



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, ILLINOIS 60532-4352

March 16, 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: NOTICE OF VIOLATION; NRC REACTIVE INSPECTION REPORT
NO. 03038279/2017002 (DNMS) - JUBILANT DRAXIMAGE
RADIOPHARMACIES, INC. D/B/A TRIAD ISOTOPES

Dear Dr. Bjurstrom:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on November 14, 2017, at your Triad Isotopes facility in Saginaw, Michigan, with continued in-office review through January 2, 2018. The purpose of the inspection was to determine the circumstances surrounding a transportation event reported to the NRC on October 23, 2017. During this inspection, apparent violations of NRC requirements were identified. The significance of the issues and the need for lasting and effective corrective actions were discussed with you during the exit meeting on January 4, 2018. Details regarding the apparent violations were provided in NRC Inspection Report No. 03038279/2017002 (DNMS), dated February 1, 2018. A copy of the inspection report can be found 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> under accession number ML18033A655.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated February 26, 2018, you provided a response to the apparent violations, which can be found in the NRC's ADAMS at Accession Number ML18059A829.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report dated February 26, 2018, the NRC has determined that two violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The first violation involved the failure to securely close a containment system within 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 Department of Transportation (DOT) requirements in 49 CFR 173.412(d). The second violation involved the 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). These failures resulted in the external radiation level of the package measuring 1.9 mSv per hour (190 millirem per hour).

The NRC considers these violations significant because they resulted in an incorrectly labeled package with dose rates on external surfaces of the package that could have led to unintended radiation exposures to workers or members of the public. Therefore, these violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$7,250 is considered for a Severity Level III problem.

Because your facility has not been the subject of escalated enforcement actions within the last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. *Corrective Action* credit was warranted for corrective actions that included: (1) notifying all pharmacy personnel of the incident; (2) conducting training to pharmacy personnel on how to properly secure and challenge the vial shield container lid prior to shrink wrapping; (3) submitting, for immediate processing, the whole body dosimetry for the driver who transported the package; and (4) planning to revise the DOT HazMat Outgoing Package and Wipes Survey Policy and Procedure to include a statement for individuals to ensure the top lid to vial shield containers are properly closed and securely locked prior to placing into shipping packages.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III problem constitutes escalated enforcement action that may subject you to increased inspection effort. The NRC also includes significant enforcement actions on its website at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was or will be achieved is already adequately addressed on the docket in Inspection Report No. 03038279/2017002 (DNMS) and your letter dated February 26, 2018. Therefore, you are not required to respond to this letter unless the description therein 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.

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's Public Document Room and in ADAMS. 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 personal privacy or proprietary information is necessary to provide an acceptable response, if you choose to provide one, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your

response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Sincerely,

/RA by Patrick L. Loudon acting for/

K. Steven West
Regional Administrator

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

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

Letter to R. Bjurstrom from S. West; dated March 16, 2018

SUBJECT: NOTICE OF VIOLATION; NRC REACTIVE INSPECTION REPORT
No. 03038279/2017002 (DNMS) - JUBILANT DRAXIMAGE
RADIOPHARMACIES, INC. D/B/A TRIAD ISOTOPES

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DOCUMENT NAME: EA-17-202 Triad Isotopes final action.docx

OFC	RIII	RIII	RIII	OE	RIII-EICS	RIII-ORA
NAME	Lambert SB for	McCraw	Giessner CAL for	ABoland ¹	Skokowski	West PLL for
DATE	03/06/18	03/07/18	03/07/18	03/14/18	03/15/18	03/16/18

OFFICIAL RECORD COPY

¹ OE concurrence provided via e-mail from Leelavathi Sreenivas on March 14, 2018

NOTICE OF VIOLATION

Jubilant DraxImage Radiopharmacies, Inc.
d/b/a Triad Isotopes
Saginaw, Michigan

Docket No. 030-38279
License No. 09-32781-03MD
EA-17-202

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on November 14, 2017, with continued in-office review through January 2, 2018, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

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.

- A. Title 49 CFR 173.412(d) states that, in addition to meeting the general design requirements prescribed in 49 CFR 173.410, 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. Special form Class 7 (radioactive) material, as demonstrated in accordance with § 173.469, may be considered as a component of the containment system. If the containment system 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.

Contrary to the above, on October 23, 2017, the licensee failed to use a containment system that was securely closed by a positive fastening device that could not be opened unintentionally during normal transport. Specifically, the licensee failed to securely close the lid of a shielded containment system that formed a separate unit of a Type A package containing a Class 7 (radioactive) material with a positive fastening device.

- B. Title 49 CFR 172.403(c) states, in part, that the maximum radiation level at any point on the external surface of a package with a WHITE-I label is less than or equal to 0.005 millisieverts per hour (mSv/h) (0.5 millirem per hour (mrem/h)).

Contrary to the above, the licensee shipped a package containing Class 7 (radioactive) materials with a WHITE-I label applied with a maximum radiation level on the external surface greater than 0.005 mSv/h. Specifically, the package was received by the customer with external radiation levels at the surface exceeding 1.9 mSv/h (190 mrem/h).

This is a Severity Level III problem (Section 6.8).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when

Enclosure

full compliance was or will be achieved, is already adequately addressed on the docket in Inspection Report No. 03038279/2017002 (DNMS) and letter from the licensee dated February 26, 2018. 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, EA-17-202," 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, 2443 Warrenville Road, Lisle, IL 60532 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC's Public Document Room or in 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, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available 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 16th day of March 2018