

February 26, 2018

U.S. Nuclear Regulatory Commission
Nuclear Materials Licensing Section, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4351

**RE: Response to the Apparent Violation in Inspection Report No. 03038279/2017002(DNMS);
EA-17-202**

Jubilant Draximage Radiopharmacies Inc. d/b/a Triad Isotopes RAM License # 09-32781-03MD
2795 Universal Drive
Saginaw, MI 48603

Dear Mr. McCraw,

This communication is to provide a written response to the NRC reactive inspection report number 03038279/2017002(DNMS) dated February 1, 2018 and received February 9, 2018. During the inspection of our Saginaw, Michigan Radiopharmacy location on November 14, 2017 two apparent violations were identified. Upon receipt of the reactive inspection report a review of the circumstances which led to the apparent violations was conducted to include the following:

- Interviews with pharmacy personnel involved in the incident and management personnel.
- Review of the Bill of Lading for Type A package involved in the incident.
- Review of training records for individuals preparing, shipping and transporting radioactive material.
- Observations of involved package and containment systems within the package.
- Review of prior internal audits of the Saginaw pharmacy location.
- Review of DOT HazMat Outgoing Package and Wipes Survey Policy and Procedure.

A review of the circumstances which led to the apparent violations has been completed and the following corrective actions are provided below:

Apparent Violation 1:

Licensee's failure to securely close a containment system of a Type A package by a positive fastening device such that it cannot be opened unintentionally or by pressure that may arise within the package during normal transport as required by 10 CFR 71.5(a) and 49 CFR 173.412(d).

Reason for apparent violation:

Upon evaluation of all data, Jubilant Draximage Radiopharmacies Inc. d/b/a Triad Isotopes has determined that the shielded containers in the Type A package were all properly shrink wrapped and package surveys conducted in accordance with procedure. Upon examination of shielded containers inside the Type A package it was observed that the top lid to the vial shield container used to ship a bulk Tc-99m dose became separated during transport to customer. Therefore the primary root cause of the incident is failure of pharmacy personnel to securely lock the top lid to the vial shield container prior to shrink wrapping and placing dose into the Type A package.

Corrective actions that have been taken:

1. The Pharmacy Manager/RSO notified all pharmacy personnel of the incident. **(Completed 11/20/2017)**
2. The Pharmacy Manager/RSO conducted training to all pharmacy personnel on how to properly secure and challenge vial shield container lid, identical to that which is used to ship bulk Tc-99m, prior to shrink wrapping dose and placement into Type A package. **(Completed 11/20/2017)**
3. The Pharmacy Manager/RSO submitted, for immediate processing/read the whole body dosimeter for driver who transported Type A package to customer. Results showed no exposure. **(Completed 10/26/2017).**

Corrective actions that will be taken:

Jubilant Draximage Radiopharmacies Inc. d/b/a Triad Isotopes will revise our DOT HazMat Outgoing Package and Wipes Survey Policy and Procedure. Revision will include a statement for individuals to ensure top lid to vial shield containers are properly closed and securely locked prior to placing them into packages. **(Expected Completion Date 5/31/2018)**

Date when full compliance will be achieved:

Full compliance was achieved at our Saginaw pharmacy location on 11/20/2017.

Apparent Violation 2:

Licensee's failure to limit the external radiation levels of a package containing U.S. DOT Class 7 (radioactive) material with a WHITE-I label to 0,005 millisievert (mSv)/hr at the external surface, as required by 10 CFR 71.5(a) and 49 CFR 172.403(c).

Reason for apparent violation:

Upon evaluation of all data, Jubilant Draximage Radiopharmacies Inc. d/b/a Triad Isotopes has determined that the shielded containers in the Type A package were all properly shrink wrapped and package surveys conducted in accordance with procedure. Upon examination of shielded containers inside the Type A package it was observed that the top lid to the vial shield container used to ship a bulk Tc-99m dose became separated during transport to customer. Therefore the primary root cause of the incident is failure of pharmacy personnel to securely lock the top lid to the vial shield container prior to shrink wrapping and placing dose into the Type A package.

Corrective actions that have been taken:

1. The Pharmacy Manager/RSO notified all pharmacy personnel of the incident. **(Completed 11/20/2017)**
2. The Pharmacy Manager/RSO conducted training to all pharmacy personnel on how to properly secure and challenge vial shield container lid, identical to that which is used to ship bulk Tc-99m, prior to shrink wrapping dose and placement into Type A package. **(Completed 11/20/2017)**
3. The Pharmacy Manager/RSO submitted, for immediate processing/read the whole body dosimeter for driver who transported Type A package to customer. Results showed no exposure. **(Completed 10/26/2017).**

Corrective actions that will be taken:

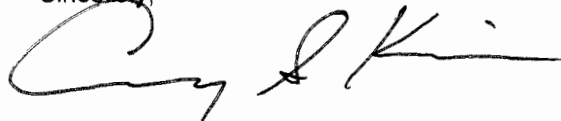
Jubilant DraxImage Radiopharmacies Inc. d/b/a Triad Isotopes will revise our DOT HazMat Outgoing Package and Wipes Survey Policy and Procedure. Revision will include a statement for individuals to ensure top lid to vial shield containers are properly closed and securely locked prior to placing them into packages. **(Expected Completion Date 5/31/2018)**

Date when full compliance will be achieved:

Full compliance was achieved at our Saginaw pharmacy location on 11/20/2017.

Should you have any additional questions regarding our written response to this incident, you may contact me at (407) 257-8998 or by email at skinne@triadisotopes.com

Sincerely,



Craig S. Kinne, CHP
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Triad Isotopes Quality and Safety Department