

1 June 2011

Document Control Desk  
U.S. Nuclear Regulatory Commission  
Washington, D.C., 20555

RE: Reply to a Notice of Violation  
Docket No. 03038269  
Inspection Report No. 03038269/2010001  
Triad Isotopes, Inc.- Milford, CT.  
180 Pepes Farm Rd  
Milford, CT 06460

Dear Gentleman:

Triad Isotopes, Inc. hereby responds to the notice of violation letter dated 5-23-2011 ("Letter" in Attachment A) for the inspection of the Milford, CT pharmacy that was conducted on November 3, 5 and 8, 2010 by Steven Courtemanche. Triad Isotopes, Inc. desires to operate its facilities in accordance with sound radiation protection and safety principles and applicable regulations and program standards, including radioactive materials license conditions. Thus, the following corrective actions are noted below to address findings from the inspection:

1. The driver of a motor vehicle containing hazardous material, i.e, Technetium-99m, did not ensure that the shipping paper required by section 49 CFR 177.817(e)(2)(ii) was readily available to, and recognizable by, authorities in the event of an accident or inspection. Specifically, when the driver was not at the vehicle's controls, the driver did not store the shipping papers in a holder mounted to the inside of the door on the on the driver's, or on the driver's seat of the vehicle.
  - a. At the time of the inspection, Triad Isotopes, Inc. was in the process of converting to an internal fleet model with completion of staffing continuing through January 2011. The in-house fleet model was replacing the use of third party courier services, which Triad viewed as a risk point. As of February 1, 2011, Triad Isotopes, Inc. fully implemented the internal driver model with use of Triad Isotopes, Inc. employed drivers and fleet vehicles. All newly hired Triad Isotopes, Inc. drivers have completed documented training that complies with the requirements in 49 CFR 172.704. Certificates are maintained on file at the pharmacy for review. The switch to an all internal driver model will enable better management of training needs and provide additional spot checks of the effectiveness of the training provided. The spot checks will be conducted by the site RSO and during annual internal audits conducted by the Quality and Safety Department.

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2. Packages were not blocked or braced so that they could not change position during conditions normally incident to transportation. Specifically, the packages were placed in a wooden restraining structure for side to side movement but no means were used to brace the packages against upward movement and the wooden restraining structure was not blocked or braced against movement.
  - a. At the time of the inspection, Triad Isotopes, Inc. was in the process of converting to an internal fleet model with completion of staffing continuing through January 2011. The in-house fleet model was replacing the use of third party courier services, which Triad viewed as a risk point. As of February 1, 2011, Triad Isotopes, Inc. fully implemented the internal driver model with use of Triad Isotopes, Inc. employed drivers and fleet vehicles. The newly acquired fleet vehicles have a commercially installed blocking and bracing system that prevents the movement of packages in all directions during conditions normally incident to transportation per the requirements set forth in 49 CFR 177.842(d). With the implementation of internal drivers and fleet vehicles, Triad Isotopes, Inc. has a dedicated fleet manager that continually responds and reacts to changes needed in proper blocking and bracing and vehicle needs.

We trust that this response adequately addresses the findings of your inspection. If it does not, please notify me. Triad's Quality and Safety team will work with the pharmacy manager and site RSO to assure full implementation of required corrective actions. Please do not hesitate to contact me at (904)-220-7210 if you have any questions or concerns. The site manager/RSO, Joseph Remesz-Guerrette, can also be reached for questions at 203-882-9903.

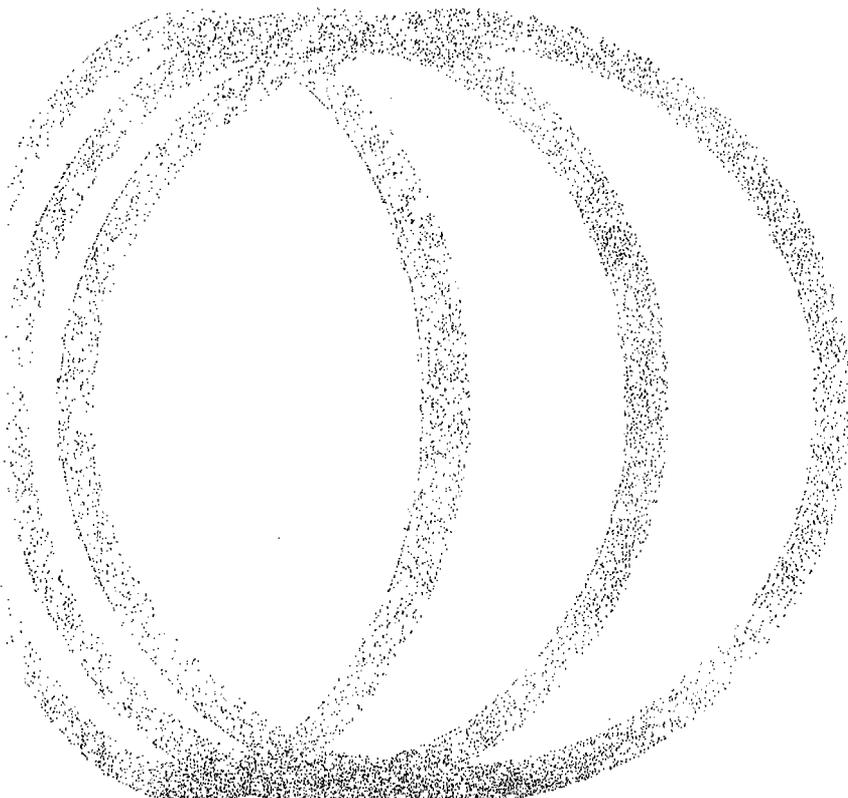
Sincerely,

Brigette Nelson, MS, PharmD, BCNP  
Sr. Director Quality and Safety  
1554 Nottingham Knoll Drive  
Jacksonville, FL 32225  
(904)-220-7210 (office)  
(904)-220-6980 (fax)  
(904)-562-8260 (cell)  
bnelson@triadisotopes.com

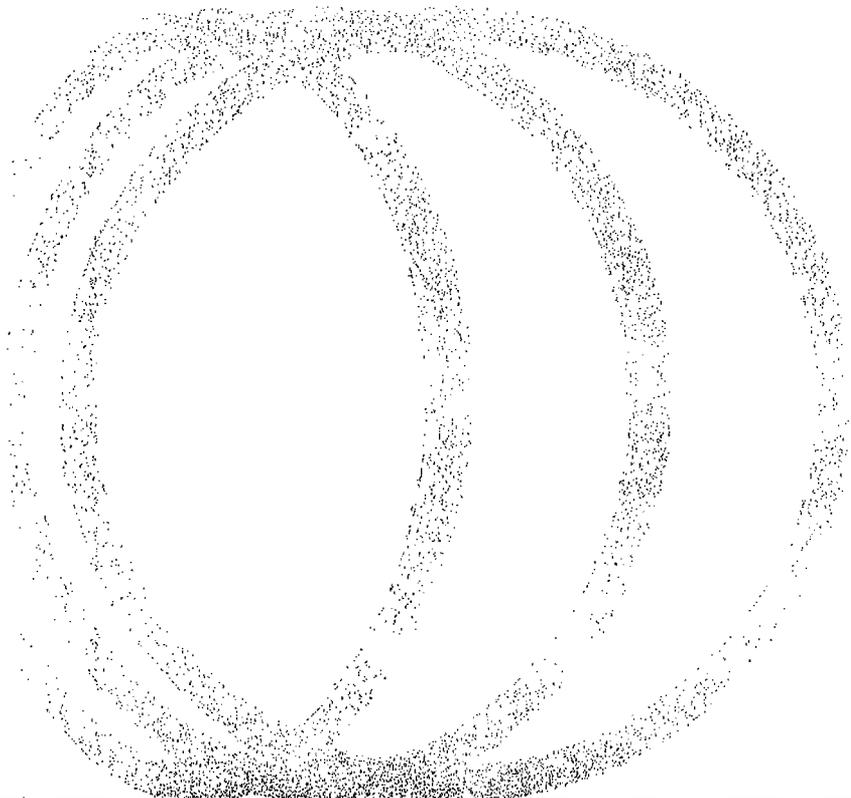
Attachment

cc: Brigette Nelson, Sr. Director Quality and Safety; Regional Administrator, Region I; Neil Stubbs; file

**Attachment A**



**Attachment A**





UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

May 23, 2011

Docket No. 03038269

License No. 09-31406-01MD

William F. McCormick  
Senior VP/General Counsel  
Triad Isotopes, Incorporated  
200 South Orange Avenue  
Suite 2100  
Orlando, FL 32801

SUBJECT: NRC INSPECTION REPORT NO. 03038269/2010001, TRIAD ISOTOPES,  
INCORPORATED, MILFORD, CONNECTICUT SITE AND NOTICE OF  
VIOLATION

Dear Mr. McCormick:

On November 3, 5 and 8, 2010, Steven Courtemanche of this office conducted a safety inspection at 180 Pepe's Farm Road, Milford, Connecticut of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. Additional information provided in the telephone conversation on November 5, 2010, between Joseph Remesz-Guerrette, R.Ph. of your organization and this office, was also examined as part of the inspection. The findings of the inspection were discussed with Brigette Nelson, Head of the Quality and Safety Department and other members of your staff at the conclusion of the inspection on May 19, 2011.

Based on the results of this inspection and in accordance with the NRC Enforcement Policy, the NRC has determined that 2 Severity Level 4 violations of NRC requirements occurred. The violations involved: 1) the failure to store shipping papers in a readily available location and to be recognizable to authorities while the driver was not at the controls of the motor vehicle in accordance with 49 CFR 177.817(e)(2)(ii); and, 2) the failure to block and brace packages so that they cannot change position during conditions normally incident to transportation in accordance with 49 CFR 177.842(d).

The violations are cited in the enclosed Notice of Violation (Notice), because the violations were identified by the NRC.

During our preliminary inspection exit meeting on November 8, 2010, you and Mr. Remesz-Guerrette indicated that you were concerned with the Commission's findings. Mr. Remesz-Guerrette stated that the licensee has taken or will take corrective and preventative actions to address each violation and that Triad Isotopes, Inc. is committed to radiation safety and to compliance with NRC regulations and licensed conditions. Further, Mr. Remesz-Guerrette stated verbally that, as corrective and preventative actions, the licensee will discontinue using the courier service involved and will commit to performing spot checks of the activities of anyone involved in transporting hazardous materials.

During the exit meeting conducted on May 19, 2011, Ms. Nelson stated that the facility has completely switched over to its own courier service. Ms. Nelson further stated that the switch allows the licensee to provide better oversight over the handling of radioactive materials, the training of personnel and compliance with the regulations.

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 Public Document Room or from the NRC document system (ADAMS), accessible from the NRC 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 available to the Public without redaction.

Current NRC regulations are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications Page**. The current Enforcement Policy is included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **About NRC; How We Regulate; Enforcement**; then **Enforcement Policy**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Steven Courtemanche at 610-337-5075 if you have any questions regarding this matter.

Sincerely,



James P. Dwyer, Chief  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

Enclosure:  
Notice of Violation

cc:  
Joseph Remesz-Guerrette, R.Ph., Radiation Safety Officer  
State of Florida  
State of Connecticut

## **NOTICE OF VIOLATION**

Triad Isotopes, Incorporated  
Orlando, FL

Docket No. 03038269  
License No. 09-31406-01MD

During an NRC inspection conducted on November 3, 5 and 8, 2010, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

10 CFR 71.5(a) requires that each licensee who transports licensed material outside 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 requirements of the DOT regulations in 49 CFR 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

- (1) 49 CFR 177.817(e)(2)(ii) requires, in part, that a driver of a motor vehicle containing hazardous material ensure that the shipping paper required by this section is readily available to, and recognizable by, authorities in the event of an accident or inspection. Specifically, the driver shall store the shipping paper as follows: (A) In a holder which is mounted to the inside of the door on the driver's side of the vehicle; or (B) on the driver's seat of the vehicle.

Contrary to the above, on November 1 and 2, 2010, the driver of a motor vehicle containing hazardous material, i.e., Technetium-99m, did not ensure that the shipping paper required by this section was readily available to, and recognizable by, authorities in the event of an accident or inspection. Specifically, when the driver was not at the vehicle's controls, the driver did not store the shipping papers in a holder mounted to the inside of the door on the driver's side, or on the driver's seat of the vehicle. Instead, the driver removed all of the shipping papers from the vehicle while making a delivery while hazardous material remained in the vehicle for other deliveries

This is a Severity Level IV violation.

- (2) 49 CFR 177.842(d) requires that packages must be so blocked and braced that they cannot change position during conditions normally incident to transportation.

Contrary to the above, on November 1 and 2, 2010, packages were not blocked or braced so that they could not change position during conditions normally incident to transportation. Specifically, the packages were placed in a wooden restraining structure for side to side movement but no means were used to brace the packages against upward movement and the wooden restraining structure was not blocked or braced against movement.

This is a Severity Level IV violation.

Pursuant to the provisions of 10 CFR 2.201, Triad Isotopes, Incorporated is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, 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 for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous 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.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 23rd day of May 2011