

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  Triad Isotopes, Inc. 1827 Belt Way Drive Overland, Missouri 63114-5815  REPORT NUMBER(S) 17001		2. NRC/REGIONAL OFFICE  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S)  030-38276	4. LICENSE NUMBER(S)  09-32781-0IMD	5. DATE(S) OF INSPECTION  April 20, 2017	

**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)

**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			
NRC INSPECTOR	Zahid Sulaiman, Health Physicist	<i>Zahid Sulaiman</i>	5/4/17
BRANCH CHIEF	Aaron T. McCraw, Chief, MIB	<i>[Signature]</i>	5/4/17

**Docket File Information**

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6. INSPECTION PROCEDURES USED  87127	7. INSPECTION FOCUS AREAS  03.01-03.07
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**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  02500	2. PRIORITY  2	3. LICENSEE CONTACT  Carey Unthank, PharmD, Mgr and RSO	4. TELEPHONE NUMBER  (314) 427-1555
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Main Office Inspection      Next Inspection Date: 04/20/2019  
 Field Office Inspection \_\_\_\_\_  
 Temporary Job Site Inspection \_\_\_\_\_

**PROGRAM SCOPE**

This was a routine unannounced inspection of a radiopharmacy authorized under NRC license to prepare and distribute diagnostic and therapeutic doses to clients in Missouri and Southwest Illinois. The licensee was staffed with three authorized nuclear pharmacists (ANP), two pharmacy technicians, and seven drivers. The radiopharmacy's first run began around 1:00 AM with deliveries out by 7:00 AM; the second run began around 7:00 AM and out by 12:00 PM; and additional runs were made as needed throughout the day. The licensee receives two Mo99/Tc99m generators each week for preparation and distribution of unit doses and some bulk technetium-99m. The licensee occasionally prepares and distributes unit doses of Tl-201, In-111, and Ga-67. The licensee received and redistributed Xe-133 gas vials. The licensee compounded iodine-131 therapy capsules using an automated compounding system inside the glove box. The glove box filters are changed quarterly. The licensee did not prepare or distribute any beta-emitting therapy doses. The licensee had several pharmacist turn over since the last inspection. The licensee had visiting ANP performed the pharmacist duties during the loss of two ANPs. The licensee hired two new ANPs and had submitted an amendment request to add the new pharmacist to their NRC license.

**Performance Observations:**

The inspection consisted of interviews with select licensee personnel; review of select records; tour of the facility; and independent measurements. The inspector observed a variety of activities on the licensee's second run, including generator elution, molybdenum breakthrough evaluation, kit preparation, dose drawing, client package preparation, DOT package labeling and vehicle loading, as well as client package return and waste handling. The licensee's staff also demonstrated the implementation of procedures for area surveys, I-131 capsule preparation, ventilation hood air monitoring and filter change out procedures, and decay-in-storage waste handling. The licensee's corporate office and the site radiation safety officer conducted independent annual audits of the program. The inspector observed staff monitoring their hands and feet for contamination before exiting the restricted area. The inspector reviewed the corporate and RSO audit reports, dose calibrator quality control, I-131 release evaluations, survey records, decay-in-storage waste disposals, DOT hazmat training, sealed source inventory, and leak test reports.

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**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Carey Unthank, PharmD, Mgr and RSO	4. TELEPHONE NUMBER (314) 427-1555
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Main Office Inspection      Next Inspection Date: 04/20/2019  
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 Temporary Job Site Inspection \_\_\_\_\_

**PROGRAM SCOPE**

The inspector performed independent and confirmatory radiation measurements which indicated results consistent with the licensee's survey results and within regulatory limits. The maximum TEDE and SDE exposures were reported as follows:

	2015	2016	YTD 2017
TEDE(mrem)	524	54	19
SDE(mrem)	19,065	9640	1630

No violations of NRC requirements were identified during this inspection.