



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

October 3, 2007

Christopher Guerdan
Site Director
Mallinckrodt, Inc.
2703 Wagner Place
Maryland Heights, MO 63043

SUBJECT: NRC INSPECTION REPORT 030-00001/07-03(DNMS) -
MALLINCKRODT, INC.

Dear Mr. Guerdan:

This refers to the inspection conducted on September 18, 2007, at the Mallinckrodt, Inc., Maryland Heights, Missouri facility. The purpose of the inspection was to observe and evaluate the biennial emergency response exercise. At the conclusion of the inspection, the inspectors discussed the findings with you and members of your 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 observations of selected exercise activities and evaluation of exercise performance. Areas observed and evaluated during the exercise included, in part, Emergency Control Center (ECC) staffing; timeliness of required notifications; command and control of the exercise scenario from the field and the ECC; Fire Department response; staff accountability; contamination control; use of dosimetry badges and other protective equipment; care of injured individuals who were contaminated; personnel and area surveys; personnel decontamination; communication effectiveness; dose estimates to licensee personnel and members of the public; and self-critique of the exercise by licensee staff.

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 accident. 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 and timely emergency response actions in response to the accident. Command and control, hazard assessment, and communication were adequate. Licensee staff discussed several ways to improve the licensee's emergency response during the post-exercise critique. The inspectors' findings were consistent with those identified by the licensee.

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

C. Guerdan

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

Sincerely,

A handwritten signature in black ink, appearing to read "John R. Madera", is written over a printed name and title. The signature is fluid and cursive, with a large initial "J".

John R. Madera, Chief
Materials Inspection Branch

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

cc: James Schuh, RSO

ENCLOSURE XX

INSPECTION RECORD

Region III

Inspection Report No. 2007-003

License No. 24-04206-01

Licensee (Name and Address):

Docket No. 03000001

Mallinckrodt, Inc.
2703 Wagner Place
Maryland Heights, MO

Location (Authorized Site) Being Inspected

2703 Wagner Place
Maryland Heights, MO

Licensee Contact: Jim Schuh, RSO Telephone No. 314-654-7981

Priority: 2 (Note: The licensee is on the Large Licensee Initiative list.)

Program Code: 03211

Date of Last Inspection: 8/20-24/07

Date of This Inspection: 9/18/07

Type of Inspection: (X) Announced () Unannounced
(X) Routine () Special
() Initial

Next Inspection Date: Anytime in Calendar Year 2008; however, 6/1/06 was entered into the LTS as the next inspection date because the licensee is on the Large Licensee Initiative list. Since the next inspection must be completed before 1/09, entering 6/1/06 as the next inspection date into the LTS will allow the LTS software to calculate the correct overdue inspection date which is 1/09.

(x) Normal () Reduced () Extended

Justification for change in normal inspection frequency:

Summary of Findings and Actions:

- (x) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- () Non-cited violations (NCVs)
- () Violation(s), Form 591 issued
- () Violation(s), regional letter issued
- () Followup on previous violations

Inspector Robert G. Gattone, Jr.
(Sign Name)

Date 10/3/07

Robert G. Gattone, Jr.
(Print Name)

Inspector Geoffrey Warren
(Sign Name)

Date 10/3/07

Geoffrey Warren
(Print Name)

Approved John R. Madera
(Sign Name)

Date 10/3/07

John R. Madera
(Print Name)

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

(License amendments issued since last inspection, or program changes noted in the license)

<u>AMENDMENT #</u>	<u>DATE</u>	<u>SUBJECT</u>
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None

2. INSPECTION AND ENFORCEMENT HISTORY:

(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

The last inspection was conducted on August 20-24, 2007. The inspectors identified two NCVs involving: (1) failure to secure a High Radiation Area; and (2) failure to conduct a timely survey of a package upon receipt.

No violations were identified during a previous inspection that was conducted on February 13, 2007. The inspection was limited to follow up on corrective actions associated with violations identified during a special inspection conducted on October 16-17, 2006, involving the release of radioactive material to the sanitary sewer system in excess of the NRC's regulatory limits and the failure to fully implement a sanitary sewer release procedure.

During an inspection on September 18-22, 2006, the inspector identified an NCV involving handling of a collected overpack that had a contact dose rate greater than 30 R/hr and a Severity Level IV violation involving failure to secure from unauthorized removal of or access to seven depleted uranium generator shields.

3. INCIDENT/EVENT HISTORY:

(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

None.

PART II - INSPECTION DOCUMENTATION

The inspection documentation part is to be used by the inspector to assist with the performance of the inspection. Note that not all areas indicated in the applicable inspection procedure(s) are required to be addressed during each inspection.

All areas covered during the inspection should be listed in Section 2. In addition, the types of records that were reviewed and the time periods covered by those records should be noted. For any violations identified, Section 4 should state the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective actions. For an NCV, indicate why the violation was not cited. Attach copies of all licensee documents and records that are needed to support violations.
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1. ORGANIZATION AND SCOPE OF PROGRAM:

(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

The most senior licensee representative onsite was the Site Director. The Environmental Health and Safety Manager also served as the Radiation Safety Officer (RSO). An individual was recently hired to be the new RSO after he completes on-the-job training and the licensee amends its license to name him as the RSO. The Maryland Heights facility had approximately 350 employees.

The locations of use were as authorized on the license. The bulk of the licensee's activities involved manufacture and distribution of radiopharmaceuticals. Mallinckrodt's main byproduct material of use was molybdenum-99 for the manufacture of molybdenum/technetium generators. Other isotopes of note, in descending order of quantity used each week, included iodine-131, xenon-133, and phosphorus-32. The licensee also operated five cyclotrons for the production of other radioactive materials used in medicine. The cyclotrons and the materials produced from them were registered and regulated by the State of Missouri.

2. INSPECTION SCOPE

INSPECTION PROCEDURE(S) USED:

Inspection Procedure 88051

INSPECTION FOCUS AREAS:

03.01-03.11, 03.13, and 03.14

The exercise scenario involved a fire in Building 400 and consolidation boxes containing various radionuclides, including iodine-131.

The following opportunities for improvement were identified during the exercise:

1. The licensee provided the exercise scenario to the NRC two weeks before the exercise. The licensee was requested to provide the NRC with future exercise scenarios at least one month prior.
2. The licensee's exercise scenarios tend to be limited to fires or spills; therefore, they should consider other types of scenarios (e.g., security events, natural events, etc.).
3. The licensee did not effectively communicate where the Fire Department should go upon arriving onsite to respond to a simulated event.
4. The Emergency Manager noted that staff assembled downwind from the fire after evacuation; therefore, he directed them to relocate to another assembly point upwind. However, the staff did not relocate to the upwind assembly point.
5. The Alert status was not communicated to the ECC until 11 minutes after the Alert was declared.
6. No units were provided for air sampling results.

7. Ingress and egress areas for radiation control areas were not marked as such.
8. Establishment of a "warm zone" (i.e., area with elevated radiation) was made within a building, rendering it difficult to observe what was happening in it.
9. The survey teams were unaware that sandbags were stored near a shed.
10. Radios did not work in the labs.
11. Communications between the Emergency Manager and the ECC required several corrections.
12. The Decontamination Team was not notified that the exercise was terminated until 19 minutes after exercise termination.

3. **INDEPENDENT AND CONFIRMATORY MEASUREMENTS:**

(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

Since licensed material was not used during the inspection, the inspectors did not conduct independent or confirmatory measurements.

4. **VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:**

(State requirement and how and when licensee violated the requirement. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

None.

5. **PERSONNEL CONTACTED:**

[Identify licensee personnel contacted during the inspection (including those individuals contacted by telephone).]

Partial List of Personnel Contacted

*April Chance, Manager, Regulatory Affairs
 *Dorothy Gerner, Human Resources Manager
 *Chris Guerdan, Site Director
 *Ron Hale, Distribution Supervisor
 *Don Hoffman, RSO in Training
 *April Jeffries Health Physics Intern
 *Bryan Lowery, Health Physics Supervisor
 *Mark Matheiss, Safety Supervisor
 *Diane Neely, Regulatory Specialist
 *Brad Nelson, Emergency Coordinator
 *Mitzi Pennington, Production Manager
 *Jaya Ramanuja, Principal Health Physicist
 *Jim Schuh, Radiation Safety Officer
 *Adam Washburn, Health Physics Technician

Use the following identification symbols:

Individual(s) present at entrance meeting (Note: Since the inspection was announced and pre-planned, no entrance meeting was conducted.)

* Individual(s) present at exit meeting