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Mallinckrodt

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May 18, 2006

Mr. James Caldwell
Regional Administrator
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

RE: NRC License 24-04206-01: Report of missing licensed material.

Dear Mr.Caldwell:

Mallinckrodt Inc. (MI) is providing this letter to the NRC in accordance with 10 CFR 20.2201(b). We contacted the NRC Emergency Operations Center on April 19, 2006 regarding the possible loss or theft of licensed material. On that date we reported that 145 depleted uranium (DU) shields used for transporting Tc-99m generators could not be accounted for, but made the notification as a precautionary measure because we had not completed our full investigation. Upon completion of the investigation and subsequent to filing the initial report, we have located the majority of the shields (127) either at customer locations or in our warehouse facility. Therefore, we have accounted for all but 18 of the shields.

i. **Description of licensed material which remains unaccounted for:**

Each shield is solid depleted uranium metal encased in stainless steel. Each shield weighs 49 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 DU shields are used to transport Tc-99m generators to our customers. Once the generators have expired, the customers return the generator shields to Mallinckrodt. Mallinckrodt uses a barcode system to track generators when they leave our site and when they are returned. When the barcode is scanned, the tracking software updates its current location. Twelve of the shields which remain unaccounted for are listed in the tracking software as being at customer locations and six of the shields are listed as being at the Maryland Heights site.

We have obtained copies of Bills of Lading (BOL's) from our customers for 9 of the 12 shields listed as being at customer locations. The customers indicate that the BOL's provide proof that the DU shields were transferred to a courier for return to Maryland Heights. In most instances, however, there is no signature on the BOL from the courier acknowledging receipt of the material. Three of the customers have not yet provided copies of the BOL's indicating they were shipped, however they have verbally indicated that they were offered for return shipment. Of those shields listed as being at customer locations, our records indicate the expected arrival dates at the Maryland Heights facility for the shipments range from November 2, 2005 to December 12, 2005.

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

Based upon the ongoing return of other DU shields on the delinquent list, it is likely that the majority of the shields will be returned through the normal distribution cycle. Our generators

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were off the market for several months and we have experienced a significant number of delays in the return of the DU shields from our customers. The older shields are being returned along with more recently distributed ones. It is believed that these shields were either being held by customers until we returned to the market or were stored in courier warehouses for consolidation into full pallets.

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 has taken several steps to attempt to recover the material. Mallinckrodt conducted a site-wide physical inventory to locate all DU shields on site. This inventory included two independent recordings of the DU safe numbers and a third individual reconciling the two records. This method of inventory identified a number of DU safes that had not been recognized in previous inventories.

Mallinckrodt reduced the number of locations where the DU safes can be stored on-site to limit the areas requiring inventory for improved future reconciliations. These safes have all been consolidated into our primary storage locations to insure tracking and accountability. This provides more control over the returned DU shields.

Mallinckrodt required courier companies to conduct a search verifying that there were no DU shields present in their warehouses. We received verification from the couriers that these searches had been completed and that all safes were either delivered to Mallinckrodt or en route.

Subsequent to the initial verification, couriers were asked to locate specific DU shields for which customers had provided BOL's indicating they had been tendered to them. We are currently awaiting responses to these requests.

Mallinckrodt contacted all customers with outstanding shields to determine their status. In some cases, arrangements were made for a special pick-up to retrieve DU shields from remote customers.

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

A new procedure has been developed to improve onsite DU shield tracking and was issued on May 05, 2006. This procedure defines the flow of DU shields through each potential path at the Maryland Heights facility. Specifically, the procedure defines the flow of shields for routine handling, non-routine QA processing, and non-routine shipping. Any deviations must be approved by the RSO or designee.

We have implemented a new process requiring couriers to provide a copy of BOL's provided to them when picking up a generator from our customers. The signed BOL will clearly indicate that the generator has been transferred from the customer to the courier. This will allow us to better identify the location of any delinquent generators.

We have implemented a new process for providing rapid communications to customers when DU shields are delinquent. We provide notification when the generator is 14 days late and again at 21 days late. We also notify the customer on the 28th day late that the shield is considered missing and that they should report the material as lost to the appropriate regulatory agency. These rapid communications with customers should assure safes are located in a timely manner.

Mallinckrodt has reduced the number of approved locations within our site where DU shields are allowed to be stored. This has resulted in increased security for some locations where DU shields are stored.

Finally, due to the number of shields initially identified as being unaccounted for, the tracking software was investigated. Mallinckrodt has subsequently validated the tracking software through our computer systems validation process. This validation identified several problems in the tracking program that could have resulted in erroneous location codes being assigned to DU shields. These errors were immediately corrected.

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

Sincerely,

James R. Schuh

James R. Schuh, CHP
Radiation Safety Officer
Manager, Environmental, Health and Safety

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TO ATTN: JAMES CALDWELL
US NRC REGION III
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