



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

August 27, 2015

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

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03038278/2015001(DNMS) AND
NOTICE OF VIOLATION – TRIAD ISOTOPES, INC.

Dear Mr. Schmelzer:

On July 21, 2015, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facility in Warren, Michigan, with continued in-office review through August 6, 2015. 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. The in-office review consisted of additional evaluation of information obtained during the inspection. Mr. Ryan Craffey conducted a final exit meeting by telephone with Ms. Erica Sztangret on August 6, 2015, to discuss the inspection findings.

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 website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation concerned the licensee's failure to maintain constant surveillance of licensed material, as required by Title 10 of the *Code of Federal Regulations* (CFR) Part 20.1802. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the enclosed Notice because the inspectors identified the violation.

The inspector determined that the root cause of the violation was a lack of understanding of regulatory requirements by the driver who delivered the material. As corrective actions, Triad Isotopes provided additional training to the driver, and ultimately terminated his employment after this incident and additional concerns regarding the driver's conduct were identified.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. Because the NRC has previously identified a similar violation at your facility, the NRC is requesting that your response include how your corrective actions to this violation will be more effective in preventing recurrence of a similar violation in the future. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC's website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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 publicly available without redaction.

Please feel free to contact Mr. Craffey or Mr. Navid Tehrani of my staff if you have any questions regarding this inspection. Mr. Craffey can be reached at 630-829-9655, and Mr. Tehrani can be reached at 630-829-9803.

Sincerely,

/RA/

Aaron T. McCraw, 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: Erica Sztangret, Radiation Safety Officer
State of Michigan

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Sincerely,

/RA/

Aaron T. McCraw, 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: Erica Sztangret, Radiation Safety Officer
State of Michigan

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NOTICE OF VIOLATION

Triad Isotopes, Inc.
Warren, Michigan

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

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on July 21, 2015, with continued in-office review through August 6, 2015, 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* (CFR) Part 20.1802 requires that licensees control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Title 10 CFR 20.1003 defines an *unrestricted area* to mean an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, on July 23, 2013, the licensee failed to maintain constant surveillance of approximately 50 millicuries of technetium-99m in a labeled transport case that was in an unrestricted area and that was not in storage. Specifically, a driver left the transport package at a non-licensed medical facility under the control of non-licensee personnel for approximately 2.5 hours, rather than with the licensed contract mobile nuclear medicine service personnel elsewhere on-site.

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

Pursuant to the provisions of Title 10 CFR 2.201, Triad Isotopes, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission (NRC), 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 of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or its severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance was or will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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 publicly available without redaction.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 27th day of August 2015.