



WEST BRANCH REGIONAL MEDICAL CENTER

JOHN TOLFREE HEALTH SYSTEM CORPORATION

2483 S M-30
WEST BRANCH, MICHIGAN 48661

989-345-3660

November 2, 2017

United States Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352
Tel: 301-816-5100 (Headquarters Emergency Response)
Fax: 301-816-5151 (Headquarters Emergency Response)
Tel: 800-522-3025 (Region III Office)
Fax: 630-515-1259 (Region III Office)

Re: Event #53030
Above Limits Package Receipt
Date of Event October 23, 2017

Following is a chronological description of the event #53030, package receipt above limits. Per our facilities policies as outlined in our Radiation Protection Program, see attached copy, this needs to be reported to the NRC. Under the direction of Geof Warren at the Region III office (630-829-9500), I am reporting this under 10 CFR 20.1906 paragraph D2 which is referenced in 10 CFR 71.47 paragraph B.

10/23/2017 at approximately 6:30

Triad Isotopes – Saginaw courier delivered case #3119. Per the nuclear medicine technologist Claude Rohrer CNMT, nothing unusual happened during delivery. The package was not dropped or turned over. The courier was escorted into the hot lab of the nuclear medicine department in the hospital, the suspect case placed on the floor, and the door locked.

10/23/2017 at 7:40

As part of normal opening procedures, nuclear medicine technologist David Barratt CNMT performed a package receipt on case #3119, a Type I UN2915 package. Case was visually inspected as undamaged and identified as being delivered to the correct facility. Upon survey, it was found to be above limits on both the 1 meter and surface readings. Survey details as follows:

Survey Meter	Bicron Surveyor 2000 S/N B700L, side window
Survey Meter QC prior to use	Battery Check – Pass
	High Voltage – Pass
	Check Source 0.7 mR/h – Pass
	Background 0.01 mR/h – Pass
Survey at 1 meter	0.7 mR/h (Limit \leq Background) – Fail
Survey at Surface	190 mR/h (Limit < 0.5 mR/h) – Fail

Wipe testing was performed verifying no removable contamination was present. Wipe details as follows:

Well Counter	Captus 4000e S/N 940-198
Well QC prior to use	FWHM 6.9% - Pass
	Constancy 0.9% - Pass
	Background 266 cpm – Pass
Wipe over 300 cm ²	9 dpm (Limit 6600 dpm / 300 cm ²) – Pass

Case #3119 was not opened to eliminate any possible contamination in the advent of an internal leak.

10/23/2017 at 07:55

David Barratt CNMT placed case #3119 into shielded lead storage area to minimize any possible radiation exposure. After being placed into lead storage, the area was surveyed at 0.01 mR/h. Our policy, see attached copy, indicates notifying the final delivery carrier, our RSO, and NRC. Reporting and subsequent action was performed as follows:

10/23/2017 at 7:56

David Barratt CNMT notified Triad Isotopes - Saginaw pharmacy manager that case #3119 delivered this morning was above limits on 1 meter survey, and surface survey. Conveyed that surface survey was 190 mR/h and that the wipe test showed no removable contamination. Triad contact as follows:

Robert Bjurstrom
 Pharmacy Manager
 Triad Isotopes – Saginaw
 2795 Universal Drive
 Saginaw, MI 48603
 Tel: 989-799-7669
 Fax: 989-799-7868
 NRC License # 09-32781-03MD

10/23/2017 at 7:56

David Barratt CNMT notified Dr. Matthew Waack, the facilities RSO, of case being received this morning above limits on 1 meter and surface survey. RSO information is as follows:

Dr. Matthew Waack, MD
Radiation Safety Officer
John Tolfree Hospital (d/b/a West Branch Regional Medical Center)
2463 South M-30
West Branch, MI 48661
Tel: 989-343-3196
Fax: 989-343-3136
NRC License # 21-18892-01

10/23/2017 Beginning at 9:11 thru 10/27/2017

David Barratt CNMT notified NRC via phone of case being received above limits on 1 meter and surface survey. The information was conveyed over multiple calls and multiple NRC representatives throughout the next several days, ending on 10/27/2017. The person(s) taking the information along with approximate times are listed chronologically as follows:

10/23/2017 at 9:11

David Barratt CNMT called Jeff Herrera of the NRC for initial verbal report. All preliminary information about event was taken. Reported case contents to be estimated at <100 mCi Tc-99m based upon what was ordered. Told NRC contact that actual contents were not verified since case was not opened. A packing slip was not available at that time. At this time, was advised to fax written report to 301-816-5151. NRC contact for this call as follows:

Jeff Herrera
Head Quarters Operations Officer
United States Nuclear Regulatory Commission
Headquarters Emergency Response
Rockville, MD 20852
Tel: 301-816-5100
Fax: 301-816-5151

10/23/2017 at 9:40

David Barratt CNMT notified facilities Medical Physicists, Michelle Kritzman of event. Recommended surveying with a secondary meter. Physicist information is as follows:

Michelle L. Kritzman, M.S.
Nuclear Medical Physics, DABR
Medical Physics Consultants, Inc.
214 E. Huron St
Ann Arbor, MI 48104
Tel: 734-662-3197
Fax: 734-662-9224

10/23/2017 at 9:55

Triad Isotopes - Saginaw courier Joe Groves delivered replacement case for above limits case #3119. With courier present, David Barratt CNMT removed case #3119 from lead storage and resurveyed. Surface survey results showed reading slightly higher than initial survey at > 200 mR/h. Upon survey completion, case placed back into lead storage. Courier information and survey results as follows:

Joe Groves
Courier
Triad Isotopes - Saginaw
2795 Universal Drive
Saginaw, MI 48603
Tel: 989-799-7669
Fax: 989-799-7868

Survey Meter	Bicron Surveyor 2000 S/N B700L, side window
Survey at Surface	> 200 mR/h (Limit < 0.5 mR/h) - Fail

Exact mR/h reading could not be obtained. Meter limit on 100 X scale is 200 mR/h. Meter reading exceed 100 X scale limit.

10/23/2017 at 10:00

David Barratt CNMT requested that Triad Isotopes - Saginaw fax a copy of the packing list that would have been enclosed in case #3119. Faxed copy of packing list received, contents matched expected items based on order placed.

10/23/2017 at 10:20

David Barratt CNMT surveyed case #3119 with a secondary meter. Upon survey completion, case placed back into lead storage. Survey details as follows:

Survey Meter	Ludlum 14C S/N 257428, end window
Survey Meter QC prior to use	Battery Check – Pass
	Check Source 0.6 mR/h – Pass
	Background 0.01 mR/h – Pass
Survey at 1 meter	0.9 mR/h (Limit \leq Background) – Fail
Survey at Surface	>200 mR/h (Limit < 0.5 mR/h) – Fail

Exact mR/h reading could not be obtained. Meter limit on 100 X scale is 200 mR/h. Meter reading exceed 100 X scale limit. Verified case contents per labeling on Type I UN2915 label to exceed the <100 mCi as earlier reported. Case contents per label was 21.5412 GBq Tc-99m. Calibration time was 10/23/2017 at 3:00 per Robert Bjurstrum at Triad Isotopes. This would have been the time the case left their facility. Activity calculated at time of initial survey as follows:

Decay factor for Tc-99m for 4 hours 40 minutes = 0.5839

Decay corrected activity at 7:40 = 21.5412 Gbq X 0.5839 = 12.5779 GBq (339.9 mCi)

10/23/2017 at 15:30

Call made to Geof Warren of the NRC seeking guidance. CFR guidance provided to report this event under 10 CFR 20.1906 paragraph D2 which is referenced in 10 CFR 71.47 paragraph B. Multiple return calls from NRC were made seeking supplemental information. Was advised to resurvey tomorrow looking for appropriate decay to help identify case contents. Trying to confirm as short lived isotope, in particular Tc-99m. NRC contact for these call as follows:

Geof Warren
Senior Health Physicist
United State Nuclear Regulatory Commission, Region III Office
Lisle, IL 60532
Tel: 630-829-9742

10/23/2017 at 15:45

Call from Steven Vitto of the NRC. Supplemental information taken and event follow up. NRC contact for this call as follows:

Steven Vitto
Inservice Response Group
United States Nuclear Regulatory Commission
Rockville, MD 20852
Tel: 301-816-5148

10/24/2017 at 8:40

Call from Geof Warren of the NRC. Follow up on results of second survey to identify as short lived isotope, see survey results below. Survey results were higher than expected. Confirmed contents were a short lived isotope. Still felt contents most likely Tc-99m.

Was advised to perform a repeat survey tomorrow to try to better identify case contents.

Advised have 30 days to submit report to NRC. NRC contact for this call as follows:

Geof Warren

Senior Health Physicist

United State Nuclear Regulatory Commission, Region III Office

Lisle, IL 60532

Tel: 630-829-9742

Survey Meter

Bicron Surveyor 2000 S/N B700L, side window Survey

Meter QC prior to use

Battery Check – Pass

High Voltage – Pass

Check Source 0.7 mR/h – Pass

Background 0.01 mR/h – Pass

Survey at Surface

25 mR/h (Limit < 0.5 mR/h) – Fail

Initial Survey 10/23/2017 at 9:55 of >200 mR/h Surface

Current Survey 10/24/2017 at 8:40 of 25 mR/h Surface

Time Lapse of 22 hours 45 minutes.

Decay factor for Tc-99m for 22 hours 45 minutes = 0.0726

Decay corrected survey results = >200 mR/h X 0.0726 – >14.52 mR/h expected

10/25/2017 at 10:00

Repeat survey performed to try to better identify case contents. Survey results confirmed short lived isotope, most likely Tc-99m. Survey results below:

Survey Meter

Bicron Surveyor 2000 S/N B700L, side window

Survey Meter QC prior to use

Battery Check – Pass

High Voltage – Pass

Check Source 0.7 mR/h – Pass

Background 0.01 mR/h – Pass

Survey at Surface

1.6 mR/h (Limit < 0.5 mR/h) – Fail

Prior Survey 10/24/2017 at 8:40 of 25 mR/h Surface

Current Survey 10/25/2017 at 10:00 of 1.6 mR/h Surface

Time Lapse of 25 hours 20 minutes.

Decay factor for Tc-99m for 25 hours 20 minutes = 0.0539

Decay corrected survey results = 25 mR/h X 0.0539 = 1.3 mR/h expected

10/25/2017 at 10:30

Call from Bob Gattone of the NRC. Follow up on results of subsequent survey to identify as short lived isotope. Gave results listed for surveys performed on 10/24/2017 at 8:40 of 25 mR/h and second survey performed 10/25/2017 at 10:00 of 1.6 mR/h. Survey results confirmed short lived isotope, most likely Tc-99m.

Reported that case contents of <100 mCi Tc-99m was incorrect. Gave corrected activity level for case #3119 per Type I UN2915 labeling to be 21.5412 Gbq Tc-99m calibrated on 10/23/2017 at 3:00. Decay corrected contents to be 12.5779 GBq (339.9 mCi) on 10/23/2017 at 7:40, time of initial survey. NRC contact for this call as follows:

Bob Gattone

Senior Health Physicist/Inspector

United State Nuclear Regulatory Commission, Region III Office

Lisle, IL 60532

Tel: 630-829-9823

10/27/2017 at 10:04

David Barratt CNMT removed case #3119 from lead storage, inspected and verified to be free from damage with security tie in place. Case was then surveyed and wipe tested and found to be within NRC limits for a Type I UN2915 package. Inspection, survey and wipe testing performed with Claude Rohrer CNMT and Triad Isotopes representative Robert Bjurstorm present. Survey and Wipe tests results listed below. Case was within acceptable limits. Case was opened to identify cause of prior above limit surveys. Enclosed packing list matched packing list previously faxed from Triad Isotopes. Contents verified to match contents listed on packing list. See attached copies of packing list. Internal contents of case were wipe tested with no removable contamination found. Findings showed that the lid on the bulk vial shield had an approximate 1.2 cm separation from the base of the vial shield. Shrink wrapping was still intact over separated lid and base. Contents of the bulk vial per the packing list were 60 mCi Tc-99m calibrated on 10/23/2017 at 11:00. Bulk vial with shrink wrapping in place was also wiped tested with no removable contamination found. See attached photos showing case from all sides and case contents, 8 photos total. Case was then closed and returned to Triad Isotopes as a Limited Quantity UN2910 package.

Survey Meter	Bicron Surveyor 2000 S/N B700L, side window
Survey Meter QC prior to use	Battery Check – Pass
	High Voltage – Pass
	Check Source 0.7 mR/h – Pass
	Background 0.01 mR/h – Pass
Survey at 1 meter	0.01 mR/h (Limit \leq Background) – Pass
Survey at Surface	0.01 mR/h (Limit $<$ 0.5 mR/h) – Pass
Well Counter	Captus 4000e S/N 940-198
Well QC prior to use	FWHM 6.9% - Pass
	Constancy -0.6% - Pass
	Background 213 cpm – Pass
External Wipe over 300 cm ²	8 dpm (Limit 6600 dpm / 300 cm ²) – Pass
Internal Wipe over 300 cm ²	-58 dpm – Pass
Bulk Vial Wipe	-34 dpm – Pass

10/27/2014 at 11:14

Call from Bob Gattone of the NRC. Final follow up on case received above limits. Complete rundown on findings as listed above. Also all photos that are included in this report were emailed for clarification to the email listed below. Again, verified written reporting requirements to be within 30 days. Copy of report to be faxed to original NRC contact, Jeff Herrera at 301-816-5151. A second copy of report to be faxed to final NRC contact, Bob Gattone at 630-515-1259. Asked to call before faxing for notification that report has been sent. Final copy of report to be electronically transferred to email listed below. NRC contact for this call as follows:

Bob Gattone
 Senior Health Physicist/Inspector
 United State Nuclear Regulatory Commission, Region III Office
 Lisle, IL 60532
 Email rgg@nrc.gov
 Tel: 630-829-9823
 Fax: 630-515-1259

If there are any questions or additional information is required, please contact us at numbers listed below.

David Barratt, CNMT
Nuclear Medicine Technologist
John Tolfree Hospital
d/b/a West Branch Regional Medical Center
2463 South M-30
West Branch, MI 48661
NRC License # 21-18892-01
Tel: 989-343-3218
Fax: 989-343-3136

Dr. Matthew Waack, MD *Matthew Waack MD*
Radiation Safety Officer
John Tolfree Hospital
d/b/a West Branch Regional Medical Center
2463 South M-30
West Branch, MI 4866
NRC License # 21-18892-01
Tel: 989-343-3196
Fax: 989-343-3136

David Barratt, CNMT

Cc: Triad Isotopes – Saginaw

22 PROCEDURE FOR OPENING/ RETURNING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Put on gloves to prevent hand contamination.
2. Visually inspect the package for any sign of damage (e.g., wet or crushed). If damage is noted, stop and notify the RSO.
3. Measure and record the exposure rate from the package at 1 meter and at the package surface. If the rate is greater than 10 mR/hr, stop and immediately notify the RSO, the final delivery carrier and the NRC regional office by telephone (301-816-51000) and fax.
4. Measure and record the exposure rate on the surface of the package in the same orientation as the data taken in step 3 above. If greater than 200 mR/hr stop the procedure and immediately notify the RSO, the final delivery carrier and by telephone and fax the regional office of the NRC.
5. Wipe 300 cm² external surface area of the package in compliance with 10 CFR 20.1906. Assay the wipe sample with a suitable instrument sufficient to detect 2200 dpm to determine if there is any removable activity. If there is any contamination in excess of 6600 dpm/300cm², immediately notify the RSO, the final delivery carrier and the regional office of the NRC by telephone (301-816-5100) and fax. **DO NOT OPEN THE PACKAGE!!**
6. Follow the steps listed below when opening the package.
 - a. Remove the packing slip.
 - b. Open the outer package following the supplier's instructions, if available.
 - c. Open the inner package and verify that the contents agree with the packing slip.
 - d. Check the integrity of the final source container. Look for broken seals or vials, loss of liquid, condensation, or discoloration of the packing material.
 - e. if anything unusual is noticed, stop and notify the RSO.
7. Verify that the material received is the material ordered.
8. Verify that the manufacturer receives the material being returned.
9. Monitor the packing material and the empty packages for contamination with a GM survey meter before discarding. If contaminated, treat as radioactive waste. If not contaminated, deface all radiation labels before discarding.

WEST BRANCH REGIONAL MEDICAL CENTER



10. Record the receipt and all readings taken.

The diamond label used is determined by the exposure measurements noted below.
Make sure your package conforms to these exposure levels / label pairings.

	<u>Surface</u>	<u>One Meter</u>
WHITE I	<0.5 mR/hr	Background
YELLOW II	0.5 - 50 mR/hr	< 1 mR/hr
YELLOW III	50 - 200 mR/hr	1 - 10 mR/hr
YELLOW III	200 - 1000 mR/hr	> 10 mR/hr
Exclusive Use Only		

COPY OF PACKING LIST FAXED FROM TRIAD ISOTOPIES

Triad Isotopes*

West Branch RMC (113)

Triad Isotopes - Saginaw

2795 Universal Drive

Saginaw, MI 48603

(989) 799-7669

Shipment Report

Delivery Date/Time: 10/23/2017 04:30

Box: 001

Ship Container: 3119

OrderID: 03999

West Branch RMC (113)

2483 South M-30

West Branch, MI 48661

989-343-3218



Item	Volume	Quantity	Cal Date/Time	Exp Date/Time	Time
248111	60.00 mCi Sodium Pertechnetate Tc-99m HEU 5 ml	1	10/23/2017	10/24/2017	11:00 01:55
248112	0.25 mCi Sodium Pertechnetate Tc-99m HEU 0.045 ml	1	10/23/2017	10/23/2017	06:30 10:08
248398	1.00 each Mebrofenin (Generic) Kit 1 vial	5	11/30/2018		23:59

THIS CASE WAS NEVER OPENED. ABOVE LIMITS ON 1 METER & SURFACE SURVEYS. PLACED INTO DECAY STORAGE AREA. WILL BE RESURVEYED AND REWIPE AFTER SUFFICIENT TIME TO GET TO BACKGROUND LEVELS. ~~CONTENTS ASSIGNED~~

BUT NOT VERIFIED TO MATCH SHIPPER. THIS SHIPPER IS NOT FROM ORIGINAL CASE 3119 BUT A SECONDARY COPY FAXED FROM TRIAD. 215412 GBq ON TYPE 1, UN2915 LABEL AS ACTIVITY CONTAINED IN CASE.

TIME	INSTRUMENT	RESULTS
7:40	BICRON B700L	0.7 mR/h @ 1 METER, 190 mR/h SURFACE
	CAPTUS 4000R	9 dpm / 300 cm ²
9:55	BICRON B700L	> 200 mR/h SURFACE.
10:20	LUDLUM 14C	> 200 mR/h SURFACE, 0.9 mR/h @ 1 METER.

DAVID BARRATT, CNMT

David Barratt

Printed on: 10/23/2017 2:35:09 PM

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ORIGINAL PACKING LIST



Triad Isotopes - Saginaw
2795 Universal Drive
Saginaw, MI 48603
(989) 799-7669
Shipment Report

CustomerID: 03999 Delivery Date/Time: 10/23/2017 04:30
West Branch RMC (113)
2463 South M-30
West Branch, MI 48661
989-343-3218

Box: 001 Ship Container: 3119



Item	60.00 mCi	Sodium Pertechnetate Tc-99m HEU	Cal Date/Time	10/23/2017	11:00
RX #	248111	Volume 5 ml Quantity 1	Exp Date/Time	10/24/2017	01:55
Item	0.25 mCi	Sodium Pertechnetate Tc-99m HEU	Cal Date/Time	10/23/2017	06:30
RX #	248112	Volume 0.045 ml Quantity 1	Exp Date/Time	10/23/2017	10:08
Item	1.00 each	Mebrofenin (Generic) Kit	Cal Date/Time		
RX #	248396	Volume 1 vial Quantity 5	Exp Date/Time	11/30/2018	23:59

ACTUAL PACKING LIST REMOVED FROM CASE.
ON 10-27-2017 @ 10:05.

CASE SURVEYED AT 0.01mR/h SURFACE, 0.01mR/h 1 METER
SURVEY METER - BICRON B700L

CASE WIPE AT 8 dpm OVER 300 cm²

WELL COUNTER CAPTUS 4000e S/N 940-198

CONTENTS OF CASE VERIFIED AS MATCHING SHIPPER

CASE WAS SURVEYED AND WIPE AND OPENED IN THE
PRESENCE OF TRIAD ISOTOPE REPRESENTATIVE
ROBERT BJURSTROM, ALSO PRESENT JOHN TOLPREE
HOSPITAL NUCLEAR MEDICINE TECHNOLOGISTS

CLAUDE ROHRE, CNMT

DAVID BARRATT, CNMT

PAGE 13 OF 21 David Barratt CNMT.

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THE

• **Triad Isotopes**[®]
Patient focused. Community driven.



7620
27 10 02AM

PALE 150F21

USA D.O.T.
7A-TYPE A
**RADIOACTIVE
MATERIAL**

27 10:02AM

File 16021



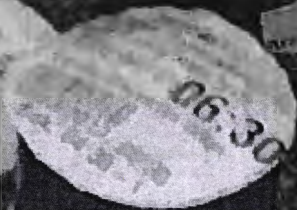
27 10:03 AM

AGE 170521



27 10:03AM

APK 180521



11-10-05AM

PAK 196-21



27 10:13AM

ACTIVE 1

5412 GB1

PAK 20 & 21

West Branch - Saginaw

10/23/2017 04:30

Unit Name West Branch RMC (113)

10/23/2017 04:30 Container: 1

S/O Per Physician Order
Sodium Pertechnetate Tc
Bath Vial

Matthew Wasch MD

Amount 60 mCi Quantity 1

Date Time 10/23/2017 11:00

Amount 242 523 mCi Quantity 1 Volume

Date Time 10/24/2017 01:55

West Branch

10/23/2017 - 003 1 252

FLUX 1410 VIAL

10/23/2017 04:30

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Isotopes - Saginaw

West Branch RMC (113)

10/23/2017 04:30 Container:1

S/O Per Physician Order
Sodium Pertechnetate Tc-99m

Bulk Vial

Matthew Waack, MD

Amount: 60 mCi Quantity: 1

Date: 10/23/2017 11:00

Count: 242.523 mCi Quantity: 1 Volume: 1

Date: 10/24/2017 01:55

20171023-003 1.252

ELUTE INTO VIAL

ONLY