

MEMORANDUM TO FILE;

Mallinckrodt, LLC
Docket No. 030-12559

FROM:

Ken Lambert, Senior Health Physicist *KL*

SUBJECT:

INSPECTION FOLLOWUP ITEM

Please follow up the issued discussed in the attached letter regarding the failure of the licensee to investigate timely (within 20 days) two hazardous waste shipments where the waste disposal facility had not acknowledged the receipt of the shipment at the waste facility. Appendix G to 10 CFR Part 20 requires the licensee to conduct an investigation if the shipment receipt is not acknowledged within 20 days after transfer.



January 24, 2013

U.S. Nuclear Regulatory Commission - Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

RE: NRC License 24-17450-01
Docket Numbers: 030-12550 9

Dear Sir or Madam:

Mallinckrodt LLC (Mallinckrodt) is providing this letter to the Nuclear Regulatory Commission (NRC) in accordance with 10 CFR 20 Appendix G. During a self audit, Mallinckrodt identified that we had not received acknowledgement of receipt of radioactive waste from the waste consignee for two waste shipments. Upon identifying this issue, Mallinckrodt initiated an investigation, including tracing the waste, to determine why we had not received the acknowledgment documentation.

For both shipments, Mallinckrodt in Hazelwood, MO was the shipper, Adcom Express Inc. in Tinley Park, IL was the carrier and TOXCO MMC in Oak Ridge TN was the consignee. Mallinckrodt utilized ADCO Services (also Tinley Park, IL) as a waste broker to assist in preparing the shipment and associated paperwork. ADCO Services and Adcom Express are affiliated companies. The shipments were made on July 22, 2012 and September 18, 2012. The waste manifests for the shipments were 12-0106L and 12-0144L respectively.

The manifests for both waste shipments include the signature of the representative of Adcom Express in box 6 of the Uniform Low-Level Radioactive Waste Manifest. This is the box used by the authorized carrier to acknowledge receipt of the waste.

For previous shipments, the receipt acknowledgement from the consignee was provided by TOXCO to ADCO who subsequently forwarded them to Mallinckrodt. In an attempt to locate the waste materials several phone calls and E-mails were made to ADCO to determine the status of the waste shipments..

On January 15, 2013, James Bell Jr., the Facility Manager for the ADCO Services facility in Tinley Park IL, contacted me in response to my inquiries. Mr. Bell indicated that the material from the two shipments was still in his possession. He indicated that he was planning on delivering the material to the TOXCO MMC site within the next 30 days. I requested that he notify me if that plan changed in any way.

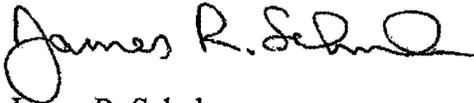
675 McDONNELL BOULEVARD
HAZELWOOD, MO
63042

The July 22nd waste shipment was a 1.4 cubic feet package containing a total activity of 12.5 mCi. The isotopes in the package were C-14, Cs-137, I-125 and Ni-63. The September 18th waste shipment was a 7.5 cubic feet package containing a total activity of 11.4 mCi. The isotopes in the package were H-3, I-125 and Lu-177

Mallinckrodt has identified several corrective actions in response to this incident. These include, but are not limited to, procedural changes to insure that inquiries regarding the status and receipt of waste shipments begin before the 20 day timeframe identified in 10 CFR 20 Appendix G.

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

Sincerely,

A handwritten signature in black ink that reads "James R. Schuh". The signature is written in a cursive style with a large initial "J" and a long horizontal stroke at the end.

James R. Schuh
Radiological Programs Director

cc: Eric Berry – Covidien/Mallinckrodt
Pat Duft – Covidien/Mallinckrodt
Rick Roberts – Covidien/Mallinckrodt
John Snider – Covidien/Mallinckrodt
Kay Yoder – Covidien/Mallinckrodt