

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED

Mid-America Isotopes, Inc.
706 E. Liberty Lane
Ashland, MO 65010

REPORT NUMBER(S) 2016001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-31896

4. LICENSE NUMBER(S)

24-26241-01MD

5. DATE(S) OF INSPECTION

May 17, 2016

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- ☐ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s):

- ☒ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

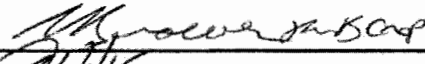


(Violations and Corrective Actions)

Contrary to Title 10 of the Code of Federal Regulations (CFR) 20.1802 on May 17, 2016 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, three licensee drivers left their vehicles unattended and not under direct surveillance with a maximum of 495 mCi of technetium-99m and 225 mCi of fluorine-18 while going back to the pharmacy to load more packages.

The cause of the violation was the drivers' misunderstanding of what constitutes adequate surveillance. As corrective action, the Radiation Safety Officer has talked to each of the drivers and retrained them on adequate surveillance.

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE	SCOTT C BROWER RPH BCNP		6/8/16
NRC INSPECTOR	Luis Nieves Folch		6/7/2016
BRANCH CHIEF	Aaron T. McCraw		6/8/16

Docket File Information

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6. INSPECTION PROCEDURES USED

87127

7. INSPECTION FOCUS AREAS

03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02500

2. PRIORITY

2

3. LICENSEE CONTACT

Scott C. Brower R.Ph

4. TELEPHONE NUMBER

(573) 657-1776

☒ Main Office Inspection

Next Inspection Date: May 17, 2018

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, routine inspection of a radiopharmacy. This site, located in Ashland, Missouri, routinely served 15-20 clients. The pharmacy operated Monday through Friday, with limited hours on weekends. The pharmacy distributed around 200 doses each weekday, primarily in one of two runs. The first run began around 2:00am, with deliveries out around 3:30 am. The second run began around 9:00 am, with deliveries out around 10:00 am. In addition to compounding doses of technetium-99m and other common isotopes, the pharmacy also compounded a handful of iodine-131 capsules each week. The licensee had 2 Authorized Nuclear Pharmacists, 2 pharmacy technicians and 9 drivers on staff at the time of the inspection.

Performance Observations

The inspector toured the facility to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent surveys of restricted and unrestricted areas, and found no residual contamination or exposures to members of the public in excess of regulatory limits. The inspector observed a variety of activities during the licensee's first run, including dose preparation, outgoing package preparation, client package return and waste handling, incoming generator and, area surveys and delivery vehicle loading. The licensee's staff also demonstrated the implementation of procedures for air effluent monitoring and bioassay for personnel preparing I-131 capsules. Through these observations, demonstrations and other discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed a selection of records, including internal and external audits, ALARA and incident reports, dose calibrator quality control records, air effluent monitoring reports, survey meter calibration certificates, hazmat training records, bioassay results, and dosimetry reports.

One violation was identified during this inspection, concerning maintaining direct surveillance of the material when its on the vehicle and not under direct surveillance. The three drivers were retrained on adequate surveillance since then. Radiopharmacy management confirmed these corrective actions.

Nieves Folch, Luis

From: Nieves Folch, Luis
Sent: Wednesday, June 08, 2016 2:14 PM
To: 'Scott Brower'
Subject: NRC Inspection Report 591
Attachments: image2016-06-08-150625.pdf

Mr. Brower

Attached is the inspection report with the violation that we previously discussed.

-----Original Message-----

From: NRCDigitalSender@nrc.gov [mailto:NRCDigitalSender@nrc.gov]
Sent: Wednesday, June 08, 2016 2:06 PM
To: Nieves Folch, Luis <Luis.NievesFolch@nrc.gov>
Subject:

This document was digitally sent to you using Dell Digital Sending device.