

Cardinal Health
Nuclear Pharmacy Services
Quality & Regulatory
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.4120
fax 614.652.4598

www.cardinal.com



CardinalHealth

May 7, 2018

Kevin Null
U.S. NRC Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

RE: Report of contamination for Radioactive Materials License Number 34-29200-01MD,
NRC Event Report 53320, Cardinal Health, Dublin, Ohio.

Dear Mr. Null:

Cardinal Health 414, LLC (Nuclear Pharmacy Services, hereafter Cardinal Health) submits a report of our investigation concerning a package containing radioactive materials which was reported to be contaminated above NRC reporting limits by our customer, McLaren Greater Lansing Hospital, NRC licensee 2104073-01. This occurred on April 8, 2018 following delivery of radioactive materials to our customer. The unit dose shields inside the package were not contaminated above limits and doses were used by our customer.

Cardinal Health reviewed all applicable survey records for personnel, delivery vehicle, and the pharmacy located in Jenison, Michigan. Pursuant to applicable sections of 10 CFR 71.5 and 49 CFR 173.443, the attached report describes the most likely root cause and our corrective actions, including steps taken or planned to prevent recurrence of a similar event within the control of Cardinal Health.

If you have any questions concerning this incident, please contact me at 614-757-9586.

Sincerely,

Glenn P. Sullivan
Corporate Radiation Safety Officer
Director, Health Physics
Quality and Regulatory
Nuclear Pharmacy Services

Enclosure: Investigation of Customer Package Contamination
Attachment A – Surveys and Transportation US DOT Records

cc: Glenn Sullivan, CRSO
Phillip Heim, PRSO, Loc. 11
Steven S. Miller, Loc. 11
Rick Hasselkus
Consolidated NRC File (5)

Melissa George, RSO, Loc. 7010
John Alexander, RSO, Loc. 7002
Phillip F. Heim, RSO, loc. 7011
Mathew Svejck, RSO, Loc. 7013
Christie Holland, RSO, Loc. 7016
William Balogh, RSO, Loc. 7025
Frederick White II, RSO, Loc. 7028
Earl Robertson, RSO, Loc. 7030
Jay Simmons, RSO, Loc. 7088
Brian Porter, RSO, Loc. 7109
Dane Dishman, RSO, Loc. 7120
John A. Miller, RSO, Loc. 7128
Bobby Bartlett, RSO, Loc. 7172
Mark Peters, RSO, Loc. 7200
Nate Johnson, RSO, Loc. 7201
Thomas Sundrla, Loc. 7231
Cynthia Martin, RSO, Loc. 7232
Micah Rydman, RSO, Loc. 7306
David Webb, RSO, Loc. 7341
Justin Goodnite, RSO, Loc. 7545

CARDINAL HEALTH INVESTIGATION

On April 8, 2018 McLaren Greater Lansing Hospital (MGLH) reported to Cardinal Health that a package containing radioactive materials had removable contamination levels above NRC reporting limits with no damage to the Type A package observed. The contents of the Type A shipping containers is itemized in **Attachment A**. The total activity of Technetium-99m in two Type A packages delivered to MGLH was less than 28.1 GBq, (16.05 GBq or 434 millicuries + 12.06 GBq or 326 millicuries, respectively, or less than 1000 times the quantity specified in Appendix C of 10 CFR 20).

INCIDENT CHRONOLOGY

April 8, 2018 approximately 05:07 CDT, the Cardinal Health Type A package was surveyed at the dispensing pharmacy and the US DOT shipping papers were completed for the shipment from the nuclear pharmacy located at 1864 Pine Ridge Drive, Suite A, Jenison, MI to our customer, MGLH address 401 W. Greenlawn Avenue, Lansing, Michigan. A copy of the hazardous materials shipping paper is attached for the UN2915, Radioactive Material two (2) Type A packages labeled with DOT Type I, T.I. = 0: container ID numbers 23929 and 71666, with the packing list ID's 15832688 and 15832590 to itemize radioactive materials ordered by MGLH are enclosed in Attachment A.

ROOT CAUSE

Prior to dispatch of packages, a package was dislodged from the counter and subsequently a vial was found broken within the shielded container. Although no removable contamination was measured on either Type A package above limits before they left the pharmacy on April 8, 2018 for delivery to the customer, cross contamination may have occurred.

It was noted that no removable contamination above limits was found in the surveys of the vehicle, personnel protective clothing or the dispensing pharmacy. Again, it is possible that cross contamination may have occurred during handling by Cardinal Health, if proper glove replacement techniques were not used by handlers or if safe handling practices were not implemented.

CORRECTIVE ACTIONS:

1. The Corporate Radiation Safety Officer has communicated our findings and actions planned or taken with the customer MGLH Radiation Safety Officer after receiving and reviewing information from the dispensing nuclear pharmacy located in Jenison, Michigan. The results of our review for surveys and transportation records indicates that there are no survey results above limits for removable contamination in the pharmacy, the vehicles used for delivery to MGLH or personnel handling the packages delivered or on the package exterior surface. We acknowledge this does not rule out cross contamination during transit or within the customer location restricted areas.
2. Training was completed for all occupational exposed personnel to review the report of package contamination from our customer and methods to reduce exposures ALARA, precautionary procedures for reducing the spread of contamination: for example, in the event of a spill or release of radioactive materials, frequent change of gloves, package handling and personnel monitoring. A record of the training completed on April 12, 2018 is enclosed in Attachment A.

ATTACHMENT A

US DOT Shipping Papers Survey Records Documentation of Training



SHIPPING DOCUMENTS FOR DANGEROUS GOODS

Committed D/T : 04/08/2018 06:30 ET

SHIPPER CARDINAL HEALTH 414, LLC GRAND RAPIDS 1864 PINE RIDGE DR SUITE A JENISON, MI 49428 1 616 662-5013	RECEIVER GREATER LANSING MCLAREN 401 W GREENLAWN AVE LANSING, MI 48910-2819
---	---

CARRIER : Same as Shipper	Ship Container ID : 23929	Packing List ID: 15832688
----------------------------------	----------------------------------	----------------------------------

<u>Identification Number</u> UN2915	<u>Proper Shipping Name</u> Radioactive Material, Type A Package	<u>Hazard Class</u> 7
--	---	--------------------------

NATURE AND QUANTITY OF DANGEROUS GOODS				
<u>NO. OF PIECES WITHIN CONTAINER</u>	<u>RADIONUCLIDE</u>	<u>CHEMICAL FORM/ PHYSICAL STATE</u>	<u>ACTIVITY - Bq</u>	<u>ACTIVITY - mCi</u>
1	Tc-99m	Inorganic Salt / Liquid	162705	(385.6917)
1	Tc-99m	Protein / Liquid	17765	(48.0071)
Total Activity Contained in one (1) Container			160450	(433.6987)

RADIOACTIVE LABEL CATEGORY WHITE I	Transport Index : 0
--	----------------------------

Emergency Spill-Leak-Fire-Exposure or Accident Contact : CHEMTREC 800-424-9300 Customer #204503

This is to certify that the above named materials are properly classified, described, packaged, marked and labeled and is in proper condition for transportation according to applicable regulations for the Department of Transportation.

Certified By : david.elzinga		Courier Signature		Receiver Signature	
Date	Time	Date	Time	Date	Time
04/08/2018	05:07				

Run : Sun/Hol Run 1 Route : 05:00-Sun-Lansing



Packing List

CARDINAL HEALTH 414, LLC
GRAND RAPIDS
1864 PINE RIDGE DR SUITE A
JENISON MI 49428
1 616 662-5013

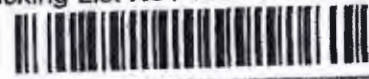


15832688

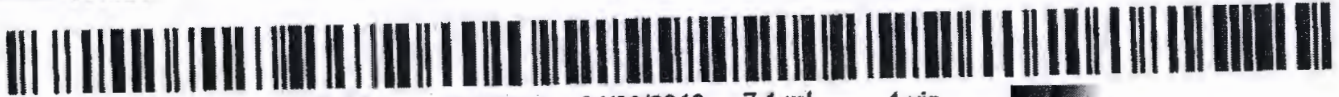
REDACTED COPY

Customer ID: 2100056050
GREATER LANSING MCLAREN
401 W GREENLAWN AVE
LANSING MI 48910-2819

Container Id: 23929
Packing List No.: 15832688



Description Product Code	Activity	Cal D/T	Exp D/T	Vol	Qty	Rx# Order #	Patient Name/ID
Tc-99m Mac. Agg. Alb. Unit Dose 111001	7.69 mCi	04/08/2018 21:00 ET	04/08/2018 22:33 ET	1.5 mL			



Tc-99m Sodium Pertechnetate Multi Dose	219.62 mCi	04/08/2018 10:00 ET	04/09/2018 04:30 ET	7.1 mL	1 via		
---	---------------	------------------------	------------------------	--------	-------	--	--





CardinalHealth

SHIPPING DOCUMENTS FOR DANGEROUS GOODS

Committed D/T : 04/08/2018 06:30 ET

SHIPPER CARDINAL HEALTH 414, LLC GRAND RAPIDS 1864 PINE RIDGE DR SUITE A JENISON, MI 49428 1 616 662-5013	RECEIVER GL HEART MCLAREN 401 W GREENLAWN AVE LANSING, MI 48910-2819
---	--

CARRIER : Same as Shipper	Ship Container ID : 71666	Packing List ID: 15832590
----------------------------------	----------------------------------	----------------------------------

<u>Identification Number</u>	<u>Proper Shipping Name</u>	<u>Hazard Class</u>
UN2915	Radioactive Material, Type A Package	7

NATURE AND QUANTITY OF DANGEROUS GOODS				
<u>NO. OF PIECES WITHIN CONTAINER</u>	<u>RADIONUCLIDE</u>	<u>CHEMICAL FORM/ PHYSICAL STATE</u>	<u>ACTIVITY - GBq</u>	<u>ACTIVITY - mCi</u>
8	Tc-99m	Organic Compound / Liquid	(326.0636)	(326.0636)
Total Activity Contained in one (1) Container			(326.0636)	(326.0636)

RADIOACTIVE LABEL CATEGORY	Transport Index : 0
WHITE I	

Emergency Spill-Leak-Fire-Exposure or Accident Contact : CHEMTREC 800-424-9300 Customer #204503

This is to certify that the above named materials are properly classified, described, packaged, marked and labeled and is in proper condition for transportation according to applicable regulations for the Department of Transportation.

Certified By : david.elzinga		Courier Signature		Receiver Signature	
Date	Time	Date	Time	Date	Time
04/08/2018	04:44				

Run : Sun/Hol Run 1 Route : 05:00-Sun-Lansing



Packing List

CARDINAL HEALTH 414, LLC
GRAND RAPIDS
1864 PINE RIDGE DR SUITE A
JENISON MI 49428
1 616 662-5013

REDACTED COPY



15832590

Customer ID: 2100056044
GL HEART MCLAREN
401 W GREENLAWN AVE
LANSING MI 48910-2819

Container Id: 71666
Packing List No: 15832590



Description Product Code	Activity	Cal/D/T	Exp D/T	Vol	Qty	Order#	PatentName/ID
Tc-99m Sestamibi Unit Dose 123001	10.96 mCi	04/08/2018 08:00 ET	04/08/2018 21:38 ET	0.5 mL			
Tc-99m Sestamibi Unit Dose 123001	10.94 mCi	04/08/2018 08:30 ET	04/08/2018 21:38 ET	0.5 mL			
Tc-99m Sestamibi Unit Dose 123001	11.00 mCi	04/08/2018 09:00 ET	04/08/2018 21:38 ET	0.5 mL			
Tc-99m Sestamibi Unit Dose 123001	10.99 mCi	04/08/2018 09:30 ET	04/08/2018 21:38 ET	0.5 mL			
Tc-99m Sestamibi Unit Dose 123001	30.40 mCi	04/08/2018 10:00 ET	04/08/2018 21:38 ET	1.3 mL			
Tc-99m Sestamibi Unit Dose 123001	32.99 mCi	04/08/2018 10:30 ET	04/08/2018 21:35 ET	0.5 mL			
Tc-99m Sestamibi Unit Dose 123001	32.64 mCi	04/08/2018 11:00 ET	04/08/2018 21:35 ET	0.5 mL			
Tc-99m Sestamibi Unit Dose 123001	31.68 mCi	04/08/2018 11:30 ET	04/08/2018 21:35 ET	0.6 mL			



Survey Report

Cardinal Health NPS JENISON
1864 PINE RIDGE DR
JENISON, MI 49428
1 616 662-5013

Test Date: 4/9/2018

Next Due Date: 04/10/2018

Make: Ludlum

Model: 3 (DOT)

Serial #: 87401

Instrument Location: RA

Last Cal Date: 6/29/2017

Lab ID:

Frequency: Daily

Background: 0.03 mR/hr

Survey Area #	Survey Test Location	Survey Actual Reading (mR/hr)	Survey Net Reading (mR/hr)	Classification	Survey Action Level (mR/hr)	Survey Test Status	Retest	Comments
01	Generator Room Surfaces	0.8	0.77	Restricted	5	Pass		
02	Drawing Hood 1	0.03	0	Restricted	2	Pass		
03	Floor in front of Drawing Hood 1	0.03	0	Restricted	2	Pass		
04	Drawing Hood 2	0.03	0	Restricted	2	Pass		
05	Floor in Front of Drawing Hood 2	0.03	0	Restricted	2	Pass		
06	Drawing Hood 3	0.03	0	Restricted	2	Pass		
07	Floor in front of Drawing Hood 3	0.03	0	Restricted	2	Pass		
08	Bio Hood Ledge	0.03	0	Restricted	2	Pass		
09	Blood Room Computer/ Centrifuge	0.03	0	Restricted	2	Pass		
10	RA Phones	0.03	0	Restricted	2	Pass		
11	Admin Desk	0.03	0	Restricted	2	Pass		
12	RA/URA Door-Front	0.03	0	Restricted	2	Pass		
13	Wrap Counter	0.03	0	Restricted	2	Pass		
14	QC Area and Computer	0.1	0.07	Restricted	2	Pass		
15	Main DOT Station	0.03	0	Restricted	2	Pass		



Survey Report

Cardinal Health NPS JENISON
1864 PINE RIDGE DR
JENISON, MI 49428
1 616 662-5013

Test Date: 4/9/2018

Next Due Date: 04/10/2018

Make: Ludlum

Model: 3 (DOT)

Serial #: 87401

Instrument Location: RA

Last Cal Date: 6/29/2017

Lab ID:

Frequency: Daily

Background: 0.03 mR/hr

Survey Area #	Survey Test Location	Survey Actual Reading (mR/hr)	Survey Net Reading (mR/hr)	Classification	Survey Action Level (mR/hr)	Survey Test Status	Retest	Comments
16	Secondary DOT Station	0.03	0	Restricted	2	Pass		
17	RA/JRA Door-Back	0.03	0	Restricted	2	Pass		
18	Breakdown Counter	0.03	0	Restricted	2	Pass		
19	Fumehood Ledge	0.3	0.27	Restricted	2	Pass		
20	Glovebox	0.1	0.07	Restricted	2	Pass		
21	Floor in Front of Glovebox	0.03	0	Restricted	2	Pass		

Performed By: Matthew Crawford MWC

Comments:

Test Status: Pass

RSO Signature:		Date:	
----------------	--	-------	--



Wipe Report

Cardinal Health NPS JENISON
 1864 PINE RIDGE DR
 JENISON, MI 49428
 1 616 662-5013

Test Date: 04/09/2018

Next Due Date: 04/10/2018

Make: Capintec

Model: Caprac-T

Serial #: 010272

Instrument Location: Wipe Test

Count Time (min):1

Wipe Area Sample Size (cm): 100

Background (cpm): 112

Lab ID: wr

Frequency: Daily

Radionuclide	Efficiency Test Date	MDA in uCi	LLD in CPM	Counting Efficiency
Ba-133	02/13/2018	2.360E-05	49	93.63%
Co-57	02/13/2018	2.210E-05	49	99.87%

Wipe Area #	Wipe Test Location	Analyzer Reading (cpm)	Wipe Net Reading (cpm)	Efficiency %	Net Results (dpm)	Classification	Wipe Action Level (dpm)	Wipe Test Status	Retest	Comments
01	Generator Room Surfaces	80	-32	99.87	0	Restricted	220	Pass		
02	Drawing Hood 1	160	48	99.87	48	Restricted	220	Pass		
03	Floor in front of Drawing Hood 1	130	18	99.87	18	Restricted	220	Pass		
04	Drawing Hood 2	200	88	99.87	88	Restricted	220	Pass		
05	Floor in Front of Drawing Hood 2	170	58	99.87	58	Restricted	220	Pass		
06	Drawing Hood 3	140	28	99.87	28	Restricted	220	Pass		
07	Floor in front of Drawing Hood 3	150	38	99.87	38	Restricted	220	Pass		
08	Bio Hood Ledge	90	-22	99.87	0	Restricted	220	Pass		
09	Blood Room Computer/Centrifuge	110	-2	99.87	0	Restricted	220	Pass		
10	RA Phones	140	28	99.87	28	Restricted	220	Pass		



Wipe Report

Cardinal Health NPS JENISON
 1864 PINE RIDGE DR
 JENISON, MI 49428
 1 616 662-5013

Test Date: 04/09/2018

Next Due Date: 04/10/2018

Make: Capintec

Model: Caprac-T

Serial #: 010272

Instrument Location: Wipe Test

Count Time (min):1

Wipe Area Sample Size (cm): 100

Background (cpm): 112

Lab ID: wr

Frequency: Daily

Wipe Area #	Wipe Test Location	Analyzer Reading (cpm)	Wipe Net Reading (cpm)	Efficiency %	Net Results (dpm)	Classification	Wipe Action Level (dpm)	Wipe Test Status	Retest	Comments
11	Admin Desk	110	-2	99.87	0	Restricted	220	Pass		
12	RA/URA Door-Front	100	-12	99.87	0	Restricted	220	Pass		
13	Wrap Counter	130	18	99.87	18	Restricted	220	Pass		
14	QC Area and Computer	160	48	99.87	48	Restricted	220	Pass		
15	Main DOT Station	110	-2	99.87	0	Restricted	220	Pass		
16	Secondary DOT Station	150	38	99.87	38	Restricted	220	Pass		
17	RA/URA Door-Back	120	8	99.87	8	Restricted	220	Pass		
18	Breakdown Counter	120	8	99.87	8	Restricted	220	Pass		
19	Fumehood Ledge	90	-22	93.63	0	Restricted	220	Pass		
20	Glovebox	130	18	93.63	19	Restricted	220	Pass		
21	Floor in Front of Glovebox	100	-12	93.63	0	Restricted	220	Pass		

Performed By: Matthew Crawford MWC

Comments:

Test Status: Pass



Wipe Report

Cardinal Health NPS JENISON
1864 PINE RIDGE DR
JENISON, MI 49428
1 616 662-5013

Test Date: 04/09/2018

Next Due Date: 04/10/2018

Make: Capintec

Model: Caprac-T

Serial #: 010272

Instrument Location: Wipe Test

Count Time (min):1

Wipe Area Sample Size (cm): 100

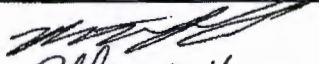
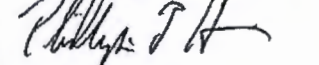





Background (cpm): 112

Lab ID: wr

Frequency: Daily

RSO Signature:		Date:	
----------------	--	-------	--

FIGURE 8.59-1

RS-59 IN-SERVICE ATTENDANCE RECORD		
LECTURE TITLE: <u>Re-wiping & surveying outgoing cases post spill</u>		
DATE: <u>4-12-18</u>		
INSTRUCTOR: <u>Steve</u>		
ATTENDED BY THE FOLLOWING:		
NAME (print)	SIGNATURE	POSITION
Matt Crawford		NPT II
Phillip Heirn		RPh
Steven Roth		RPh
Brian McNett		CSA / Dispatcher
Leah Carniford		NPTII
David Glizya		CSA / Dispatcher
Richard Zeller		RPh
TOPICS COVERED:		
<p>If a spill or potential spill happens with radioactivity outside of the cleanroom, each outgoing case will be re-wiped and re-surveyed prior to exiting the restricted area regardless if it has already been completed & documented.</p>		

Cardinal Health
Nuclear Pharmacy Services
Quality & Regulatory
7000 Cardinal Place
Dublin, OH 43017
tel 614.757.5000
fax 614.652.4598

www.cardinal.com



To Whom It May Concern

FROM: Tiffany Olson, President, Cardinal Health Nuclear & Pharmacy

CC: Paul Gotti, R.Ph. (West Region) VP, Nuclear Pharmacy Services
Luis E. Garcia, R.Ph. (East Region) VP, Nuclear Pharmacy Services
David Pellicciarini, CHP VP, Regulatory Management, Nuclear Pharmacy Services

DATE: February 6, 2017

SUBJECT: Signature Authority

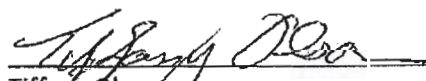
Evan Western, Manager, Health Physics, Cardinal Health Nuclear Pharmacy Services, is authorized to manage the Radiation Safety Program and make legally binding statements on behalf of Cardinal Health 414, LLC, dba: Cardinal Health Nuclear Pharmacy Services, its subsidiaries and affiliates, pertaining to regulatory issues, radioactive materials licenses, permits and registrations.

The following individuals may sign as the certifying official on behalf of Nuclear Pharmacy Services to request, respond, initiate or verify implementation of corrective actions; and to ensure compliance with applicable regulations.

Glenn Sullivan, Director Health Physics, Corporate Radiation Safety Officer

Evan Western, Manager, Health Physics, Quality and Regulatory Department

David Pellicciarini, Vice President, Regulatory Management, Nuclear Pharmacy Services


Tiffany Olson
President, Nuclear & Pharmacy
Cardinal Health 414, LLC