

October 14, 2005

Roland Sawyer
Manager, Environmental Health and Safety
Radiation Safety Officer
Mallinckrodt, Inc.
2703 Wagner Place
Maryland Heights, MO 63043

SUBJECT: NRC INSPECTION REPORT 030-00001/05-003(DNMS) -
MALLINCKRODT, INC.

Dear Mr. Sawyer:

This refers to an inspection conducted on September 27, 2005, at the Mallinckrodt, Inc., Maryland Heights, Missouri facility. The purpose of the inspection was to observe the biennial emergency response exercise. At the conclusion of the inspection on September 27, 2005, the NRC inspectors discussed the findings with you and members of the Mallinckrodt staff.

The inspection was conducted to determine whether Mallinckrodt personnel could successfully implement the Contingency Plan for the Maryland Heights, Missouri facility. The inspection consisted of the observation and evaluation of performance during the exercise. Areas observed and evaluated during the exercise are identified in the enclosed report.

Based on the results of this emergency response exercise, the NRC determined that Mallinckrodt personnel successfully demonstrated their capability to implement the Contingency Plan for the Mallinckrodt, Inc., Maryland Heights, Missouri facility in response to a simulated radiological event.

In accordance with 10 CFR Part 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,
/RA/
John R. Madera, Chief
Materials Inspection Branch

Docket No. 030-00001
License No. 24-04206-01

Enclosure: Inspection Report 030-00001/05-003(DNMS)
See Attached Distribution

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REGION III

Docket No.: 030-00001

License No.: 24-04206-01

Report No.: 030-00001/05-003(DNMS)

Licensee: Mallinckrodt, Inc.

Address: 2703 Wagner Place
Maryland Heights, MO

Inspection Date: September 27, 2005

Exit Meeting: September 27, 2005

Inspectors: George O. Parker, Health Physicist
Deborah A. Piskura, Health Physicist

Approved By: John R. Madera, Chief
Materials Inspection Branch, Region III

Mallinckrodt, Inc.
Inspection Report No. 030-00001/05-003(DNMS)

Executive Summary

This was an announced inspection to observe and evaluate licensee personnel at the Mallinckrodt, Inc., Maryland Heights, Missouri, manufacturing facility, demonstrate their ability to implement the Contingency Plan during the required biennial exercise.

The exercise of the Contingency Plan adequately tested the licensee's capability to respond to a radiological accident. Licensee staff completed an evacuation of several buildings and took appropriate emergency response actions in response to the event in a timely manner. Command and control, hazard assessment, and communications were adequate. The exercise included limited participation by the Maryland Heights Fire Department, and the Saint Louis County HazMat Response Team. The licensee's post-exercise critique findings identified several means of improving emergency response. The inspectors' findings were consistent with those identified by the licensee.

Report Details

1.0 Emergency Plan Exercise

a. Inspection Scope

The inspectors observed the licensee's required biennial exercise of its Contingency Plan. Observations included the pre-exercise brief, response to the exercise scenario by licensee staff, and the post-exercise critique.

b. Observations and Findings

The exercise scenario simulated a large spill of iodine-131 (a rejected product lot) in the parking lot adjacent to Building 600. Specifically, the transport vehicle was involved in an accident in the parking lot which resulted in an airborne release and spill of liquid iodine-131. As a result of the accident scenario, the driver suffered injuries and personal contamination.

The exercise began with the discovery of a vehicle accident in the parking lot adjacent to Building 600 resulting in a major spill and release of iodine-131 and an injured individual. This initiated the activation of the Emergency Response Team and an audible alarm signaling all personnel to evacuate the buildings and meet at designated assembly points. Licensee emergency response staff promptly responded to the scene of the accident with proper decontamination and protective equipment. The Emergency Response Manager arrived at the scene of the accident within several minutes while the Emergency Coordinator and staff arrived at the Emergency Control Center within minutes.

The Emergency Coordinator, following communication with the Emergency Response Manager, initially classified the event as an "Alert." The Emergency Coordinator obtained a dose assessment to confirm this classification using default source term values. The licensee collected air samples from strategically determined locations in order to obtain data for dose modeling. As survey results and air sampling data became available, the Emergency Coordinator elevated the classification to a "Site Area Emergency." Exercise participants monitored staff evacuation and assembly at the designated points and noted the accountability of all individuals. Exercise participants in the Emergency Control Center made required notifications to the State of Missouri, the NRC and licensee senior management representatives. The exercise participants provided updates to the required notifications as appropriate.

Response staff assessed the radiological hazards at the scene and administered appropriate first aid care to the victim. Due to the nature and the quantity of the iodine-131 involved in the scenario, the response team appropriately moved the individual to a safe location while attending to his injuries. The responders determined the victim had abrasions and cuts requiring treatment at the hospital.

Licensee staff augmented their response to the spill by calling out the Maryland Heights Fire Department and the Saint Louis County HazMat Response Team. Licensee response staff, supervised by the Emergency Response Manager used decontamination stations and performed radiation surveys to assess and mitigate the radiological hazards associated with the event. The licensee utilized four separate survey teams in

responding to the accident, addressing radiological contamination issues, and collecting radiological data.

The Emergency Response Manager, in coordination with the Emergency Coordinator, downgraded the event from a "Site Area Emergency" to an "Alert" and initiated recovery operations based, in part, on negative air sampling results, the decontamination efforts by licensee response staff, and the containment of licensed material.

Response staff assessed the radiological hazards at the scene and administered care to the victim. Licensee response staff supervised by the Emergency Response Manager used decontamination stations and performed radiation surveys to assess and mitigate the radiological hazards associated with the event.

Licensee staff who participated in the exercise, conducted an exercise critique. The licensee staff discussed the positive and negative findings associated with the emergency plan, facilities, equipment, licensee staff training, and overall event response effectiveness. The critique findings were used as an effective means of improving emergency response and they were consistent with those identified by the inspectors.

c. Conclusions

The exercise of the Contingency Plan adequately tested the licensee's capability to respond to a radiological accident. Licensee staff completed an evacuation of several buildings and took appropriate emergency response actions in response to the event in a timely manner. Command and control, hazard assessment, and communications were adequate. The exercise included participation by the Saint Louis County HazMat Response Team and the City of Maryland Heights Fire Department. The post-exercise critique findings served as a means of improving emergency response, and were consistent with those identified by the inspectors.

2.0 Exit Summary and Management Meeting

At the conclusion of the onsite inspection, the inspectors conducted an exit meeting with licensee representatives. The inspectors discussed the preliminary inspection findings from their observations and evaluation of the exercise. The licensee did not identify any information discussed as proprietary in nature.

Partial List of Personnel Contacted

John Davison, Human Resources Manager
Craig Kramer, Production Manager
Gary Diesl, Plant Manager
Brad Nelson, Health Physicist Specialist
Jaya Ramanuja, Health Physicist
Roland (Chip) Sawyer, Manager, Environmental Health and Safety/Radiation Safety Officer
James R. Schuh, CHP, Environmental Health and Safety Manager, Pharmacy Network
Scott Surovi, Transportation Compliance Program Manager
Kay Yoder, Chairperson, Radiation Safety Committee

Several players in the emergency exercise were also contacted during this inspection.

Keith Henke, Planner, Missouri Department of Health and Senior Services

All the above individuals attended the onsite exit meeting.