

December 30, 2013

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 December 3, 2013. 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 consists of four (4) 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 four lost generator shields were shipped to Mallinckrodt customers during the time period September-November, 2012. 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 the 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. In addition, during the generator breakdown process, each depleted uranium shield number is documented during a survey step. These documents do not indicate that these four depleted uranium shields were processed for reuse.

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i. Statement of probable disposition of the licensed material:

Mallinckrodt believes the packages most likely remain within control of the couriers involved in transporting these 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 rate and the physical form of the material (solid encased in stainless steel) radiation exposures and total effective dose rate 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 has modified the software associated with its DU shield tracking system to immediately provide an indication when shields are returned through the normal generator return program. Such a notification may allow us to trace return shipments to determine where the generator had been located.

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 depleted uranium shields will be altered. Listed below are short term and long term actions that will be taken.

- Mallinckrodt's procedures on depleted uranium shield tracking will be revised to allow for more timely identification and reporting of lost/stolen depleted uranium shields. These procedure revisions will allow for more timely searches for shields suspected of being lost and the subsequent investigations to determine the root causes of such events.
- Mallinckrodt's Maryland Heights Reclamation department will perform a test to determine the level of accountability during the shield receipt process. This will verify if courier deliveries are accurate, to allow for an improved accuracy of onsite shield inventories.



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- A project has been developed and is in progress to determine if RFID technology is feasible in tracking outgoing and incoming depleted uranium shields. This will allow for more timely updates of the onsite shield inventory.

Mallinckrodt expects the package may still be returned to the Maryland Heights plant at which time we would become aware of this by virtue of the DU shield tracking 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 Gary Bosgraaf at 314-654-7661.

Sincerely,

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FOR Dexter Evans
Senior Site Director

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