

February 3, 2014

Ms. Cynthia Pederson
U.S. Nuclear Regulatory Commission - Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

RE: NRC License 24-04206-01
Docket Numbers: 030-00001
NRC Event No. 46615

Dear Ms. Pederson:

Mallinckrodt is providing this letter to the Nuclear Regulatory Commission (NRC) in accordance with 10 CFR 20.2201(b). Specifically, Mallinckrodt reported a loss of licensed material to the NRC Operations Center on January 6, 2014. On January 10, 2014, the generator was located by FedEx personnel in a distribution center in Pompano Beach, Florida. The generator was returned to the Maryland Heights site on January 13, 2014, and a visual inspection confirmed that it was the generator of concern. Mallinckrodt initiated an immediate investigation in an effort to identify potential causes for the incident.

i. Description of licensed material:

The relevant material consisted of one Mo-99/Tc-99m generator with a depleted uranium shield. The generator contained 11 curies of Molybdenum-99 and the depleted uranium shield contained 8.1 mCi of Uranium-238. The shield is solid depleted uranium metal encased in stainless steel and weighs approximately 65 pounds. Each shield is stamped with a unique serial number and the legend "Caution-Radioactive Shielding – Uranium."

ii. Circumstances under which the possible loss or theft occurred:

On December 27, 2013 (day of initial event), another generator was being shipped to a customer's facility in Pompano Beach, Florida. This customer has their generator shipped on American Airlines on a standing order basis every Friday. Any additional orders for this customer would be shipped via FedEx. The customer made changes to their generator order on the day of the incident which resulted in the order defaulting to FedEx routing.

When the generator for the customer in Pompano Beach, Florida, was processed on the day of the incident, the routing for this generator was FedEx. When a generator is routed via FedEx, the Dangerous Goods statement and the shipping label will generate automatically when it is processed at the Mallinckrodt Maryland Heights distribution center drop station. The distribution technician noticed that this particular customer order usually ships via American Airlines every Friday and changed the order to ship with the airline in error. The FedEx paperwork originally processed for the customer was not pulled from the packaging line. A second technician then applied the FedEx label to a subsequent generator being processed. That generator was going to a customer in Missoula, Montana. This is confirmed by referencing the tracking history of the order for the customer in Pompano

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Beach, Florida. The tracking history shows the generator of concern being processed as a FedEx order but the route being changed to ship with American. This was also confirmed via visual inspection of the shipping labels when the generator of concern was returned to the Mallinckrodt site in Maryland Heights, Missouri.

iii. Statement of probable disposition of the licensed material:

The generator is at the Mallinckrodt site in Maryland Heights, Missouri.

iv. Exposure of individuals to radiation and possible total effective dose equivalent to persons in unrestricted areas:

Since the generator of concern was controlled by FedEx during shipment and the Pompano Beach, Florida, distribution center is a restricted area, the general public was not exposed to any radiation above normal levels that would occur during transportation.

v. Actions that have been taken, or will be taken to recover the material:

The generator of concern was found at the Pompano Beach, Florida, FedEx distribution center and returned to the Mallinckrodt site in Maryland Heights, Missouri.

vi. Procedures or measures that have been, or will be, adopted to ensure against a recurrence.

The investigation conducted by Mallinckrodt determined that the root cause was human error. The distribution technician whose actions were in error was retrained on the proper way to ship customer orders with emphasis on the need for attention to detail during shipping processes. This event will be a topic during a distribution department meeting to ensure all distribution technicians understand the issue, to reduce the chance for reoccurrence.

If you have any questions related to this matter, please feel free to contact me at 314-654-3923 or Scott Surovi at 314-654-7444.

Sincerely,

Dale Eyman
Site Director

cc: Eric Berry – Mallinckrodt
Tim Dowell -- Mallinckrodt
Ken Lambert – U.S. NRC Region III
Jim Schuh – Mallinckrodt
Scott Surovi – Mallinckrodt
Kay Yoder – Mallinckrodt

FedEx Express

earthsmart
FedEx carbon-neutral
envelope shipping

RT 493 1 D
FZ 495 8846
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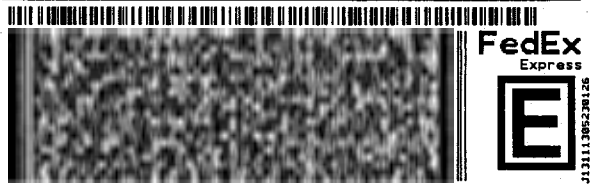
ORIGIN ID: ZSVA (800) 525-3689
SHIPPING DEPT
WALL INCKROOT MEDICAL INC.
2703 WAGNER PLACE
MARYLAND HEIGHTS, MO 63043
UNITED STATES US

SHIP DATE: 04FEB14
ACTWGT: 0.2 LB
CAD: 0052090/CAFE2704

BILL SENDER

TO **ATTN MS.CYNTHIA PEDERSON**
US NRC REGION III
2443 WARRENVILLE RD. STE 210
MATERIAL LICENSING SECTION
LISLE IL 605324523

DEPT: SHIPPING REF: 024720



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