NRC FORM 591M PART 1
(10-2003)
10 CFR 2 201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1 LICENSEE/LOCATION INSPECTED	2. NRC/REGIONAL OFFICE
Mallinckrodt, Inc. St. Louis, MO 63134 Warren, MI pharmacy REPORT 2005-001	U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351

3. DOCKET NUMBER(S)	4. LICENSEE NUMBER(S)	5. DATE(S) OF INSPECTION
030-29675	24-04206-10MD	Nov. 30, 2005

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

☒ 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):

☐ 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		**Deborah A. Piskura**	D A Piskura	11/30/05

NRC FORM 591M PART 3 (10-2003) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Mallinckrodt, Inc., Warren MI pharmacy REPORT NUMBER(S) 2005-001	**Region III** **2443 Warrenville Road, Suite 210** **Lisle, IL 60532**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-29675	24-04206-10MD	Nov. 30, 2005

6. INSPECTION PROCEDURES	7. INSPECTION FOCUS AREAS
87127	03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, and 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	G 2	*Michael Klug, R.Ph., site RSO*	568.268.5300

[X] Main Office Inspection — Next Inspection Date: November 2007

[ ] Field _____

[ ] Temporary Job Site _____

PROGRAM SCOPE

The Warren, Michigan Mallinckrodt pharmacy employed 3 pharmacists, 3 pharmacy technicians, and 8 drivers. Currently the licensee had 40 customers located in the Detroit, and Southeastern Michigan area and distributed approximately 250-325+ doses/day. The licensee received 4 Mo^{99}/Tc^{99m} generators from Mallinckrodt, St. Louis, each week. Xenon-133 gas vials were received and re-distributed to their customers (the inner containers were not opened in the pharmacy). The pharmacy redistributed I-131 therapy liquid vials and/or capsules weekly. Note that this pharmacy did not use I-131 to compound therapy capsules. The pharmacy did not distribute beta-emitting radiopharmaceuticals at the time of this inspection. The corporate office conducted unannounced, semi-annual audits of the pharmacy's safety program (last 6/2005, with minor findings).

During this inspection, the inspector observed morning runs. This included performing dose calibrator QC/QA tests, drawing doses, packaging doses for shipment and conducting surveys for compliance with NRC and DOT requirements. The inspector also performed independent radiation surveys of select working areas, reviewed select records, and interviewed select licensee personnel.

The maximum whole body and extremity exposures (in millirem) were recorded as follows:

	2003	2004	YTD- 11/2005
Whole Body	102	197	211
Extremity	9,967	8,796	19,522*

*NOTE: The inspector discussed this extremity exposures at great length with the RSO. The inspector noted that the 2005 extremity exposures appeared quite higher than expected (compared with previous years). The RSO informed the inspector that the early morning shift pharmacist received these exposures as a result of methodical work practices. He showed improvement with training and changes in technique. The licensee stated that they were also concerned about these extremity exposures and discussed it with the individual. The RSO would continue to monitor this issue.