INSPECTION RECORD

**Region III** **Inspection Report No.** 2015001 **License No.** 09-32781-02MD
**Docket No.** 030-38278

**Licensee**: Triad Isotopes, Inc.
2252 East 14 Mile Road
Warren, Michigan 48092

**Locations Inspected**: Same as above

**Licensee Contact**: Erica Sztangret, Radiation Safety Officer **Telephone No**. 586-268-5300

**Program Code**: 02500 **Priority**: 2

**Type of Inspection**: ( ) Initial (X) Routine ( ) Announced
( ) Special (X) Unannounced

**Last Inspection Date**: 03/01/2013 **Date of This Inspection**: 07/21/2015

**Next Inspection Date**: 07/21/2017 (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval: N/A

**Summary of Findings and Actions:**

( ) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
(X) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector(s) Ryan Craffey, Health Physicist

***/RA/*** Date ***08/24/2015***
*Signature*

Navid Tehrani, Health Physicist

***/RA/*** Date ***08/25/2015***
*Signature*

Approved Aaron T. McCraw, Chief, MIB

***/RA/*** Date: ***08/27/2015***
*Signature*

## PART I – LICENSE, INSPECTION, INCIDENT/EVENT AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

| AMENDMENT # | DATE | SUBJECT |
|---|---|---|
| 07 | 12/09/14 | Notification of courier service contract |
| 06 | 06/16/14 | New RSO, removed two Authorized Nuclear Pharmacists (ANPs) |
| 05 | 08/20/13 | Added ANP |
| 04 | 08/01/13 | Renewal (removed authorization for calibrator) |

2. INSPECTION AND ENFORCEMENT HISTORY:

The NRC last conducted a routine inspection of Triad Isotopes in Warren, Michigan, on March 28, 2013. As a result of that inspection, the NRC identified one SLIV violation for the licensee's failure to maintain constant surveillance of licensed material that was not under the control of a licensee. The agency also identified an additional example of a violation cited in the previous routine inspection.

The NRC performed that inspection on April 13, 2011, and identified one SLIV violation for the licensee's failure to comply with U.S. Department of Transportation (DOT) requirements for the use of shipping labels. This violation was not closed during the 2013 inspection, because an additional example of the violation was identified at the time.

3. INCIDENT/EVENT HISTORY:

No open items or events since the last routine inspection.

## PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Triad Isotopes, Inc. was authorized by NRC Materials License No. 09-32781-02MD to operate a radiopharmacy in Warren, Michigan. The pharmacy operated seven days a week and distributed over 500 doses daily to approximately 50 clients on one of up to four runs. The pharmacy's first run began around 11:30 pm, with deliveries out around 4:30 am. The second run began around 5:30 am, with deliveries out around 7:45 am. The third run began around 8:00 am, with deliveries out around 10:45 am. The fourth run, if necessary, began after 11:00, with deliveries out around 1:00 pm. In addition to the unit and bulk doses of technetium-99m, the pharmacy also compounded indium-111 twice per week, thallium-201, gallium-67 and various other isotopes when needed, and up to 20 iodine-131 capsule per week (typically in the afternoon) using an automated dispensing system.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87127

Focus Areas Evaluated: All

The inspectors toured the pharmacy to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspectors observed a variety of activities on the licensee's second run, including generator elution, molybdenum breakthrough evaluation, kit preparation, dose drawing, client package preparation and vehicle loading, as well as client package return, waste handling, and area surveys. The licensee's staff demonstrated the implementation of procedures for I-131 capsule preparation. Through these observations, demonstrations, and various discussions, the inspectors found the licensee's staff to be knowledgeable of radiation protection principles and licensee procedures.

The inspectors also reviewed a selection of licensee records, including those for dose calibrator quality control, air monitoring and COMPLY code runs, area surveys, annual audits, bioassays, and personnel dosimetry, which indicated maximum exposures in 2014 of 187 millirem (mrem) whole body / 18,290 mrem extremity, and 44 mrem whole-body / 6,010 mrem extremity in 2015 through May 31st.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Using a Ludlum 2403 survey meter calibrated on January 5, 2015 with a model 44-9 pancake probe with dose equivalent filter, the inspectors conducted independent and confirmatory surveys of the facility. The inspectors found no readings which would indicate residual contamination or exposures to members of the public in excess of regulatory limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

A. Control of Licensed Material

On July 21, 2015, during a review of the licensee's annual audit records, the inspectors identified a Severity Level IV violation of Title 10 of the Code of Federal Regulations (CFR) Part 20.1802 for the licensee's failure to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. Specifically, on July 23, 2013, one of the licensee's drivers left a labeled package containing approximately 50 millicuries of technetium-99m at a non-licensed medical facility under the control of non-licensee personnel, rather than with the licensed contract mobile nuclear medicine service personnel on-site. Licensee personnel did not receive the package until approximately 2.5 hours after delivery.

The licensee documented the incident in its 2013 program audit. However, the inspectors considered this incident to be self-revealing, as the licensee was notified by the nuclear medicine service provider that the material was missing. The inspectors also considered the violation to be repetitive, as the licensee had been cited previously in IR 03038278/2013001(DNMS) for a nearly identical violation involving a different driver, and corrective actions for that violation had been completed on October 10, 2012, well before the second incident.

The inspector determined that the root cause of the violation was a lack of understanding of regulatory requirements by the driver who delivered the material.

The licensee took corrective action including retaining and eventually terminating the employment of the driver who left the material with non-licensee personnel.

B. Closure of Previous Violations

The licensee was previously cited in IR 03038278/2011001(DNMS) for a violation relating to the labeling of outgoing packages containing radioactive material. The inspector reviewed the licensee's corrective actions, which appeared to be adequate, and found the violations to be non-recurring. Therefore, the NRC considers this violation of 49 CFR 172.403 (as required by 10 CFR 71.5(a)) to be closed.

As mentioned above, the licensee was previously cited in IR 03038278/2013001(DNMS) for a violation relating to the licensee's maintaining control and constant surveillance of licensed material in unrestricted areas and not in storage. The inspector reviewed the licensee's corrective actions, but found the violation to be recurring. Therefore, the NRC will not consider this violation of 10 CFR 20.1802 to be closed until found to be non-recurring in a future inspection.

5. PARTIAL LIST OF PERSONNEL CONTACTED:

# Erica Sztangret, PharmD – Authorized Nuclear Pharmacist, RSO
Gina Webb, PharmD – Authorized Nuclear Pharmacist

# Attended preliminary exit meeting on July 21, 2015, and final telephonic exit meeting on August 6, 2015.

-END-