



Mallinckrodt Inc.

December 19, 2008

Mr. James Caldwell
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
Event Notification Report 44676

Dear Mr. Caldwell:

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 November 21, 2008. This letter provides details associated with that report.

The affected material is a single I-131 capsule, 109 mCi on November 19, 2008 (time of shipment), physical form – solid, chemical form – salt. The capsule is a radiopharmaceutical intended for oral administration to a single patient.

On November 19, 2008, Mallinckrodt consigned sixty packages of radioactive material to a courier for delivery to multiple customers in the Northeast United States. The packages were transferred by the initial courier to a Charter Aircraft courier. The Charter Aircraft courier made stops in Richmond, VA, Beltsville, MD and Teterboro, NJ. At each location freight was transferred to one or two additional courier services for ultimate delivery to customers. The missing package was destined for a Mallinckrodt Pharmacy in Folcroft, PA. It was routed to the Teterboro, NJ terminal for courier pick-up and delivery on November 20, 2008. The package was initially reported missing by the Folcroft Mallinckrodt Pharmacy on November 20, 2008.

Upon receipt of the report, Mallinckrodt immediately began to search for the package. Search activities included:

- Inventory reconciliation at the Maryland Heights facility to verify that the package had been transferred to the initial courier
- Search of the Maryland Heights Production and Distribution areas to verify no unaccounted for Iodine sources
- Physical visual checks of the initial courier's warehouse

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- Physical visual checks in the aircraft freight area at each of the affected airports
- Physical visual checks at each of the final delivering couriers' warehouses in all three destination cities
- Physical vehicle checks for each of the final delivering couriers in all three destination cities
- Contact by Mallinckrodt to all customers who received packages from the affected flight to verify that they did not receive an extra package

Once it was determined that the package could not be located in the distribution cycle, Mallinckrodt immediately notified the NRC Operations Center of the lost material.

Mallinckrodt believes the package remains within the control of one of the four courier services involved in handling packages from the initial consignment. While physical facility searches have not yet located the package, Mallinckrodt believes it is likely that the package remains within one of the courier's freight handling system.

As of December 18, 2008, the package has not been located. Mallinckrodt has continued to communicate with all affected couriers in an effort to locate the package. Since November 20, 2008 the couriers have performed multiple searches of their freight handling areas and vehicles.

Potential radiation exposures associated with the lost material are low. The package exposure rate at time of shipment was 0.7 mR/hr at 1 meter from the surface. It is highly unlikely that a member of the public would receive a significant external radiation exposure from this source. As of December 18, 2008, the activity of the missing source is calculated to be 8.9 mCi.

Mallinckrodt is currently working with our courier services to require signatures each time a package is transferred between courier services. We anticipate this requirement will be in place for our primary couriers by January 31, 2009.

If you have any questions related to this matter, please feel free to contact me at 314-654-7695 or Jim Schuh at 314-654-7981.

Sincerely,



Mitzi Pennington
Site Director

cc: Patricia H. Duft – Mallinckrodt
Jim Schuh – Mallinckrodt
Kay Yoder – Mallinckrodt
Robert G. Gattone – U.S. NRC Region III

FEDEX

Express

ORIGIN ID: ZSVA (800) 525-3689
SHIPPING DEPT
MALLINCKRODT MEDICAL INC.
2703 WAGNER PLACE
MARYLAND HEIGHTS, MO 63043
UNITED STATES US

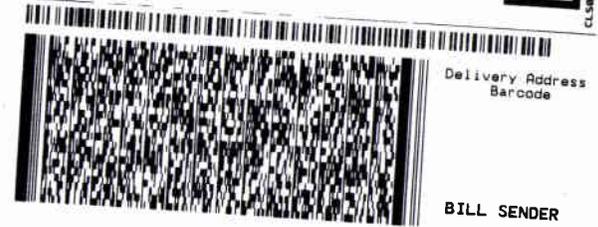
Ship Date: 19DEC08
ActWgt: 0.1 LB
System#: 0052080/CAFE2358
Account: S 063001317

TO ATTN: MR. JAMES CALDWELL
US NRC REGION III
2443 WARRENVILLE RD. STE 210



LISLE, IL 605324352

Ref: 021050
Dept: traffic



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