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 Overland, MO pharmacy REPORT NUMBER(S) 2008-001	**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
030-18546	24-04206-08MD	May 23, 2008

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):

☐ 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	Deborah A. Piskura	05/23/2008

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

Docket File Information

U.S. NUCLEAR REGULATORY COMMISSION

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1. LICENSEE	2. NRC/REGIONAL OFFICE
Mallinckrodt Inc. REPORT NUMBER(S) 2008-001	Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87127	03.01 – 03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02500	2	April Chance, Manager, Reg. Affairs	314-654-7444.

- [ ] Main Office Inspection — Next Inspection Date: May 2010
- [X] Field Office — 1827 Belt Way Drive, Overland, MO pharmacy
- [ ] Temporary Job Site Inspection

PROGRAM SCOPE

The Mallinckrodt St. Louis pharmacy employed 2 ANPs (currently recruiting a third ANP), 2 pharmacy technicians, and 8 drivers/couriers. The pharmacy served approximately 20 customers located in the St. Louis area and distributed approximately 200+ doses daily. The licensee received 3 Mo99/Tc99^m generators each week. Xenon-133 gas vials were received and re-distributed to their customers, however, the inner containers were not opened by the pharmacy. The pharmacy compounded I-131 therapy capsules at this pharmacy. Occasionally, the pharmacy prepared and distributed Sm-153, Y-90/In-111 (Zevalin), and I-131 (Bexxar) dosages. These beta doses were measured, using a correction factor, in the licensee's dose calibrator prior to transfer to the customer. The corporate office conducted semi-annual audits of the pharmacy.

This inspection consisted of interviews with licensee personnel, a review of selected records, tour of the radiopharmacy, and independent measurements. During this inspection, the inspector observed early and midmorning runs. These observations included observing licensee personnel performing dose calibrator QC/QA tests, drawing doses, receiving packages, packaging doses for shipment and conducting surveys for compliance with NRC and DOT requirements.

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

	YTD 5/04/2008	2007	2006
Whole body	17	100	118
Extremity	2,893	7,032	6,706