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

February 20, 2018

EN 53030
NMED NO. 170492 (CLOSED)

Dr. Matthew Waack
Radiation Safety Officer
John Tolfree Hospital
d/b/a West Branch Regional Medical Center
2463 South M-30
West Branch, MI 48661

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03017321/2017002(DNMS) – JOHN TOLFREE HOSPITAL D/B/A WEST BRANCH REGIONAL MEDICAL CENTER

Dear Dr. Waack:

On November 14, 2017, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at your facility in West Branch, 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. Mr. Edward Harvey, of my staff, presented the final results of the inspection to you during a final exit meeting via telephone on January 29, 2018. 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. No violations were identified as a result of this inspection.

In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection 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.

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/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-17321
License No. 21-18892-01

Enclosure:
IR 03017321/2017002(DNMS)

cc w/encl: State of Michigan

Letter to Matthew Waack, M.D., from Aaron T. McCraw, February 20, 2018
SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03017321/2017002(DNMS) – JOHN TOLFREE HOSPITAL D/B/A WEST BRANCH REGIONAL MEDICAL CENTER

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DATE	02/20/2018		02/20/2018					

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-17321
License No.:	21-18892-01
Report No.:	03017321/2017002(DNMS)
NMED No.:	170492
Licensee:	John Tolfree Hospital d/b/a West Branch Regional Medical Center
Facility:	2463 South M-30 West Branch, MI 48661
Inspection Dates:	November 14, 2017, with continued in-office review to January 2, 2018
Exit Meeting Date:	January 29, 2018
Inspector:	Edward Harvey, Health Physicist
Approved by:	Aaron T. McCraw, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

John Tolfree Hospital d/b/a West Branch Region Medical Center
NRC Inspection Report 03017321/2017002(DNMS)

This was a reactive inspection of John Tolfree Hospital d/b/a West Branch Regional Medical Center (licensee) in response to a notification received by the NRC on October 23, 2017 that the licensee had received a package with external radiation levels that exceeded NRC limits.

Based on a review of the circumstances surrounding the event, the NRC concluded that the licensee had appropriately responded to receipt of this package by: (1) performing the required external surveys of the package; (2) performing a wipe test to check for external contamination; (3) storing the package in a secure shielded cabinet to minimize ambient radiation levels; (4) notifying the appropriate licensee personnel, including the Radiation Safety Officer (RSO) and any other staff that may enter the room with the package; (5) notifying the radiopharmacy that delivered the package; and (6) notifying the NRC of the incident, as required by Title 10 of the *Code of Federal Regulations* (CFR) 20.1906(d).

No violations were identified during this inspection.

REPORT DETAILS

1.0 Program Overview and Inspection History

John Tolfree Hospital d/b/a West Branch Regional Medical Center (licensee) is authorized under NRC Materials License No. 21-18892-01 to use byproduct material to perform diagnostic and therapeutic administrations of radiopharmaceuticals.

The last routine inspection of the licensee was on July 12, 2017. No violations were identified as a result of this inspection.

2.0 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 with abnormally high radiation levels.

2.2 Observations and Findings

At approximately 0630 on October 23, 2017, the licensee received a White I labeled package containing radioactive material from an NRC-licensed radiopharmacy. A nuclear medicine technologist (NMT) employed by the licensee escorted the driver of the package to the main nuclear medicine department hot lab, where 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 check. Upon turning on his survey meter, he noticed abnormally elevated readings. The NMT exited the hot lab and continued his survey meter's battery and source response checks 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 in 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 notified the licensee's RSO, the radiopharmacy, and the NRC.

At 0955, another driver from the radiopharmacy delivered a replacement package to the licensee. 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 radiopharmacy.

The NRC conducted a reactive inspection at the licensee's facility in West Branch, Michigan, on November 14, 2017. The inspector interviewed all licensee personnel involved with the receipt of the package with elevated external radiation levels. Based on a review of the circumstances surrounding the event, the inspector concluded that the licensee had appropriately responded to receipt of this package by (1) performing the required external surveys of the package; (2) performing a wipe test to check for external contamination; (3) storing the package in a secure shielded cabinet to minimize ambient radiation levels; (4) notifying the appropriate licensee personnel, including the RSO and any other staff that may enter the room with the package; (5) notifying the radiopharmacy that delivered the package; and (6) notifying the NRC of the incident, as required by 10 CFR 20.1906(d).

The licensee provided a written report, dated November 2, 2017, providing its assessment of the incident. An electronic copy of the licensee's report can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) under Accession Number ML17338A842.

2.3 Conclusions

The inspector reviewed the circumstances of the event reported to the NRC on October 23, 2017, regarding a package received by the licensee with abnormally high radiation levels. No violations of NRC requirements were identified.

3.0 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 29, 2018. The licensee acknowledged the findings presented.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

LIST OF PERSONNEL CONTACTED

David Barratt, CNMT
Tom Desch, Imaging Director
Claude Rohrer, RT
#* Matthew Waack, MD, RSO

Attended preliminary exit meeting on November 14, 2017
* Attended final exit meeting on January 29, 2018

INSPECTION PROCEDURES USED

87103: Inspection of Material Licensees Involved in an Incident or Bankruptcy
87131: Nuclear Medicine Programs, Written Directive Required