

March 28, 2013

Mr. Franz E. Schmelzer
Pharmacy Manager, Detroit
Triad Isotopes, Inc.
2252 East 14 Mile Road
Warren, MI 48092

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03038278/13001(DNMS) AND
NOTICE OF VIOLATION – TRIAD ISOTOPES, INC.

Dear Mr. Schmelzer:

On March 1, 2013, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your facility in Warren, Michigan. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. An exit meeting was held between you and Mr. Geoffrey Warren of my staff at the completion of the on-site visit.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation concerned the failure to maintain constant surveillance of licensed material that was not under the control of a licensee, as required by Title 10 of the Code of Federal Regulations (CFR) 20.1802. On October 2, 2012, one of the pharmacy's drivers left a package containing approximately 50 millicuries of technetium-99m for a mobile nuclear medicine client at a non-licensed facility in Southgate, Michigan. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation because it was self-revealing as a result of a client reporting the missing doses rather than being self-identified.

The root cause of the violation was the driver's failure to follow written procedures for delivery of licensed materials. As a contributing factor, the mobile nuclear medicine company had provided incorrect information in ordering the materials. As corrective action, you provided retraining for all drivers by October 10, 2012, concerning the procedure for delivery of cases containing licensed materials. This training emphasized that cases for the mobile nuclear medicine company must be left with the technologist and that the driver must call the pharmacy if the technologist is not at the site. As such, you are now in compliance with NRC requirements.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

The inspector identified an additional Severity Level IV violation of NRC requirements concerning the delivery of a case on September 28, 2011, with incorrect shipping labels, as required by 10 CFR 71.5(a) and 49 CFR 172.403. At the time of the violation, you had not yet completed corrective actions for the violation of the same requirements cited in NRC Inspection Report No. 03038278/11-01(DNMS) dated April 13, 2011. Therefore, this violation constitutes an additional example of the previous violation. No additional response to this violation is required. Further corrective actions for this additional example were taken in conjunction with corrective actions for the previously cited violation. The violation remains open for a future inspection to verify that the corrective actions are sufficient.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-38278
License No. 09-32781-02MD

Enclosure:
Notice of Violation

cc w/encl:
State of Michigan
William P. McCormick, SVP/General Counsel

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Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-38278
License No. 09-32781-02MD

Enclosure:
Notice of Violation

cc w/encl:
State of Michigan
William P. McCormick, SVP/General Counsel

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NOTICE OF VIOLATION

Triad Isotopes, Inc.
Warren, Michigan

Docket No. 030-38278
License No. 09-32781-02MD

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on March 1, 2013, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the Code of Federal Regulations (10 CFR) 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

10 CFR 20.1003 states that *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on October 2, 2012, the licensee failed to control and maintain constant surveillance of approximately 50 millicuries of technetium-99m in a transport package that was in an unrestricted area and that was not in storage. Specifically, a driver left the transport package at a medical facility in Southgate, Michigan, under the control of non-licensee personnel, and the medical facility was not a licensed facility.

This is a Severity Level IV violation (Section 6.7).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the letter transmitting this Notice of Violation (Notice). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, IR 03038278/13001(DNMS)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 28th day of March 2013.

Enclosure