

CONVERSATION RECORD

TIME | DATE

7/31/2009

VISIT

CONFERENCE

TELEPHONE

INCOMING

OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

Darrel Wiedeman.

9808

SUBJECT

Follow-Up to event during next inspection

SUMMARY

This event (contaminated package) requires a follow up during the next routine inspection. This item is also an open item in the NMED data base and should be closed after the follow up inspection. This event should also be tracked in NMED to the supplier (Mallinckrodt/ Covidien).

ACTION REQUIRED

Place in ADAMS.

cc: T. Bloomer

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

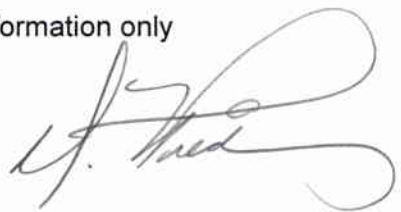
DATE

Darrel Wiedeman

ACTION TAKEN

Information only

SIGNATURE



TITLE

DATE

7/31/2009

July 23, 2009

Tamara Bloomer
Region III, NRC
2443 Warrenville Rd, Suite 210
Lisle, IL 60532-4352

RE: Event Notification # 45217, reported to Howie Crouch, Operations Center at 15:41 EDT, July 21, 2009. Also notified: State of Michigan, FED EX (carrier) and Covidien (supplier).

Dear Ms. Bloomer;

Enclosed is the written report of the package contamination issue at St. Francis Hospital, Escanaba, MI, NRC License No. 21-16481-01. The enclosed was written by the senior Nuclear Medicine Technologist.

The package was received on July 21, 2009. I was contacted as the consultant health physicist from Medical Physics Consultants, Ann Arbor, MI. After repeated testing by the OSF technologist of the contaminated area and counting the wipes for several hours yesterday, I have concluded that the contamination was Tc-99m, not Tl-201, which is the material in the package. The instrumentation at OSF did not permit spectral analysis. Since the package was at last down to background this morning, it was opened, the box and contents wipe tested and surveyed with pancake GM and found to be free of contamination. The techs there have been given a sensitivity factor for wipe counting of x 5 as a very conservative conversion from cpm to dpm. Had a more realistic conversion of x 2 been used this event would not have risen to the reportable level of 22,000 dpm. We routinely perform a Co-57 sensitivity of the well counter but continue to use the conservative x 5 in practice. We will reevaluate this factor at the next audit.

No person was exposed to radiation at greater than allowable levels. The surveys of the FedEx drivers were at background levels. The wipe test of Bruce's hands showed contamination until the wipe was removed from the packaging. Alcohol prep pads are used. A 2 x 2" pad is pre-soaked with alcohol and packaged in a paper packet. The fact that the packet was hotter than the wipe implies cross-contamination of the wipe by the technologist. A repeat of Bruce's hands was background. After hand washing the technologist was also at background. I was told today by the RSO of FED EX that he contacted their operations in Memphis and was told that only one other shipment went through there to Milwaukee with our package and no complaints were reported.

RECEIVED JUL 28 2009

There are three plausible scenarios for the origin of this contamination. (1). The package was contaminated with high dose Tc-99m at the production facility. I was informed by Covidien that Tl-201 and Tc-99m are shipped from a common location. The liquid could have dried completely on the cardboard box precluding contamination to persons handling the box with dry hands. The intervening hours until receipt at OSF would have decayed the Tc-99m to the relative low level detected. Survey with the GM found the typical level of radiation. The wipes were wet with alcohol, which could have leached the Tc-99m back out of the cardboard. (2) The contamination occurred at OSF from handling by either Kay or Joe prior to testing. Or (3) the contamination occurred at OSF after the box was placed in the hot lab for processing. This is a very small room and a slight spill or spray of Tc-99m could have managed to reach the box.

The technologists learned a very good lesson regarding contamination control. The senior tech said that she went through 2 boxes of gloves during the investigation to avoid any further contamination.

If you have any questions regarding this report, please contact me at (906) 225-6967.

Sincerely,

A handwritten signature in purple ink that reads "Shan Marlette". The signature is written in a cursive style with a large initial "S" and "M".

Shan Marlette, M.S.

Enc.

RECEIPT OF CONTAMINATED PACKAGE

1. On July 21, 2009 at approximately 11:30am, OSF St. Francis Hospital received a package from Mallinckrodt/Covidien containing Thallium 201 Chloride (3 vials, 9.9 mCi each). The package was delivered to the facility by FedEx. The package was received by Kay Carlson from storeroom person Dan Tryan.
2. About 12:30pm, Christina Casey started the process of opening the package by doing wipe test of the outside of the package. The first wipe test reading was above allowable limits. (5623 cpm, background 323 cpm = 26500dpm)
3. Christina Casey rewiped package several times and in different areas of the top of the package. All wipes were above allowable limits (2631cpm, 2182cpm, 1635cpm, with a background of 323cpm and a fifth time 601cpm with background of 292cpm).
4. At this point, Christina Casey surveyed the package and obtained a surface reading of 3.0mR/hr. Christina Casey was later informed that Joseph Russo had wiped the package prior to Christina Casey wiping and surveying the package. Wipe counts were not recorded, but Joseph did say they were above allowable limits.
5. In review of Hot Lab records, the only dose drawn in the hot lab between the hours of 11:30am and 12:30pm was a dose of DMSA (1.9 mCi) drawn by Christina Casey.
6. Christina Casey called the facility's physicist, Shan Marlette, around 1:15pm. We decided to have the FedEx driver return to the facility for wipe testing, to survey and wipe test Dan's hands, cart and table.

Surveys

Dan 0.02mR/11r

Cart 0.03mR/Hr

Table 0.03mR/11r

Background 0.03mR/Hr

Christina Casey notified the facility's RSO, Dr. Leon Kinasiewz.

7. Christina had the storeroom call the FedEx driver to return and a package handler/driver also volunteered to come in.
8. Mallinckrodt/Covidien was notified by Shan Marlette and Christina later called them to give/verify information.
9. Shan Marlette notified the DEQ for the facility.
10. Bruce, FedEx handler/driver, came in. Kay Carlson surveyed and wiped his hands (survey=0.03mR/Hr, wipe=24054cpm with background=312). Tina then removed the outside packaging of the wipe and recounted the wipe (1867 cpm with Background of 313 cpm). Christina went back down to storeroom to rewipe Bruce but he had left. He was called and told to return immediately. Kay Surveyed her hands(0.04mR/11r, Background 0.03MR/hr). Since Kay seemed to be above background, she was sent to wash her hands and repeat surveys. After one washing she fell below background.

11. In the meantime, Christina and Kay recalibrated the well counter. Wipes were recounted with similar results.

Wipes

Package 584

Dan 309

Cart 337

Table 324

Background 319

12. Driver, Kim and Bruce both drove in about 3:00pm.

Surveys were done and wipes were done

	<u>Surveys</u>	<u>Wipes</u>
Bruce	0.03mR/Hr	396cpm
Kim Hands	0.03mR/Hr	425cpm
Kim truck	0.02mR/11r	412cpm
Kim steering wheel	0.03	461cpm

Background 0.03

325cpm

Both drivers were released back to work.

13. Christina Casey put package in plastic trash bag and put in storage closet to decay.
14. Christina Casey received a phone call from FedEx physicist Dr. Roy Parker. It was decided to recount any package wipes in morning (if wipes were available) and repeat counting them in AM and PM until background is reached.

July 22, 2009

1. Christina Casey wiped package, calibrated well counter and count wipe (6:30am 361cpm, background 294).
2. She was able to recover two wipes from the trash that were wrap in gloves (8:30am #1=499cpm, #2=334, am wipe=334cpm, and background =277cpm).

<u>Time</u>	<u>Bkgd cpm</u>	<u>Wipe cpm</u>	<u>#1cpm</u>	<u>#2cpm</u>
0630	294	361		
0830	277	334	499	334
1030	285	324	454	321
1230	291	355	389	286
1430	260 and 297	313	350	283

3. Christina received phone calls from Shan, Dr. Parker and physicist, Tim, from Mallinckrodt/Covidien. She also met with FedEx manager, Escanaba office.
 - a. Shan told Christina NRC would be notified.
 - b. Mallinckrodt/Covidien inform Tina that a report was on the NRC website and she answered a few questions for them.
 - c. Manager of FedEx had questions for her.
 - d. Dr. Parker had talked with Mallinckrodt/Covidien and it was agreed that the package should be wiped, surveyed, opened and wipes done on the inside of the package. If the wipes were below allowable limits, the

contents should be removed and the empty packaging surveyed.

4. At 1:00pm, Christina performed these tasks. Results are as follows:

Background	302cpm
Outside of box	277cpm
Vial #1	305cpm
Vial #2	318cpm
Vial #3	327cpm
Top Styrofoam	320cpm
Inside top flap	314cpm
Inside side	316cpm

Survey of empty packaging

Background	0.02mR/Hr
1 meter	0.02mR/Hr
Package	0.03mR/Hr

Wipes were placed in plastic bag, put in package and package stored in decay closet.

5. Christina informed Shan and Dr. Parker of wipe and survey results.

6. RSO, Imaging Manager and CEO of hospital of been updated.

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1. Continuation of wipe counting:

<u>Time</u>	<u>Bkgd cpm</u>	<u>Wipe cpm</u>	<u>#1 cpm</u>	<u>#2cpm</u>
0630	291	321	313	341 and 311
1030	273	253	302	296
1430	294	302	293	270

July 24, 2009

<u>Time</u>	<u>Bkgd cpm</u>	<u>Wipe cpm</u>	<u>#1cpm</u>	<u>#2cpm</u>
1030	299	302	287	285