



April 14, 2015

Ms. Cynthia Pederson
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

SUBJECT: EVENT NOTIFICATION NUMBER 50902, MATERIALS LICENSE NUMBER
24-04206-01 (DOCKET NUMBER 030-00001)

Dear Ms. Pederson:

In accordance with Title 10 of the Code of Federal Regulations, Part 20, Section 2201 (10 CFR 20.2201), *Reports of Theft or Loss of Licensed Material*, Mallinckrodt, LLC reported the loss of licensed radioactive materials to the U.S. Nuclear Regulatory Commission (NRC) Operations Center on March 19, 2015. Mallinckrodt reported the loss of one (1) depleted uranium (U-dep) shield associated with our molybdenum-99 / technetium-99m (Mo-99/Tc-99m) generator product, deemed lost on February 26, 2015. Mallinckrodt notified NRC within thirty days (March 19, 2015) of the occurrence as required per 10 CFR 20.2201(a)(ii).

This letter contains a written description of the aforementioned notification in conformance with the requirements of 10 CFR 20.2201(b).

Mallinckrodt conducted an investigation in an effort to locate the missing package containing the generator and associated U-dep shield. A summary of events and contributing factors for the loss of the radioactive material are presented below.

Description of the Licensed Material

The lost radioactive material consists of one (1) U-dep shield containing a total of 8.1 millicuries (mCi) of activity and having a total gross weight of 65 pounds. The lost material is used to provide shielding to Mo-99/Tc-99m generators produced at the Mallinckrodt – Maryland Heights facility. The solid U-dep is encased in stainless steel and stamped with a unique serial number, barcode and a legend reading “*Caution – Radioactive Shielding – Uranium.*”

Potential Circumstances under which the Loss of Material Occurred

Mallinckrodt shipped the Mo-99/Tc-99m generator to the customer on January 5, 2014. The customer provided documentation confirming the generator's use and subsequent offer for transportation to Mallinckrodt's facility located in Maryland Heights, Missouri. The generator was accepted by a Mallinckrodt-contracted ground courier at the time of pick-up at the customer facility.

It is typical for ground couriers to consolidate generators being returned to Mallinckrodt at one of their warehouse facilities. They may further consolidate the collected generators for a given region and transfer them to a line-haul transport system for subsequent delivery to Mallinckrodt. Mallinckrodt uses barcode scanning technology to inventory all the U-dep shield generators delivered to the Maryland Heights, Missouri, facility. Mallinckrodt has no indication via the barcode tracking system that the aforementioned generator has been received at the Maryland Heights, Missouri, facility.

Upon receipt, Mallinckrodt personnel disassemble the returned generator units for the reuse of components in support of the Mo-99/Tc-99m production. For U-dep shields, when the unit is disassembled, Mallinckrodt personnel record the unique serial number into a tracking database for inventory and accountability purposes. Mallinckrodt has no indication that the serial number associated with the lost shield has been entered into the tracking system for reuse.

Immediate Actions

Mallinckrodt requested the courier involved to conduct a search of their immediate and/or regional warehouses. The courier indicated that a search was conducted and that the package containing the lost Mo-99/Tc-99m generator and U-dep shield was not located. Simultaneously, Mallinckrodt personnel conducted a search for the lost package within the Maryland Heights facilities. Mallinckrodt personnel were unable to locate the lost package.

Potential Radiological Impacts to Individuals in Unrestricted Areas

Since the elapsed time is greater than ten (10) half-lives for Mo-99 (66 hours) and Tc-99m (6 hours), the generator's activity is expected to be decayed. Additionally, the exposure rates observed on individual U-dep shields are 3.1 mR/hr on-contact and 1.2 mR/hr at a

distance of one (1) foot from the surface of the generator shield. As a result of the low exposure rates, as well as the physical form of the material, the radiation exposure and associated total effective dose equivalent (TEDE) are expected to be minimal.

Corrective Measures

Previous corrective measures included the efforts to improve Mallinckrodt's shield inventory tracking. Mallinckrodt evaluated the potential use of radiofrequency identification (RFID) labels to automatically account for the DU shields delivered to the Maryland Heights' facility. However, the RFID initiative proved to be cost-prohibited and did not completely address the clients/couriers failure to return the generators in an acceptable timeframe. Mallinckrodt implements training for clientele receiving DU shields as part of Mo-99/Tc-99m generator orders. The training includes explanations and instructions for the handling and return of DU shields.

Mallinckrodt believes that the package containing the lost generator and U-dep shield remains in the control of the courier involved in the transportation of the package. Mallinckrodt expects the package may still be returned to the Maryland Heights, Missouri, facility. Mallinckrodt will advise NRC of new information regarding this matter as it becomes available.

Please do not hesitate to contact Mr. Manuel Díaz, Health Physics Manager/Radiation Safety Officer, at (314) 654-7661 if you have questions and/or require further information.

Sincerely,



Dale Eyman
Site Director

MDL:de

cc: File

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