



May 28, 2015

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

SUBJECT: EVENT NOTIFICATION NUMBER 51048, 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 May 7, 2015. Mallinckrodt reported the loss of one (1) UN2915 Radioactive Type A Radioactive Material package containing 0.4699 GBq (12.7 mCi) of In-111, deemed lost on April 21, 2015. Mallinckrodt notified NRC within thirty days 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. 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) UN2915, Radioactive Material, Type A Package containing 0.4699 GBq (12.7 mCi) of In-111, marked as Yellow-II, and having a total gross weight of 3 pounds. The lost material is associated with Mallinckrodt's Octreoscan® radioactive product processed at the Mallinckrodt – Maryland Heights, Missouri, facility. The radioactive material is lead shielded in the package configuration. The radioactive package contained all the labeling and markings required by U.S. Department of Transportation (DOT) in 49 CFR for transportation purposes. Additionally, the Octreoscan®

package contains precautionary markings, "Caution, Radioactive Materials," on the product packaging (i.e., lead shield).

Potential Circumstances under which the Loss of Material Occurred

Mallinckrodt shipped the radioactive package to its customer on April 7, 2015, through approved couriers. The radioactive package was transported via ground and air in a consolidation package for shipping purposes. The radioactive consolidation package was received by the courier at the airport destination. The courier sorted the individual packages for delivery. Upon completion of deliveries, the courier discovered that an individual Octreoscan® package was unaccounted.

Immediate Actions Taken to Recover the Material

Mallinckrodt requested the courier involved to conduct a search of its immediate sorting location, transport vehicles and/or regional warehouses. The courier indicated that a search was conducted and that the package containing the lost package containing the In-111 was not located. Mallinckrodt personnel contacted the customers in an effort to locate the missing package. Simultaneously, Mallinckrodt personnel conducted a search for the lost package within the Maryland Heights facilities with the possibility of this package never leaving the site. Mallinckrodt personnel were unable to locate this package.

Potential Radiological Impacts to Individuals in Unrestricted Areas

Since the elapsed time is greater than ten (10) half-lives for In-111 (2.8 days), the radioactivity is expected to have been decayed. The average exposure rate observed on individual Octreoscan® (In-111) packages is 0.1 mR/hr at a distance of one (1) foot from the surface of the individual package. As a result of the low exposure rates, as well as the physical form of the material and package configuration, the radiation exposure and associated total effective dose equivalent (TEDE) are expected to be minimal.

Corrective Measures

Based on historical shipping information, this is an isolated incident. No immediate long-term corrective actions were identified.

Statement of Disposition, or Probable Disposition, of the Licensed Material Involved

Mallinckrodt believes that the package containing the lost Octreoscan® (In-111) product 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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