



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
1600 E. LAMAR BLVD.
ARLINGTON, TX 76011-4511

June 24, 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: NOTICE OF VIOLATION - NRC INSPECTION REPORT 030-00871/2014-001
AND INVESTIGATION REPORT 4-2014-042

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 containing a nickel-63 sealed source. Montana State University notified the U.S. Nuclear Regulatory Commission (NRC) Headquarters Operations Center of this issue on August 2, 2014, and submitted a written report to the NRC on September 16, 2014. The NRC inspection report was issued on February 22, 2016 (Agencywide Documents Access and Management System (ADAMS) ML16006A571) and the NRC's Office of Investigations report was issued on August 12, 2015. The preliminary inspection findings were discussed with Mr. Justin Cook of your staff at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted telephonically with you and members of your staff on January 7, 2016.

In the NRC letter dated February 22, 2016, we provided you with the opportunity to address the violations identified in the report by either attending a predecisional enforcement conference, requesting alternative dispute resolution (ADR), or by providing a written response before we made our final enforcement decision. We received your letter dated February 25, 2016 (ML16083A414) in which you provided a written response containing your corrective actions to the violations.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report, the NRC has determined that five violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involve the failure to: (1) maintain control over licensed material as required by Title 10 of the *Code of Federal Regulations* (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 the site of usage.

The failure to conduct a complete inventory of sealed sources, to conduct leak tests, and to provide complete and accurate information could prevent timely identification of a loss of licensed material. Because of the significance of these violations, four are categorized collectively, in accordance with the NRC Enforcement Policy, as a Severity Level III problem and the fifth as a Severity Level IV violation. The current Enforcement Policy is included on the NRC's Web site at: <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

In accordance with the NRC Enforcement Policy, a base civil penalty of \$3,500 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last 2 years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. Based on your prompt and comprehensive corrective actions, the NRC has determined that *Corrective Action* credit is warranted. Specifically, your corrective actions include: (1) restructuring the management organization to increase oversight; (2) immediately re-training principal investigators and authorized users; (3) immediately conducting a complete inventory and leak tests; (4) disposing of unwanted and unused sealed sources; (5) training workers who transport radioactive waste on public highways; and (6) increasing security measures to maintain control of licensed material.

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

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in Montana State University correspondence dated January 15, 2015 (ML15015A687), February 25, 2016 (ML16083A414), and in NRC Inspection Report 030-00871/2014-001. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

If you disagree with this enforcement action, you may either follow the instructions in the attached Notice or request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution 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 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 ADR program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr/post-investigation.html>. The Institute on Conflict Resolution at

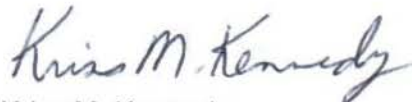
Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact Cornell at 877-733-9145 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS, accessible from the NRC Web site at: <http://www.nrc.gov/reading-rm/adams.html>.

To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

If you have any questions concerning this matter, please contact Ray Kellar at (817) 200-1191.

Sincerely,



Kriss M. Kennedy
Deputy Regional Administrator

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

Enclosure: Notice of Violation

cc:
Roy Kemp, Interim Administrator
Quality Assurance Division - DPHHS
2401 Colonial Drive
P. O. Box 202953
Helena, MT 59620-2953

NOTICE OF VIOLATION

Montana State University
Bozeman, Montana

Docket No. 030-00871
License No. 25-00326-06
EA-15-165

During a U.S. Nuclear Regulatory Commission (NRC) inspection and investigation conducted from October 7, 2014, through January 7, 2016, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1802 states, in part, that the licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Contrary to the above, 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. Specifically, the licensee lost a Varian/Agilent Gas Chromatograph containing approximately 13.73 millicuries of nickel-63.

- B. License Condition 14.A of NRC License No. 25-00326-06, Amendment No. 61, states, in part, 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.

Contrary to the above, 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 the certificate of registration referred to in 10 CFR 32.210. Specifically, the licensee failed to leak test nickel-63 sealed sources, maintained under its license, at intervals not to exceed 36 months as specified by their certificates of registration.

- C. 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 NRC, to account for all sources and/or devices received and possessed under the license.

Contrary to the above, between 2008 and 2014, the licensee failed to conduct a physical inventory every 6 months or at other intervals approved by the NRC to account for all sources and/or devices received and possessed under the license. Specifically, the licensee failed to account for two of its nickel-63 sealed sources enclosed in gas chromatographs every 6 months or at other intervals approved by the NRC.

- D. 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 licensee shall be complete and accurate in all material respects.

License Condition 14.F of NRC 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.

Enclosure

License Condition 25 of NRC 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 each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

Contrary to the above, as of July 3, 2014, the licensee failed to 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 of NRC License No. 25-00326-06, Amendment No. 61. Specifically, licensee records indicated that two nickel-63 sources had been leak tested and physically accounted for, when in fact, the sources were not in the licensee's possession at the time the leak tests and inventories were documented as having been performed. This information is material because leak test and inventory records establish the licensee's control of licensed material.

This is a Severity Level III problem (Section 6.7).

- E. 10 CFR 71.5(a), states, in part, that each licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, shall comply with the applicable requirements of the Department of Transportation regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397.

49 CFR 172.702 states, in part, that a hazmat employer shall ensure that each of its hazmat employees is trained in accordance with the requirements in 49 CFR 172, Subpart H, "Training."

49 CFR 172.704(a) states, in part, that the elements of hazmat employee training as: (1) general awareness/familiarization training, (2) function-specific training, (3) safety training, (4) security awareness training and (5) in-depth security training.

49 CFR 172.704(c)(1) states, in part, that a new hazmat employee or hazmat employee who changes job functions may perform those functions prior to the completion of training provided: (i) the employee performs those functions under the direct supervision of a properly trained and knowledgeable hazmat employee; and (ii) the training is completed within 90 days after employment or change in job function.

Contrary to the above, between August and September 2014, the licensee failed to ensure that each of its hazmat employees was trained in accordance with the requirements in 49 CFR 172, Subpart H, "Training." Specifically, the licensee allowed a hazmat employee to transport radioactive waste outside of its licensed site of usage, without having received initial hazmat training and not under the direct supervision of a properly trained and knowledgeable hazmat employee.

This is a Severity Level IV violation (Section 6.8)

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report 030-00871/2014-001 and letter from Montana State University dated February 25, 2016. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-15-165," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region IV, 1600 East Lamar Blvd., Arlington, Texas 76011-4511 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within 2 working days of receipt.

Dated this 24th day of June 2016