

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Triad Isotopes, Inc. 4205 Vineland Rd. Orlando, FL 32811</p> <p>REPORT NUMBER(S) 2017001</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>
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<p>3. DOCKET NUMBER(S)</p> <p>030-38280</p>	<p>4. LICENSE NUMBER(S)</p> <p>09-32781-04MD</p>	<p>5. DATE(S) OF INSPECTION</p> <p>8/7/17</p>
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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	Kevin G. Null	<i>Kevin G. Null</i>	8/7/17
BRANCH CHIEF	<i>David T. McCann</i>	<i>[Signature]</i>	8/18/17

Docket File Information

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<p>6. INSPECTION PROCEDURES USED</p> <p>87127</p>	<p>7. INSPECTION FOCUS AREAS</p> <p>03.01 - 03.07</p>
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SUPPLEMENTAL INSPECTION INFORMATION

<p>1. PROGRAM CODE(S)</p> <p>2500</p>	<p>2. PRIORITY</p> <p>2</p>	<p>3. LICENSEE CONTACT</p> <p>Joseph Huber, Pharmacy Manager</p>	<p>4. TELEPHONE NUMBER</p> <p>(816) 931-0515</p>
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Main Office Inspection Next Inspection Date: 08/07/2019

Field Office Inspection 712 Westport Road, Kansas City, Missouri

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine, unannounced inspection of Triad Isotopes' radiopharmacy located in Kansas City, Missouri. The licensee had approximately 25 clients in the Kansas City area, the furthest being about 55 miles away. Authorized nuclear pharmacists (ANP's) primarily tagged radiopharmaceuticals with technetium-99m, and prepared unit doses for distribution to medical facilities. Licensee staff performed a minimum of two runs per day - one beginning at about 12:30 am and the second at 6:00 am. Emergency unit doses were periodically prepared and transported to client facilities on an as needed basis. ANP's also compounded iodine-131 capsules for radiopharmaceutical therapy as needed.

Performance Observations

The inspector toured the radiopharmacy and observed an ANP prepare unit doses during the second run. The inspector also observed a pharmacy technician package, survey, and prepare unit doses for transportation by pharmacy delivery staff. The inspector noted appropriate use of calibrated survey meters during the preparation and packaging of unit doses by the technician, and the performance of surveys and smears of packages for radiation levels and removable contamination. The inspector also observed an ANP measure unit doses in a dose calibrator, use remote handling tools/devices to minimize extremity exposure, wear personal protective equipment and dosimetry, perform tests for molybdenum breakthrough, and conduct a physical inventory of sealed sources. The inspector also observed a driver secure packages in a delivery vehicle for transportation to client facilities. The driver described training that he had received in safely handling and transporting packages containing unit doses of radiopharmaceuticals.

The inspector reviewed daily and weekly surveys of both restricted and unrestricted areas; bioassay results; records of survey meter and well counter calibration; results of package surveys and smears for contamination; transportation shipping forms and records; breathing zone and air effluent results; sealed source inventory records; and leak tests results. The inspector also reviewed dosimetry records and noted that for CY 2016 the maximum whole body exposure was 79 mrem and extremity was 4,000 mrem, and for CY 2017 to date the maximum whole body exposure was 17 mrem, and extremity was 1,100 mrem.

No violations of NRC requirements were identified.