



Mallinckrodt, LLC

August 26, 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 Numbers: 030-00001
NRC Event No. 47106

Dear Mr. Satorius:

Mallinckrodt is providing this letter to the Nuclear Regulatory Commission (NRC) in accordance with 10 CFR 20.2201(b). The Roman numeral designations below represent the paragraphs of 10 CFR 20.2201(b)(1). On July 28, 2011 Mallinckrodt LLC (hereafter Mallinckrodt) reported via telephone report to the NRC Operations Center a loss of licensed radioactive material. Mallinckrodt has conducted a comprehensive investigation in an effort to locate the missing packages and to identify potential causes for the incident. Information related to the investigation is provided below.

i. Description of licensed material:

The missing material consists of three (3) depleted uranium shields used to provide shielding for our Mo-99/Tc-99m generators. Each shield is solid depleted uranium metal encased in stainless steel. Each shield weighs approximately 65 pounds and contains approximately 8.09 mCi of U-238. 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:

The three lost generator shields were shipped to Mallinckrodt customers during the time period from April-June 2010. The customers were able to provide documentation that the packages were subsequently picked up for return to our Maryland Heights Facility by a Mallinckrodt contracted courier. The courier consolidates depleted uranium shields and subsequently delivers them to the Maryland Heights Facility. Mallinckrodt routinely uses barcode scanning technology to scan all depleted uranium shields soon after receipt at the site. There is no indication in the barcode tracking system that the depleted uranium shields were received at the Maryland Heights site.

i. Statement of probable disposition of the licensed material:

Mallinckrodt believes the packages most likely remain within the control of the couriers involved in transporting the packages.

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

Exposure to individual members of the public is expected to be minimal. The dose rate measured from an individual shield has been measured to be 3.1 mrem/hr on contact and 1.2 mrem/hr at one foot from the surface of the container. As a result of the low dose rates and the physical form of the material (solid encased in stainless steel) radiation exposures and total effective dose equivalent are expected to be minimal.

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

Mallinckrodt required the affected couriers to conduct a search verifying that the package was not present in their warehouses. Mallinckrodt received verification from the couriers that these searches had been completed.

Mallinckrodt contacted all customers who received deliveries from the consignment to determine if they had in their possession any of the packages in question. Mallinckrodt received verification from the customers that they did not have the packages.

In addition, the affected generators have been flagged within our depleted uranium shield tracking program. If any of the 3 shields are returned to the site and scanned in with the bar code reader, this will result in notification of site management personnel and the RSO.

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

As indicated above Mallinckrodt has conducted a thorough investigation of this event and has identified several areas in which the tracking of DU shields might be improved. Listed below are short-term and longer-term actions that will be taken to identify and implement such improvements.

Short-term measures include the following:

- Determine the feasibility of performing a physical verification of the Serial Number of all returned depleted uranium shields within 24 hours of receipt in the Reclaim Department.

- Communicate instructions to customers for completing and promptly faxing bills of lading associated with depleted uranium shields being returned to the Maryland Heights site.
- Conduct a review of Mallinckrodt provided customer training regarding depleted uranium shield returns and update the training materials to emphasize the need to promptly and correctly package and return depleted uranium shields to the Maryland Heights site

As a potential longer-term solution, Mallinckrodt is investigating available electronic tracking systems such as radiofrequency identification (RFID) for the depleted uranium shields. Such a system could provide better accountability of the shields throughout the transportation cycle.

Mallinckrodt expects the packages may still be returned to the Maryland Heights plant. At that point we would become aware of the return this by virtue of the existing barcode scanning system. We will advise you of any new information regarding this matter as it becomes available.

If you have any questions related to this matter, please feel free to contact me at 314-654-7695 or Dan Hoffman at 314-654-7906.

Sincerely,

A handwritten signature in black ink that reads "Dale Eymán". The signature is written in a cursive style and is positioned above the printed name and title.

Dale Eymán
Interim Site Director

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

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MALLINCKRODT MEDICAL INC.
2703 WAGNER PLACE
MARYLAND HEIGHTS, MO 63043
UNITED STATES US

SHIP DATE: 28AUG11
ACTWT: 6.3 LB
CAD: 0062080/CAFE2507
BILL SENDER

TO **ATTN: MR. ROBERT G GATTONE**
US NRC REGION III
2443 WARRENVILLE RD. STE 210

LISLE IL 605324523

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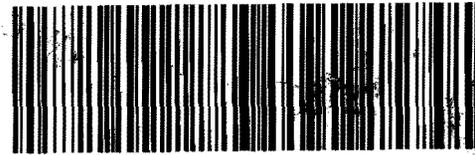
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