



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

October 23, 2006

EA-06-246
NMED No: 060266

Mr. Dale Simpson
Plant Manager
Mallinckrodt, Inc.
2703 Wagner Place
Maryland Heights, MO 63043

SUBJECT: NRC INSPECTION REPORT NO. 030-00001/06-001(DNMS)
NRC 591X, PART1

Dear Mr. Simpson:

This letter and attached NRC 591X, Part 1 refers to the routine inspection conducted on September 18 through 22, 2006, at your facilities in Maryland Heights, Missouri. The inspection results were discussed with you and members of your staff on September 22, 2006.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements, and observations of activities in progress.

Within the scope of this inspection, one non-cited violation and one Severity level IV violation of NRC requirements were identified. The violations are documented on the NRC Form 591M Part 1, which is enclosed. No response to this letter or the enclosed NRC Form 591M is required.


In accordance with 10 CFR 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 NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

D. Simpson

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Should you have any questions concerning this inspection, please contact Darrel Wiedeman of my staff at (630) 829-9808.

Sincerely,

A handwritten signature in black ink, reading "Kenneth J. Lambert". The signature is written in a cursive style with a large, stylized initial "K".

Kenneth J. Lambert, Acting Chief
Materials Inspection Branch

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

Enclosure:
As stated

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Mallinckrodt, Inc. 2703 and 2600 Wagner Place Maryland Heights, MO		2. NRC/REGIONAL OFFICE REGION III US NUCLEAR REGULATORY COMMISSION 2443 WARRENVILLE ROAD LISLE, IL 60532-4351	
REPORT 2006-001			
3. DOCKET NUMBER(S) 030-00001	4. LICENSEE NUMBER(S) 24-04206-01	5. DATE(S) OF INSPECTION 9/18-22/ 2006	

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

1. Based on the inspection findings, no violations were identified.

2. Previous violation(s) closed.

3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

License Condition No. 23.B., requires the licensee to conduct its program in accordance with statements, representations and procedures contained in documents dated February 28, 2001. In the letter dated February 28, 2001, the licensee committed to implement procedures and policies for safe waste handling. Standard Operating Procedure 15-16 states "no overpacks will be collected that have a contact dose rate reading greater than 30 R/hour.

Contrary to the above requirement, on or around June 15, 2006, a waste handler collected an overpack that had a contact dose rate greater than 30 R/hour.

4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations and Corrective Actions)

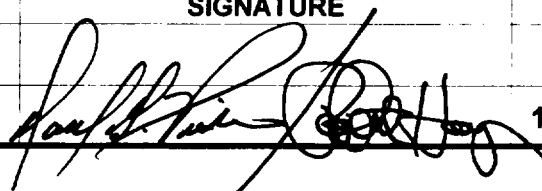
10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. 10 CFR 20.1802 requires that the licensee control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage. As defined in 10 CFR 20.1003, *controlled area* means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason; and *unrestricted area* means an area, access to which is neither limited nor controlled by the licensee.

Contrary to the above, as of September 22, 2006, the licensee failed to secure from unauthorized removal or access to seven depleted uranium generator shields, each containing a nominal 8 millicuries of uranium-238 located at the licensee's manufacturing facility, which is a controlled area, nor did the licensee control and maintain constant surveillance of this license material. Specifically, a physical inventory of depleted uranium (DU) shields conducted between February 24, 2006, and September 19, 2006, determined that seven DU shields (serial numbers 493, 688, 1019, 1849, 2001, 2822, 4375) could not be located and accounted for by the licensee at its manufacturing facility.

This is a Severity Level IV violation (Supplement IV).

STATEMENT OF CORRECTIVE ACTIONS

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE			
NRC INSPECTOR	Darrel G. Wiedeman/Robert Hays		10/23/ 2006

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE Mallinckrodt, Inc.		2. NRC/REGIONAL OFFICE Region III	
REPORT NUMBER(S)			
3. DOCKET NUMBER(S) 030-00001	4. LICENSE NUMBER(S) 24-04206-01	5. DATE(S) OF INSPECTION 9/18-22/2006	

(Continued)

The licensee implemented corrective actions which consisted of: 1) developing a new procedure including a bar code system to improve onsite DU shield tracking; 2) implementing a new process requiring couriers to provide Mallinckrodt a copy of each Bill of Lading provided to them when picking up a DU shield from Mallinckrodt customers; 3) implementing a new process for providing rapid communication to notify customers when returning DU shields are delinquent; 4) reducing the number of storage areas as a method of better controlling DU shields at Mallinckrodt's facilities; 5) investigating any DU tracking software errors through a computer system validation process; and 6) charging the customer for non-returns of any DU shield. The inspectors reviewed the licensee's corrective actions and did not identify any issues.

Docket File Information
SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION

1. LICENSEE Mallinckrodt, Inc. Maryland Heights, MO 63043		2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532	
REPORT NUMBER(S) 2006-001		3. DOCKET NUMBER(S) 030-00001	4. LICENSE NUMBER(S) 24-04206-01
6. INSPECTION PROCEDURES USED 87125		5. DATE(S) OF INSPECTION 9/18-22/ 2006	
7. INSPECTION FOCUS AREAS 03.01 - 0.3.07			

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03211	2. PRIORITY 1	3. LICENSEE CONTACT John Schuh, RSO	4. TELEPHONE NUMBER (314) 654-7981
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Main Office Inspection

Next Inspection Date: **9/2007**

Field Office _____

Temporary Job Site _____

PROGRAM SCOPE

Depleted Uranium Generator Shield (DU) Tracking - During the last inspection in August 2005, the inspectors followed-up on the licensee's courtesy notifications of three lost depleted uranium (DU) shields. The three losses occurred after the used generators (containing the DU shields) were shipped from clients (i.e., the licensee did not receive them). The inspectors determined that the licensee did not implement actions to identify if the missing DU shields were found. The inspectors noted that the licensee used a computerized DU shield inventory tracking system and questioned licensee staff about how the licensee could identify if any of the missing DU shields were located. In response to the inspectors' questioning, licensee staff searched its DU shield inventory tracking system and identified that all three of the missing DU shields were received at the licensee's facility since they were reported missing.

The inspectors continued their follow-up to physically verify that the DU shields were found. Two of the three missing shields were located. Based on information from the licensee's DU shield inventory tracking system, the third missing DU shield (Serial 002771) was at the licensee's facility, but the staff could not locate it before the inspection ended. Therefore, the licensee agreed to monitor its DU inventory system to identify when the missing shield is shipped out and notify the NRC.

An inspector periodically contacted the licensee regarding the missing DU shield. In February 2006, the RSO requested staff to conduct a physical inventory of all DU shields. The DU tracking system indicated that 20 DU shields were at client facilities, but the clients said they didn't have them (unaccounted for). In addition, the DU tracking system indicated 125 DU shields (including Serial 002771) were at the Mallinckrodt facility, but the shields were unaccounted for. Therefore, a total of 145 DU shields were unaccounted for (the 20 that were unaccounted for at clients' facilities plus the 125 that were unaccounted for at Mallinckrodt's facilities).

The RSO did not believe that DU shield Serial 002771 or any of the aforementioned, unaccounted for shields were missing. Rather, the RSO believed that the problem was inaccuracy/flaws in the DU tracking system.

During another physical inventory in late April 2006, the licensee identified that the February 2006 DU physical inventory had flaws. For example, the licensee staff identified that several errors were made while recording the DU serial numbers. During the April 2006 inventory, the staff located 115 of the 125 DU shields that were previously considered missing at their facility.

The licensee located all but 7 of the shields. The licensee expects that most of the shields will be returned through the normal distribution cycle. The licensee did not feel that the missing shields were in the public domain and indicated that if the shields were actually lost the doses to individual members of the public would be minimal. The licensee's failure to locate seven depleted uranium generator shields, each containing 8 millicuries of DU constitutes an apparent violation of 10 CFR 20.1801-20.1802. This apparent violation was identified and corrected prior to this inspection.

Corrective Actions

Prior to this inspection the licensee took actions to prevent similar problems including: (1) developing a new procedure to improve onsite DU shield tracking; (2) implementing a new process requiring couriers to provide a copy of the Bill of Lading provided to them when picking up a generator from their customer; (3) implementing a new process for providing rapid communications to customers when DU shields are delinquent; (4) reducing the number of approved onsite locations where DU shields can be stored; and (5) investigating the DU racking software through a computer systems validation process, and (5) charging the customer for non-returned generator DU shields.

Waste Handling

During this inspection the inspectors reviewed the licensee's waste handling practices. The inspectors observed an early-morning pickup of waste, transport and subsequent storage in Building 250. The inspectors also reviewed Standard Operating Procedures (SOPs) 15-16, 33-163 and 33-176. These procedures are the licensee's policy and procedures for waste handling which are required by License Condition No. 23.B. SOP 15-16 requires that no overpacks will be collected that have a contact dose rate reading greater than 30 R/hour. The inspectors identified that a waste technician collected an overpack that had a contact reading greater than 30 R/hour on or around June 15, 2006. The individual waste technician discussed this issue with his supervisor and was told that in the future he is not to pickup waste containers with a contact radiation reading in excess of 30 R/hour and was told that he must contact his supervisor or a physicist before moving waste containers with such high contact readings. This apparent violation was identified by the licensee and corrected by the licensee prior to this inspection and therefore meets the criteria for a non-cited violation.

Dosimetry

The inspectors reviewed the licensee's dosimetry records from 2005-2006 and did not identify any individual that exceeded 10 CFR Part 20 limits. The maximum wholebody exposure was 240 millirem and the highest extremity exposure was 432 millirem,