiation Safety Officer
SOP	Standard Operating Procedures
SRM	Safety Research Management

FACTUAL SUMMARY OF OI INVESTIGATION
REPORT 4-2014-042

An investigation was initiated by the Nuclear Regulatory Commission's (NRC) Office of Investigations, Region IV, on August 21, 2014, to determine if a former employee at Montana State University (MSU) willfully failed to perform a physical inventory of the Radiation Safety Program, and if documents were falsified regarding leak tests that were not performed. The NRC completed its investigation on August 12, 2015.

On August 7, 2014, MSU notified the NRC that MSU removed an employee from his position following the discovery that accurate inventory and leak test records had not been maintained. Upon this indication of program deficiencies, a program review of MSU's radiation safety program was conducted. As a result of the records review, discrepancies were discovered for two sealed sources detailed on the MSU license. Based on the review of the leak test records from 2010 to May 2013, MSU discovered that leak tests had been documented as completed with a date/time stamp from the leak test equipment in MSU's radiation laboratory even though the sources were never actually leak tested since they had not been accounted for since 2008.

Through testimonial and documentary evidence, i.e., leak test records, the NRC established that MSU's former employee apparently provided inaccurate information regarding leak tests of sealed sources. The leak test records are used to validate that MSU has accountability of all sealed sources and to validate that none of the sources were leaking.

During the OI investigation, the former employee admitted that he provided information in the documentation reflecting that he did conduct the leak tests although he did not do so. He also admitted that he knew at that time that MSU no longer possessed the sources. When asked specifically by OI, RIV, whether all information required by the NRC under an NRC license is required to be accurate and correct, he replied "yes" that it was a correct statement. The employee also admitted understanding the responsibility to produce accurate and complete information in reports utilized by the NRC.