July 6, 2012

EA-12-129

Mr. Scott C. Brower, R.Ph.
Owner and Radiation Safety Officer
Mid-America Isotopes, Inc.
706 E. Liberty Lane
Ashland, MO 65010

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03031846/2012001(DNMS) AND NON-CITED VIOLATION – MID-AMERICA ISOTOPES, INC.

Dear Mr. Brower:

On May 23, 2012, the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your facility located in Ashland, Missouri, with continued NRC in-office review until June 21, 2012. The in-office review included detailed evaluation of the information provided and the overall determination of the circumstances and significance of the issue identified during the inspection with NRC management. The purpose of the inspection was to review the circumstances surrounding the delivery of licensed material outside your facility on May 20, 2012, and to determine whether activities authorized under your license were conducted safely and in accordance with NRC requirements. The enclosed report presents the results of this inspection. A telephone exit meeting was held on June 21, 2012, between you and Mr. Geoffrey Warren of my staff.

During this inspection, the NRC staff examined activities conducted under your license as they relate to public health and safety, compliance with the Commission's rules and regulations, and compliance with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation is being treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy, which is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The NCV involved the failure to secure licensed material outside your facility in Ashland, Missouri, as required by Title 10 of the Code of Federal Regulations (CFR), Section 20.1802, and is described in the subject inspection report.

If you contest the violation or significance of the NCV, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region III; and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with Title 10 of the Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter and your response, if you choose to provide one, will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website 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.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA by Patricia J. Pelke Acting For/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-31896
License No. 24-26241-01MD

Enclosure:
Inspection Report No. 03031846/2012001(DNMS)

cc w/encl: State of Missouri

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/RA by Patricia J. Pelke Acting For/

Anne T. Boland, Director
Division of Nuclear Materials and Safety

Docket No. 030-31896
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Enclosure:
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Letter to Scott C. Brower from Anne T. Boland, dated July 6, 2012

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03031846/2012001(DNMS) AND NON-CITED VIOLATION – MID-AMERICA ISOTOPES, INC.

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Region III

Docket No.	030-31896
License No.	24-26241-01MD
Report No.	03031846/2012001(DNMS)
EA No.	EA-12-129
Licensee:	Mid-America Isotopes, Inc.
Facility:	Ashland, Missouri 65010
Date of exit meeting:	June 21, 2012
Inspectors:	Geoffrey M. Warren, Health Physicist Deborah A. Piskura, Health Physicist
Approved By:	Hironori Peterson, Acting Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Mid-America Isotopes, Inc.
Ashland, Missouri
NRC Inspection Report No. 03031846/2012001(DNMS)

The purpose of this reactive inspection was to review the circumstances and the root and contributing causes associated with a courier leaving packages containing a molybdenum-99/ technetium-99m generator and other materials unsecured outside the licensee's facility on May 20, 2012. The U.S. Nuclear Regulatory Commission (NRC) inspectors conducted a routine and reactive inspection at the licensee's facility on May 23, 2012, and interviewed personnel at the shipper and courier companies on May 24, 2012, to obtain additional information.

The courier realized as he was traveling toward the licensee's facility that he had forgotten to bring the key to the facility so that he could leave the materials to be delivered inside. He contacted the licensee, who gave him instructions on how to access the facility. The courier misunderstood the instructions because of a bad cell phone connection, and believed the licensee wanted him to leave the packages outside the facility. Based on this misunderstanding, he left the packages outside, covering them to prevent them from being visible. The licensee contacted him soon after to ask whether he had been able to deliver the packages; he answered that he had done so. When licensee personnel arrived at the facility, expecting the packages to be inside the building, they contacted the courier to find out where the packages had been placed, and then brought the packages inside.

The inspectors identified a violation of NRC requirements involving the failure to maintain surveillance and control of licensed materials that were not in storage, as required by Title 10 of the Code of Federal Regulations, Section 20.1802. The root cause of the violation was miscommunication between the courier and licensee staff. Neither the courier nor the licensee verified that the courier understood the delivery instructions. As corrective action, the licensee changed their policy for providing access in case of a courier forgetting the key; in all cases, the pharmacist will meet the courier at the facility rather than providing instructions for access.

This non-repetitive, licensee identified and licensee corrected violation is being treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the NRC Enforcement Policy.

Report Details

1 Program Overview

Mid-America Isotopes (licensee) is authorized under U.S. Nuclear Regulatory Commission (NRC) License No. 24-26241-01MD to manufacture and distribute licensed materials for medical uses. The licensee employed five pharmacists, nine pharmacy technicians, and eight drivers at its facility in Ashland, Missouri. The licensee had approximately 24 regular customers located in central Missouri, and distributed approximately 200 doses each weekday. The pharmacy was open weekdays from 2:30 a.m. to 4:00 p.m., with limited hours on weekends. The licensee's scheduled runs left the licensee's facility by 6:30 and 8:30 a.m., with deliveries made as needed after that time. The licensee received molybdenum-99/technetium-99m (Mo/Tc-99m) generators for preparation of technetium-99m unit doses and bulk technetium to clients. The licensee received and redistributed iodine-123 capsules and xenon-133 vials, and prepared diagnostic and therapeutic unit doses for distribution from additional radiopharmaceuticals. The pharmacy compounded iodine-131 (I-131) therapy capsules for distribution. All I-131 material was manipulated and stored in a glove box.

The licensee has not had any escalated enforcement within the last two years or last two inspections. No violations were identified during the last two routine inspections in May 2008 and July 2010.

This was a reactive inspection resulting from the licensee's reporting to the NRC Region III office on May 21, 2012, that a courier left material unsecured outside the licensee's facility on May 20, 2012. The NRC inspectors conducted a routine and reactive inspection at the licensee's facility on May 23, 2012, and interviewed personnel at the shipper and courier companies on May 24, 2012, to obtain additional information. In addition, continued NRC in-office review was conducted through June 21, 2012, which included detailed evaluation of information provided by the licensee and the overall determination of the circumstances and significance of the issue identified during the inspection with NRC management.

2 Sequence of Events and Licensee Response

2.1 Inspection Scope

The inspectors interviewed all personnel involved with the delivery and receipt of the packages at the pharmacy, at the shipper and courier companies, and reviewed records concerning the package receipt.

2.2 Observations and Findings

On Sunday, May 20, 2012, a courier transported three packages from the shipping company to the licensee's facility. These packages included: (1) a Mo/Tc-99m generator, (2) 30 millicuries of thallium-201, and (3) several 200-microcurie iodine-123 capsules. At around 7:30 p.m., while transporting the packages to the pharmacy, the courier realized that he had forgotten to bring the pharmacy key. This key allowed access into the area where packages were to be secured until licensee personnel arrived and could survey and process the packages. This area provided access only to

an entry area and not access to the material already in the possession of the licensee. The courier pulled to the side of the road and contacted his dispatcher by cell phone. The dispatcher gave him the telephone number for the on-call pharmacist (Pharmacist A) at the licensee's facility. The courier contacted Pharmacist A and reported that he had forgotten his key.

The licensee allowed a pharmacist to tell the courier how to gain access into the licensee's facility if the pharmacist knew the courier, but required the pharmacist to meet the courier at the facility if the courier was unknown. In this case, Pharmacist A knew the courier, so he told him how to gain access into the facility. Pharmacist A also told the courier to call him back if he had any difficulty. After this call, Pharmacist A contacted the licensee's office manager to tell him about the courier forgetting his key.

The courier had a poor cell phone connection for this call, and believed that Pharmacist A had told him to leave the packages at a certain location outside the building. He did not verify this understanding with Pharmacist A and did not call Pharmacist A back. The courier stated that, against his better judgment, he left the packages at this location, covering the packages with a pallet to prevent them from being visible.

Approximately one hour later, Pharmacist A contacted the courier to ask whether he had been able to deliver the packages. The courier answered that he had, so Pharmacist A believed that the courier had been able to gain access and place the packages properly inside. He did not directly verify this understanding with the courier.

At around 3:00 a.m. on Monday, May 21, the early-shift pharmacist (Pharmacist B), the office manager, and a technologist arrived at the licensee's facility to start preparing doses for the day. Pharmacist B noted that the packages were not in the expected area inside the building. The office manager told him about the courier forgetting his key the previous evening, and then contacted Pharmacist A. Pharmacist A contacted the courier, who told him where he had left the packages. Pharmacist A relayed this information to the personnel at the pharmacy. Pharmacist B retrieved the packages and performed receipt surveys; the surveys indicated that the packages were in good condition and had no evidence of contamination.

When the licensee's radiation safety officer (RSO) arrived at work at around 8:30 a.m., he contacted the NRC Region III office to report the situation.

Having these materials left unsecured outside the licensee's facility is a violation of Title 10 of the Code of Federal Regulations (CFR), Section 20.1802, which 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. The root cause of the violation was miscommunication between the courier and licensee staff. Neither the courier nor Pharmacist A verified that the courier understood the delivery instructions.

In order to prevent a future violation, the licensee changed their policy on couriers who forget their keys. Pharmacists were instructed that the on-call pharmacist is now required to meet the courier at the facility even if they know the courier, and the licensee has documented this policy statement.

In determining the significance of the violation, the NRC evaluated the specifics of this incident, including the isolated nature of the incident, the duration that the material was not secured, the location of the material, and the interaction between your staff and the courier. Based on those factors, the NRC determined the significance to be at Severity Level IV.

This non-repetitive, licensee-identified and licensee-corrected violation is being treated as an NCV, consistent with Section 2.3.2 of the NRC Enforcement Policy.

2.3 Conclusions

The inspector identified a violation of 10 CFR 20.1802 concerning material being left unsecured outside the licensee's facility. The violation is being treated as a NCV, consistent with Section 2.3.2 of the NRC Enforcement Policy.

3 Other areas inspected

3.1 Inspection Scope

The inspectors observed licensed activities, interviewed the RSO, pharmacists, technologists, and drivers, and reviewed selected records concerning the radiation safety program. In addition, the inspector performed independent and confirmatory radiation measurements.

3.2 Observations and Findings

Except for the situation described above, all licensed materials were secured or under supervision at all times. Inventories were consistent with licensee possession of sealed and unsealed materials. Surveys of work areas and public areas were performed at required frequencies. Licensee personnel wore appropriate dosimetry and personal protective equipment and used long-handled tools to reduce extremity exposure. Survey meters and dose calibrators were calibrated and checked at the required frequencies and were used correctly. Transportation of packages was done in accordance with Department of Transportation (DOT) requirements. Personnel were trained annually on radiation safety and other topics and every three years on DOT Hazmat requirements. The RSO performed quarterly program audits and an outside physicist performed independent quarterly audits to ensure all program requirements were being met.

Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector's radiation measurements indicated results consistent with licensee survey records and postings. Dosimetry records indicated maximum readings of 840 millirem (mrem) whole body dose and 22.6 rem extremity dose for calendar year 2011, and 308 mrem whole body dose and 6.4 rem extremity dose for January through April of 2012.

3.3 Conclusions

The inspectors did not identify any additional violations of the NRC requirements.

4 Exit Meeting Summary

The NRC inspector presented a preliminary inspection debrief following the onsite inspection on May 23, 2012. A telephone exit meeting was held on June 21, 2012. The licensee did not identify any documents or processes reviewed by the inspectors as proprietary. The licensee acknowledged the findings presented.

PARTIAL LIST OF PERSONNEL CONTACTED

*^ Scott C. Brower, R.Ph., Radiation Safety Officer, Mid-America Isotopes, Inc.
Brent McHugh, Pharmacist, Mid-America Isotopes, Inc.
* William Tuck, Office Manager, Mid-America Isotopes, Inc.
* Jon Woodward, Pharmacist, Mid-America Isotopes, Inc.
And personnel at the shipper and courier companies.

* Attended preliminary debrief on May 23, 2012, at Mid-America Isotopes, Inc.
^ Attended telephone exit meeting on June 21, 2012