NRC FORM 591M PART 1
(06-2010)
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. 2242 East 14 Mile Road Warren, Michigan REPORT NUMBER(S): ~~2011-001~~ 11-01	U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38278	09-32781-02MD	April 13 , 2011

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, NUREG-1600, 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. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11

10 CFR 71.5(a) requires, in part, that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable ~~regulations~~ requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 107, 171-180, and 390-397.

49 CFR 172.403 requires, in part, with exceptions not applicable here, that each package of radioactive material be labeled, as appropriate, with two RADIOACTIVE WHITE-I, YELLOW-II, or YELLOW-III labels on opposite sides of the package.

- continued -

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	Franz Schmelzer, Pharmacy Manager		4/13/11
NRC INSPECTOR	Geoffrey M. Warren		4/13/11
Branch Chief	Tamara E. Bloomer		4/22/11

NRC FORM 591M PART 2
(06-2010)
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 Warren, MI REPORT NUMBER(S)	U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38278	09-32781-02MD	Apr. 13, 2011

(Continued)

Contrary to the above, on March 31, 2011, the licensee delivered to a carrier for transport approximately 300 mCi of technetium-99m without the required ~~white~~ RADIOACTIVE WHITE-I or YELLOW-II labels. As corrective action, the licensee ~~has retr~~ will retrain all staff on the appropriate shipping requirements.

NRC FORM 591 M PART 3 (06-2010) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Triad Isotopes, Inc. Warren, MI REPORT NUMBER(S) 11-01	U.S. Nuclear Regulatory Commission, Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-38278	09-32781-02MD	April 13, 2011

6. INSPECTION PROCEDURES	7. INSPECTION FOCUS AREAS
87127	03.01 – 03.07

SUPPLEMENTAL INSPECTION INFORMATION

1.PROGRAM	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	Michael Klug, R.Ph.	586-268-5300

☒ Main Office Inspection — Next Inspection Date: April 2013

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This radiopharmacy employed 4 pharmacists and 4 pharmacy technicians, and used contract drivers, though they planned to start using their own drivers soon after the inspection. The licensee distributed approximately 300 to 350 doses to approximately 30 customers in Michigan and Ohio daily. The pharmacy was open weekdays from midnight to 2:00 pm, with limited hours on weekends. The licensee's weekday runs went out at approximately 4:30, 8:00, and 10:30 am, with deliveries continuing as needed throughout the day. The licensee received three Mo-99/Tc-99m generators each week for their own use. Xenon-133 gas vials and iodine-131 and -125 doses were received and re-distributed to their customers. The licensee had not yet begun iodine-131 compounding, but intended to begin soon once equipment was installed. The pharmacy distributed In-111 tagged white blood cells prepared on site.

The licensee's corporate office conducted at least annual audits of the program, and the RSO performed annual internal audits. The maximum dose received by licensee personnel in calendar year 2010 was 97 mrem whole body and 15.1 rem extremity; from January through February 2011, the maximum was 37 mrem whole body and 2.0 rem extremity.

Performance Observations

The inspector observed generator elution and molybdenum assay, kit preparation and QC, dose drawing and verification, dose packaging and surveys, package preparation and surveys, shipping paper preparation, survey meter QC, daily surveys and wipes, package placement in vehicles, package receipt, waste handling, thyroid scans, and indium-111 blood preparation. Licensee personnel demonstrated dose calibrator constancy checks and other procedures. 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.

One violation was cited concerning the shipment of a package containing over 300 mCi of technetium-99m without required shipping labels. This had been reported to the Headquarters Operations Center on 3/31/11 by Harper University Hospital, where the package had been shipped. (Recorded as a logbook entry)