

NRC FORM 591M
PART 1
(10-2003) 10 CFR
2.201

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Mallinckrodt Inc. 675 McDonnell Boulevard PO Box 5840 St. Louis, MO 63134		2. NRC/REGIONAL OFFICE Nuclear Regulatory Commission Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532	
REPORT	2006/001		
3. DOCKET NUMBER(S) 030-18546	4. LICENSEE NUMBER(S) 24-04206-08MD	5. DATE(S) OF INSPECTION 04/25/2006	

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 to exercise discretion, were satisfied.

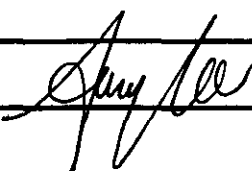
_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

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)

Licensee's Statement of Corrective Actions for Item 4, above.

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'S REPRESENTATIVE			
NRC INSPECTOR	Tony Go		04/25/2006

DOCKET FILE INFORMATION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE Mallinckrodt, Inc.		2. NRC/REGIONAL OFFICE Region III	
REPORT 2006/001			
3. DOCKET NUMBER(S) 030-18546	4. LICENSE NUMBER(S) 24-04206-08MD	5. DATE(S) OF INSPECTION 04/25/06	
6. INSPECTION PROCEDURES 87127	7. INSPECTION FOCUS AREAS 03.01 - 03.07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM 2500	2. PRIORITY 2	3. LICENSEE CONTACT Adam Kautzner, R.Ph	4. TELEPHONE NUMBER 314-654-2000
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Main Office Inspection Next Inspection Date: 04/2008

Field _____

Temporary _____

PROGRAM SCOPE

The pharmacy facility at Overland, MO, provides pharmacy service of the surrounding Missouri and Illinois areas. The pharmacy prepares on the average of 250 unit doses per day. The licensee supplied approximately 17 clients within the covering area. The RSO, Mr. Kautzner is responsible in a day-to-day radiation safety program. The licensee employed four pharmacists, two technologists, and approximately eight drivers. The licensee possessed seven vehicles (industrial vans). The licensee's facility is fully staffed. The pharmacy opened for business Monday through Friday, and half a day on Saturday or as needed. The licensee initial production run started at 1:00 a.m. through 5:00 p.m. The licensee received three Mo-Tc99m generators/week for dose productions, distributed Xenon-133 gas, and as of August 2005 the licensee compounded I-131 capsules with the licensee's automated I-131 compounding glovebox system, and also distributed non-NRC regulated nuclides. In addition, the licensee occasionally distributed therapeutic doses to clients.

Performance Observations

The inspector observed two pharmacists and two technologists dispensing and performing quality assurance of the unit doses before the second run. The inspector observed the licensee's staff included drivers and technologists as well as the pharmacists drawing doses, preparing shipment of unit and bulk doses, and conducting radiation and contamination surveys for compliance with NRC and DOT requirements. The inspector observed that the licensee's staff (pharmacists and technologists) used personal dosimetry on both hands and whole-body. The inspector also interviewed the pharmacy drivers and assessed that the DOT transport packages containing unit doses. These byproduct materials had never been left unsecured or unattended at the client sites according to the records and interviews of personnel. Copies of clients' State and NRC licenses were available and were randomly reviewed by the inspector. Additionally, the inspector also performed some confirmatory radiation surveys (GM survey meter) of the licensee's restricted areas and vehicles. The survey results did not indicate RAM contamination on the transport vehicles or at the restricted areas. The dosimetry records from 2005 to 2006 indicated the followings:

2005 TEDE= 112 mrem SDE= 9646 mrem
2004 TEDE= 79 mrem SDE= 19815 mrem

To date, the licensee had not reported any accidents involving the licensee's vehicles during transporting packages containing licensed materials. The inspector determined that DOT packages containing the licensed materials were secured and loaded onto another truck for removal from the accident scene.