

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Triad Isotopes, Inc.
1827 Belt Way Drive
Overland, MO 63114-5815

REPORT NUMBER(S) 2013-001

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)

09-32781-01MD

5. DATE(S) OF INSPECTION

4/9/13

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	Ken Lambert	<i>Ken Lambert</i>	4/9/13
BRANCH CHIEF	Tamara Bloomer	<i>T Bloomer</i>	4/26/13

Docket File Information**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

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April 9, 2013

6. INSPECTION PROCEDURES USED

87127

7. INSPECTION FOCUS AREAS

03.01-07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

2500

2. PRIORITY

2

3. LICENSEE CONTACT

Jerrold Brown, R.Ph, RSO

4. TELEPHONE NUMBER

(314) 427-1555



Main Office Inspection

Next Inspection Date: April 9, 2015



Field Office Inspection



Temporary Job Site Inspection

PROGRAM SCOPE

This nuclear pharmacy included 3 pharmacist, 2 pharmacy technicians, and 10 drivers. The licensee prepares and distributes on average 250 Tc-99m unit doses each week day. The licensee receives Mo-99/Tc-99m generators each week. In addition to the unit doses, the pharmacy distributes Xenon-133 gas vials, I-123, 5-10 I-131 compounded doses per week, and In-111 blood labeling. The licensee uses a DRAX compounding system for preparation of I-131 doses. Volatile radionuclides are stored in a hood with a set negative air flow. All air exhausts from hoods, glove boxes, the DRAX compounding system and the restricted area of the pharmacy are part of the facilities exhaust system with charcoal HEPA and charcoal filters. The filters are monitored weekly with releases well below release criteria. The pharmacy RSO and corporate staff perform periodic audits. Audit findings are reviewed and followup corrective actions are implemented and documented.

PERFORMANCE OBSERVATIONS

The inspector noted that radioactive materials were appropriately secured from unauthorized removal or access. The inspectors reviewed: (1) records of instrument calibration and response check programs including dose calibrator checks; (2) corporate radiation safety audits; (3) radiation program annual audit; (4) inventory records and leak test results; (5) air sampling equipment calibration and operation; (6) waste disposal records and (7) training records for laboratory staff and drivers. The inspector observed/discussed: (1) surveying and labeling of packages before shipment; (3) staff performing routine surveys; (4) personnel wearing appropriate PPE and required dosimetry; (5) that radioactive material packages were blocked and braced in delivery vehicles; (6) waste disposal; and (7) shipping papers were complete and stored in appropriate locations in delivery vehicles. The inspector determined that drivers were knowledgeable about transportation requirements and emergency procedures. Inspector reviewed external dosimetry results. The maximum exposure was 30 millirem DDE and 2,050 millirem SDE for January 2013; 80 millirem DDE and 19,220 millirem SDE for 2012; and 147 millirem DDE and 12,615 SDE for 2011. The inspector performed independent radiation measurements with results comparable to licensee survey data.

No violations of regulatory requirements was identified.