

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Mallinckrodt Inc. St. Louis, MO Kansas City, MO pharmacy		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4351	
REPORT NUMBER(S) 2006-001			
3. DOCKET NUMBER(S) 030-32515	4. LICENSEE NUMBER(S) 24-04206-12MD	5. DATE(S) OF INSPECTION Feb. 10, 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

- ☒ 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	<i>D. A. Piskura</i>	2/10/06

RJP

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 Mallinckrodt, Inc., Kansas City, MO pharmacy		2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532	
REPORT NUMBER(S) 2006-001			
3. DOCKET NUMBER(S) 030-32515	4. LICENSE NUMBER(S) 24-04206-12MD	5. DATE(S) OF INSPECTION Feb. 10, 2006	
6. INSPECTION PROCEDURES 87127		7. INSPECTION FOCUS AREAS 03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, and 03.08	
SUPPLEMENTAL INSPECTION INFORMATION			
1. PROGRAM CODE(S) 02500	2. PRIORITY G1 2	3. LICENSEE CONTACT David Pensinger, R.Ph., site RSO	4. TELEPHONE NUMBER 816.931.0515
<input checked="" type="checkbox"/> Main Office Inspection		Next Inspection Date: Feb. 2008	
<input type="checkbox"/> Field			
<input type="checkbox"/> Temporary Job Site			

PROGRAM SCOPE

The Kansas City, Missouri, Mallinckrodt pharmacy employed 4 pharmacists, 2 pharmacy technicians, and 11 drivers. Currently the licensee serviced 40 customers located in the Kansas City, and bi-state area and distributed approximately 300+ doses/day. The licensee received 3 Mo99/Tc99m generators from a licensed manufacturer 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 liquid to compound therapy capsules. The pharmacy occasionally distributed beta-emitting radiopharmaceuticals. The corporate office conducted unannounced, semi-annual audits of the pharmacy's safety program (last 2/8/2006, with minor findings).

During this inspection, the inspector observed morning runs. These observations included staff 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:

	<u>2004</u>	<u>2005</u>	<u>1/8/2006</u>
Whole Body	278	318	
Extremity	16,255	19,518	789

*Data not available at time of inspection