

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Triad Isotopes, Inc. 4205 Vineland Road, Suite L1 Orlando, FL 32811 Location Inspected: Kansas City, MO REPORT NUMBER(S) 2015-001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-38280	4. LICENSE NUMBER(S) 09-32781-04MD	5. DATE(S) OF INSPECTION August 20 th , 2015	

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	Ryan Craffey		8/20/15
BRANCH CHIEF	Aaron McCraw		8/28/15

Docket File Information

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6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS All
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT David Persinger, R.Ph. - RSO	4. TELEPHONE NUMBER (816) 931-0515
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Main Office Inspection Next Inspection Date: 08/20/2017
 Field Office Inspection 712 Westport Road, Kansas City, MO
 Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a radiopharmacy in Kansas City, Missouri, which served approximately 30 clients in the Kansas City metropolitan area. The pharmacy operated Monday through Friday from 12:30 am to 4:00 pm, and limited hours on weekends. The pharmacy distributed around 220 doses each weekday, most of which went out on its first run. This run typically began by 1:30 am, with deliveries out by 4:30 am. The pharmacy compounded doses on additional runs when necessary. During the inspection, the second run began around 6:00 am. In addition to unit and bulk doses of technetium-99m, the pharmacy also compounded indium-111 and thallium-201 when needed, as well as an average of eight iodine-131 capsules per week using an automated dispensing system. The pharmacy also redistributed xenon-133 gas vials without alteration to its clients.

PERFORMANCE OBSERVATIONS

The inspector toured the licensee's facility in Kansas City to evaluate the licensee's measures for materials security, hazard communication, and contamination and exposure control. The inspector conducted independent surveys of 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 on the licensee's second run, including molybdenum breakthrough evaluations, dose preparation, and client package preparation. The licensee's staff also demonstrated the implementation of procedures for vehicle loading, client package return, waste handling and air effluent monitoring. Through these demonstrations and other discussions, the inspectors found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed a selection of licensee records for dose calibrator quality control, I-131 air effluent monitoring, daily restricted area and weekly unrestricted area surveys, hazmat training, annual radiation program audits, weekly bioassay results, and personnel and area dosimetry, which indicated maximum exposures in 2014 of 67 millirem whole-body / 23,380 millirem extremity, and 32 millirem whole-body / 12,100 millirem extremity in 2015 through May 31st.

No violations of NRC requirements were identified as a result of this inspection.