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

February 1, 2018

EA-17-202
EN 53030
NMED No. 170492 (Closed)

Dr. Robert Bjurstrom, PharmD
Pharmacy Manager
Jubilant DraxImage Radiopharmacies, Inc.
d/b/a Triad Isotopes
2795 Universal Drive
Saginaw, MI 48603

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03038279/2017002(DNMS) – JUBILANT DRAXIMAGE RADIOPHARMACIES, INC. D/B/A TRIAD ISOTOPES

Dear Dr. Bjurstrom:

On November 14, 2017, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your facility in Saginaw, Michigan, with continued in-office review through January 2, 2018. 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 included a review of the circumstances surrounding an event reported to the NRC on October 23, 2017. The enclosed inspection report presents the results of the inspection.

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, two apparent violations of NRC requirements were identified and are being considered for escalated enforcement action 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 first apparent violation concerned the 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 during normal transport, as required by Title 10 of the *Code of Federal Regulations* (CFR) 71.5(a) and 49 CFR 173.412(d). The second apparent violation concerned the licensee's failure to limit the external radiation level of a package containing Class 7 (radioactive) material with a WHITE-I label to 0.005 millisievert (mSv) per hour, as required by 10 CFR 71.5(a) and 49 CFR 172.403(c).

Because the NRC has not made a final determination in this matter, the NRC is not issuing a Notice of Violation for these inspection findings at this time. Mr. Edward Harvey of my staff discussed the circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action with you during a telephonic exit meeting on January 4, 2018.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond in writing to the apparent violations addressed in this inspection report within 30 days of the date of this letter; or (2) request a Predecisional Enforcement Conference (PEC). **Please contact Aaron T. McCraw at 630-829-9650 or aaron.mccraw@nrc.gov within 10 days of the date of this letter to notify the NRC of your intended response.**

If you choose to provide a written response, it should be clearly marked as "Response to the Apparent Violation in Inspection Report No. 03038279/2017002(DNMS); EA-17-202," and should include, for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent 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 was or will be achieved. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. 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 website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, it will afford you the opportunity to provide your perspective on the apparent violations and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the PEC may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. If a PEC is held, the NRC will issue a press release to announce the time and date of the PEC. The PEC will be open to public observation.

Because your facility has not been the subject of escalated enforcement action within the last two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, based upon NRC's understanding of the facts and your corrective actions, it may not be necessary to conduct a PEC in order to enable the NRC to make a final enforcement decision. Our final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken. Please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

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. Harvey if you have any questions regarding this inspection. Mr. Harvey can be reached at 630-829-9819.

Sincerely,

/RA/

John B. Giessner, Director
Division of Nuclear Materials Safety

Docket No. 030-38279
License No. 09-32781-03MD

Enclosure:
IR 03038279/2017002(DNMS)

cc w/encl: State of Michigan

Letter to Robert Bjurstrom from John B. Giessner dated February 1, 2018

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03038279/2017002(DNMS) – JUBILANT DRAXIMAGE RADIOPHARMACIES, INC. D/B/A TRIAD ISOTOPES

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DATE	01/26/2018		01/30/2018		01/30/2018		02/01/2018	

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U.S. Nuclear Regulatory Commission

Region III

Docket No.	030-38279
License No.	09-32781-03MD
Report No.	03038279/2017002(DNMS)
EA No./NMED No.	EA-17-202 / 170492
Licensee:	Jubilant DraxImage Radiopharmacies, Inc. d/b/a Triad Isotopes
Facility:	2795 Universal Drive Saginaw, MI 48603
Inspection Dates:	November 14, 2017, with continued in-office review through January 2, 2018
Exit Meeting Date:	January 4, 2018
Inspector:	Edward Harvey, Health Physicist
Approved By:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Jubilant DraxImage Radiopharmacies, Inc. d/b/a Triad isotopes
NRC Inspection Report 03038279/2017002(DNMS)

This was a reactive inspection of a radiopharmacy in Saginaw, Michigan, that was involved in an event reported to the NRC on October 23, 2017. The event was reported to the NRC by the licensee's customer, a regional hospital, after it received a package containing radioactive material from the licensee that had abnormally high radiation levels on the external surface.

The inspector reviewed circumstances of the event and determined that two apparent violations of NRC requirements had occurred, regarding: (1) the 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); and (2) the 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)/h at the external surface, as required by 10 CFR 71.5(a) and 49 CFR 172.403(c).

As corrective action, the pharmacy manager notified all relevant personnel of the incident and implemented a procedure in which all staff who handle similar styles of vial shielding challenge the top to ensure that it is secure prior to placement within the package. This typically includes both the pharmacist drawing the dose and the driver or technologist packing it such that there are two independent staff members challenging the top. Performing this challenge of the shielding containers will help ensure that the effectiveness of the package will stay intact and that the labeling will remain accurate. As longer term corrective action, the licensee has submitted a request to their corporate office to have the written packaging procedures updated to reflect the aforementioned procedure.

REPORT DETAILS

1 Program Overview and Inspection History

Jubilant DraxImage Radiopharmacies, Inc. d/b/a Triad Isotopes (licensee) is a radiopharmacy located in Saginaw, Michigan. The licensee employed two pharmacists, two pharmacy technicians, and five drivers. The pharmacy operated Monday through Friday with limited hours on weekends depending on customer demand.

The last routine inspection of this licensee was conducted on March 22, 2017. No violations of NRC requirements were identified during the 2017 inspection. The previous NRC inspection of this licensee was conducted on June 10, 2015. No violations of NRC requirements were identified during the 2015 inspection.

2 Sequence of Events

2.1 Inspection Scope

The inspector interviewed licensee staff and management personnel concerning the circumstances of the event reported to the NRC on October 23, 2017, regarding a package received by the licensee's client with abnormally high radiation levels on the external surface.

2.2 Observations and Findings

At approximately 0630 on October 23, 2017, a licensee's customer, a regional hospital, received a WHITE-I labeled package containing radioactive material from the licensee. A nuclear medicine technologist (NMT) employed by the customer escorted the driver of the package to the main nuclear medicine department hot lab, to which the package was to be delivered. Once the package was secured in the hot lab, the NMT proceeded to a separate hot lab within the hospital's cardiology center to begin his work shift.

At approximately 0740, a second NMT entered the hot lab in the main nuclear medicine department to start his daily equipment checks. Upon turning on his survey meter, he noticed abnormally elevated radiation levels. The NMT exited the hot lab and continued his survey meter's battery test and source response check to ensure that the elevated readings within the hot lab were not an instrumentation error. Once he confirmed that the survey meter was operating properly, the NMT proceeded, with caution, into the hot lab and determined that that the source of the elevated readings was the package that had been dropped off earlier in the morning. Initial surveys of the package indicated readings of 190 milliRoentgen per hour (mR/h) at the surface and 0.7 mR/h at one meter. After performing the initial survey, the NMT determined that there was no apparent physical damage to the package and then performed a wipe test of the entire exterior of the package. Based on the wipe test readings, the NMT determined that there was no evidence of removable contamination.

With no removable contamination present, the NMT, without opening the package, stored it within a configuration of lead bricks inside a cabinet within the hot lab. Surveys of the hot lab were at background levels with the package in the shielded location. After the package was secured in a shielded location, the NMT appropriately notified the Radiation Safety Officer of the hospital, the licensee, and the NRC.

At 0955, another driver from the licensee delivered a replacement package to the customer. With the driver present, another survey was performed of the original package. This survey indicated a surface reading of greater than 200 mR/h. The exact reading could not be determined as the maximum level of detection for this instrument was 200 mR/h. Another survey was performed with a different instrument and a consistent result was obtained. Based on the labeling, the contents of the case were expected to be approximately 340 millicuries (mCi) of technetium-99m (Tc-99m).

On October 27, 2017, a survey was performed of the package and the results were within acceptable limits. With the radiopharmacy manager present, the case was opened and a wipe test of the inside of the package was performed. The results indicated no evidence of removable contamination. Upon removing the polyethylene spacers, the licensee observed that the cover of the lead shield that contained the vial of bulk Tc-99m had become separated from the bottom portion of the shielding, resulting in a gap in the shielding. The two pieces were held in place, approximately 1.2 centimeters (cm) apart, by the shrink wrap applied to the container by the licensee.

The NRC conducted a reactive inspection at the licensee's facility in Saginaw, Michigan, on November 14, 2017. The inspector interviewed all licensee personnel involved with the packaging and shipment of the package involved in this event. Licensee staff also conducted a demonstration of their packaging and loading procedures for radioactive material. The licensee determined that the most likely cause of the event was that the lid of the shielding container for the bulk dose of Tc-99m was not properly secured by the pharmacist.

Title 10 of the *Code of Federal Regulations* (CFR) 71.5(a) requires 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 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.

Title 49 CFR 173.412(d) requires, in part, that each Type A packaging must be designed so that the packaging must include a containment system securely closed by a positive fastening device that cannot be opened unintentionally or by pressure that may arise within the package during normal transport. If a containment system of a Type A package forms a separate unit of the package, it must be securely closed by a positive fastening device that is independent of any other part of the package.

Failure to fully engage the locking device of the shielding container constitutes an apparent violation of the aforementioned requirements. In addition, the failure to ensure that the containment system did not open unintentionally during routine transport caused the external radiation levels of the package to increase beyond the 0.005 millisievert (mSv) limit established by 49 CFR 172.403(c) for a WHITE-I label. This constitutes an apparent violation of 49 CFR 172.403(c). The root cause of the apparent violations was that the licensee did not have procedures to provide confidence that their containment system could not be opened unintentionally during normal transport.

As corrective action, the pharmacy manager notified all relevant personnel of the incident and implemented a procedure in which all staff who handle similar styles of vial

shielding challenge the top to ensure that it is secure prior to placement within the package. This typically includes both the pharmacist drawing the dose and the driver or technologist packing it such that there are two independent staff members challenging the top. Performing this challenge of the shielding containers will help insure that the positive fastening device is engaged and that the labeling will remain accurate. As longer term corrective action, the licensee has submitted a request to their corporate office to have the written packaging procedures updated to reflect the aforementioned procedure.

2.3 Conclusions

The inspector identified two apparent violations of NRC requirements. Contrary to 10 CFR 71.5(a) and 49 CFR 173.412(d), the licensee failed 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. Contrary to 10 CFR 71.5(a) and 49 CFR 172.403(c), the licensee failed to limit the external radiation level of a package containing U.S. DOT Class 7 (radioactive) material with a WHITE-I label to 0.005 mSv/h at the external surface.

3 Exit Meeting Summary

The inspector presented preliminary inspection findings following the onsite inspection on November 14, 2017. The inspector presented the final inspection findings to the licensee during a final exit meeting by telephone on January 4, 2018. The licensee acknowledged the findings presented.

LIST OF PERSONNEL CONTACTED

#* Robert Bjurstrom, Pharmacy Manager
Joseph Groves, Driver
Mike Powell, Pharmacy Technician
Ben Westrate, Pharmacist

Attended preliminary exit meeting on November 14, 2017
* Attended final exit meeting on January 4, 2018

INSPECTION PROCEDURES USED

87103: Materials Licensees Involved in an Incident or Bankruptcy Filing
87127: Radiopharmacy Programs