



COVIDIEN

Mallinckrodt Inc.

March 17, 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. 46615

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 February 15, 2010. 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 a Mo-99/Tc-99m generator which contained 16.0 Ci of Mo-99 at the time it was offered for shipment on February 13, 2011. The Molybdenum is solid form adsorbed onto an alumina column. The chemical form is Sodium Molybdate. As of March 17, 2011 the Mo-99 activity has decayed to less than 15 mCi.

The generator is shielded by solid depleted uranium (DU) metal encased in stainless steel. The shield weighs 49 pounds and contains approximately 8.09 mCi of U-238. The 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:

On February 13, 2011, the package was offered for transport by Mallinckrodt Inc. and transferred into the possession of Associated Couriers, Inc. (ACI) at the Maryland Heights location. ACI transported the package directly to an airport in Cahokia, IL, where it was subsequently transferred to a second courier, Airnet, to be loaded on a charter flight.

The missing material is one of 15 packages routed to Detroit, MI by way of Cleveland OH. As part of the investigation, Mallinckrodt confirmed the total number of Mallinckrodt packages transferred to this particular charter flight in Cahokia was 62 packages. Forty-seven packages were subsequently transferred from Airnet back to ACI in Cleveland, Ohio and fifteen were transferred back to ACI in Detroit (Ypsilanti). All transfers of the packages between couriers were documented by signature of the receiving courier.

At approximately 11:00 p.m. on February 13th ACI notified Mallinckrodt that the package in question could not be located.

Mallinckrodt contacted Airnet, the airport locations where the charter flight had travelled, and all customers that received deliveries from ACI in the Detroit area. Initial calls to the customers were made on Monday, February 14th and follow-up calls were made on Tuesday February 15th. Once it was determined that the package could not be located in the distribution cycle, Mallinckrodt immediately notified the NRC Emergency Operations Center of the lost material.

i. Statement of probable disposition of the licensed material:

Mallinckrodt believes the package remains within the control of one of the two courier services involved in transporting the packages or at a nuclear pharmacy in one of the delivery locations. While physical facility searches have not yet located the package, Mallinckrodt believes it is likely that the package remains within one of the couriers' freight handling systems or at a customer's facility.

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

On the date of shipment the maximum dose rate measured on contact with the package was 20 mrem/hr and the Transport Index was 1.0. Due to radioactive decay of the Mo-99, current dose rates on the surface of the package would be minimal. As a result, exposure to a member of the public is 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 received the package in question. Mallinckrodt received verification from the customers that they did not receive the package.

Mallinckrodt has modified the software associated with its DU shield tracking system to immediately provide an indication if the shield is returned through the normal generator return program. Such a notification may allow us to trace the return shipment to determine where the generator had been located.

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

ACI responded to this incident by sending its Compliance Officer to the ACI Detroit, MI location. The Compliance Officer provided training to the ACI supervisor and all drivers at that location. This training focused on the need to insure accurate piece counts during transfer between couriers and the importance of maintaining traceability of packages.

ACI has implemented a company-wide requirement for an ACI supervisor to be present at the receiving airport whenever Mallinckrodt packages are to be offloaded into ACI vehicles. The intent of this change is to improve package accountability.

Mallinckrodt has reviewed ACI's procedures and internal auditing program. Several opportunities for improvement were identified. These include (a) modification of standard operating procedures to document the accountability process for truck-to-aircraft and aircraft-to-truck transfers and (b) inclusion of package accountability as part of the internal auditing program scope.

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 Dan Hoffman at 314-654-7906.

Sincerely,



Mitzi Pennington
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