NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Triad Isotopes, Inc. 2795 Universal Drive Saginaw, Michigan REPORT NUMBER(S) 2015-001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38279	09-32781-03MD	June 10 , 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 violations(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	Geoffrey M. Warren		6/10/15
BRANCH CHIEF	Aaron T. McCraw		6/22/15

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Robert Bjurstrom, PharmD, RSO	(989) 799-7669

☑ Main Office Inspection Next Inspection Date: June 2017

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced, inspection. This radiopharmacy employed two pharmacists, two pharmacy technicians, and five drivers. The licensee distributed approximately 150 doses daily to 20 regular customers in eastern Michigan. The pharmacy was open weekdays from midnight through 4:30 pm, with limited hours on weekends. The weekday runs ran from 1:30-5 am, 6-9 am, and 10-11:30 am, with deliveries made as needed throughout the day. The licensee received two technetium-99m generators each week for preparation and distribution of unit doses and bulk technetium to clients. In addition, the licensee distributed occasional thallium-201, gallium-67, and indium-111 unit doses prepared from bulk materials. The pharmacy received and redistributed iodine-123 and iodine-131 diagnostic capsules to customers. The pharmacy did not compound iodine-131 therapy capsules; such capsules were prepared and distributed out of the Detroit pharmacy.

The licensee's corporate office and the site radiation safety officer conducted independent annual audits of the program. The maximum dose received by licensee personnel in calendar year 2013 was 106 mrem whole body and 9.9 rem extremity; in calendar year 2014, the maximum was 180 mrem whole body and 13.5 rem extremity; and in January through April 2015, the maximum was 84 mrem whole body and 4.5 rem extremity. Licensee personnel used long-handled tools for handling of licensed materials.

Performance Observations: The inspector observed generator elution, molybdenum assay, kit preparation and QC, drawing doses and bulk technetium, packaging and surveying of doses, pig and package surveys and wipes, verification of package contents, preparation of labels and shipping papers, shipment assembly, blocking/bracing of packages, placement of shipping papers, package return surveys, cleaning of pigs, waste disposal, and use of syringe shields and long-handled tools. Licensee personnel demonstrated and described daily area surveys and wipes, package receipt surveys, spill procedures, indium blood labeling, effluent monitoring, waste disposal, and other procedures. The inspector noted no concerns with these activities. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.