



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

August 4, 2015

Catherine Heyneman, PharmD
Radiation Safety Officer
Advanced Isotopes of Idaho
4968 Rainbow Lane
Chubbuck, ID 83202

SUBJECT: NRC INSPECTION REPORT 030-37048/2015-001 AND NOTICE OF VIOLATION

Dear Dr. Heyneman:

This letter refers to the inspection conducted on May 18 and 22, 2015, at your facility in Chubbuck, Idaho, with continued in-office reviews of fume hood concerns until July 13, 2015. The inspection was an examination of activities conducted under byproduct material license 11-29216-01MD as they relate to safety, security, and compliance with the Commission's rules and regulations and with the conditions of the license. Within these areas, the inspection consisted of observations of facilities, independent radiation measurements, selected examination of procedures and representative records, and interviews with personnel. On May 22, 2015, at the conclusion of the onsite portion of the inspection, the preliminary inspection findings were discussed with you. A final telephonic exit briefing was conducted with you on July 13, 2015.

Based on the results of this inspection, the Nuclear Regulatory Commission (NRC) has determined that one violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy, which can be found at the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation is described in the enclosed Notice of Violation (Notice) and is being cited in the Notice because the NRC identified it during the inspection. The violation was that the facility's fume hood setup and operation was not as described in documents listed in the license. Specifically, the fume hood had been modified, additional equipment had been interconnected with the fume hood ventilation system, the fume hood blower was not operated on a continual basis, and the system was not able to provide negative pressure in the room in which it was located.

In response to the inspector's concerns about the fume hood and lack of negative pressure in the room, you took prompt corrective action by: repairing the holes in the wall and ceiling that were allowing additional air to enter the room; removing a baffle within the charcoal filtration barrel that was obstructing airflow; operating the fume hood blower constantly; and reconfiguring the HVAC system by closing the louvers in the room. Through statements and calculations that you provided, these efforts have resulted in discernable negative pressure in

the room. Additionally, on July 17, 2015, you submitted a license amendment request to amend your license to reflect the current as built fume hood ventilation system.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in email correspondence dated May 26, 2015; June 1, 2015; June 4, 2015, and June 15, 2015, [ML15196A385] and in license amendment request dated July 17, 2015. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if any, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC's 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.

Should you have any questions concerning this inspection, please contact Dr. Janine F. Katanic, CHP, at (817) 200-1151 or the undersigned at (817) 200-1130.

Sincerely,

/RA/

G. Michael Vasquez, Chief
Nuclear Materials Safety Branch-A

Docket No.: 030-37048
License No.: 11-29216-01MD

Enclosure:
Notice of Violation (Notice)

cc: Idaho Radiation Control Program Director

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DATE	07/22/15		08/04/15		

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NOTICE OF VIOLATION

Advanced Isotopes of Idaho
Chubbuck, Idaho

Docket: 030-37048
License: 11-29216-01MD

During the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on May 18 and 22, 2015, with continued in-office review through July 13, 2015, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

License Condition 21 of NRC License 11-29216-01MD requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed in the license.

License application dated September 21, 2005, Section 7, "Equipment," provides a drawing and specifications for a Mid-America Isotopes, Inc. Lexan Glove Box (fume hood) to be used for handling and storage of iodine-131 and storage of xenon-133. Section 5, "Policy and Procedure Manual," "Radiation Safety Manual," subsection D, states, in part, that the fume hood will operate on a continual basis, that air can only enter the room through the door or the ventilation system, and that the majority of air leaving the room is through the fume hood to keep the room at negative pressure. An addendum to the license application, electronic mail dated December 7, 2005, provides a diagram illustrating the fume hood setup, including ventilation stack, location of charcoal filters, design of the manifold system, and pump placement.

Contrary to the above, as of May 18, 2015, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in the documents listed in the license. On May 18, 2015, the licensee's fume hood setup and operation was not as described in license application dated September 21, 2005, and electronic mail dated December 7, 2005. Specifically, the following failures were noted: (1) the fume hood had been physically modified by the licensee in 2006 and was not consistent with that described in license application dated September 21, 2005; (2) during early 2014, the licensee modified the fume hood filtration, exhaust, and manifold system and added an interconnected connected decay bin, which was not consistent with that described in electronic mail dated December 7, 2005; and (3) as observed on May 18, 2015, the room was not under negative pressure, in part, because the fume hood was not operated on a continual basis; and additional air was entering the room through holes in the wall and ceiling, which was not consistent with License application dated September 21, 2005.

This is a Severity Level IV violation (Section 6.3.d).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in email correspondence dated May 26, 2015; June 1, 2015; June 4, 2015, and June 15, 2015 [ML15196A385] and in license amendment request dated July 17, 2015. 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

Enclosure

Violation," 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 E. Lamar Blvd., Arlington, Texas, 76011, 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 (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 4th day of August 2015