

September 30, 2011

Mr. Mark Satorius  
U.S. Nuclear Regulatory Commission - Region III  
2443 Warrenville Road, Suite 210  
Lisle, Illinois 60532-4352

RE: NRC License 24-04206-01  
Docket Number: 030-00001  
Event Number: 47236

Dear Mr. Satorius:

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 September 2, 2011. Mallinckrodt initiated an immediate investigation in an effort to locate the missing package and to identify potential causes for the incident.

**i. Description of licensed material:**

The missing material is an OctreoScan imaging product package which contained approximately 18 millicuries of In-111 at the time it was offered for shipment on August 7, 2011. The package was marked as radioactive material in accordance with applicable regulations. The In-111 is in a sterile solution as In-111 Chloride, packaged with non-radioactive pharmaceutical products. The product is contained within a glass vial that is contained within a lead shielded container and outer packaging. As of September 30, 2011 the In-111 activity has decayed to approximately 28.8 microcuries.

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

On August 7, 2011, the package was offered for transport along with 102 other packages by Mallinckrodt Inc. and transferred into the possession of Medical Delivery Services, Inc. (MDS). MDS transported the package via truck to a meeting location in Dayton, Ohio where the packages were divided up into six additional MDS vehicles. One of the six vehicles was designated to drive packages to a meeting location in Cleveland, Ohio. It was at the Cleveland meeting location that the driver noticed he had only 2 of 3 packages for a customer located in Rochester, New York. The driver had Bills of Lading for 3 packages designated for that customer.

At approximately 21:00 on August 7<sup>th</sup> MDS notified Mallinckrodt that the package in question could not be located.

**i. Statement of probable disposition of the licensed material:**

While physical facility searches were unsuccessful in locating the package, Mallinckrodt believes the package was mistakenly delivered to a Mallinckrodt customer along the shipping route.

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

On the date of shipment the measured dose rate on the package was 5.0 mrem/hr and the Transport Index was 0.1. Based on the radioactive decay of the In-111, current dose rates on the surface of the package would be indistinguishable from background radiation levels. As a result, any potential exposure to a member of the public would be minimal.

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

In response to the notification of the missing package all drivers in the delivery chain were contacted by MDS and each driver reported that they did not have the package in their possession. Subsequently, the Mallinckrodt Traffic Dept contacted all customers that could have received the package in error. None of the customers reported that they had received an extra package.

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

MDS submitted a corrective action report to Mallinckrodt in response to this event. Corrective actions included additional measures to better ensure that the correct packages are transferred to the appropriate vehicles during intra-company transfers.

In an effort to identify best practices used by the ground transportation couriers under contract with Mallinckrodt, a questionnaire was developed and submitted to the couriers. After review of the couriers' responses Mallinckrodt identified the following practices that we will be communicating to the affected couriers.

- All ground transportation couriers shall be required to complete a documented package count that is to be signed by both drivers at the time of the transfer. This requirement shall apply to both intra-company and inter-company transfers. The documentation described above shall be retained by the courier for a minimum of 3 months.
- All ground transportation couriers shall be required to conduct verification inspections to ensure that no packages are left behind at intra-company

and inter-company transfer locations. These inspections are to be performed by the last driver leaving the meeting site.

In addition to the above actions, Mallinckrodt will continue to evaluate the feasibility of more effective package tracking systems to further reduce the potential for human error related incidents.

If you have any questions regarding this submission please contact me, Dan Hoffman at 314-654-7906 or Bryan Lowery at 314-654-7691.

Sincerely,



Dexter Evans  
Site Director

cc: Pat Duft – Mallinckrodt  
Robert G. Gattone – U.S. NRC Region III  
Dan Hoffman – Mallinckrodt  
Bryan Lowery -- Mallinckrodt  
Jim Schuh – Mallinckrodt  
Kay Yoder – Mallinckrodt

ORIGIN ID: ZSVA (800) 525-3689  
SHIPPING DEPT.  
MALLINCKRODT MEDICAL INC.  
2703 WAGNER PLACE

MARYLAND HEIGHTS, MO 63043  
UNITED STATES US

SHIP DATE: 30SEP11  
ACTWGT: 0.3 LB  
CAD: 0052080/CAFE2508

BILL SENDER

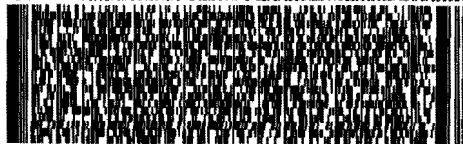
TO ATTN: MR. MARK SATORIVS  
US NRC REGION III  
2443 WARRENVILLE RD. STE 210

LISLE IL 605324523

REF: 024794

DEPT: SHIPPING

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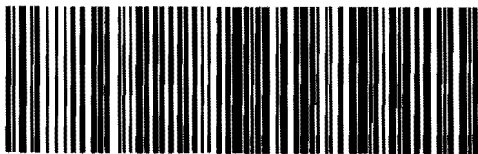


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