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SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Mallinckrodt, Inc
2795 Universal Dr
Saginaw, MI
REPORT NUMBER(S) 2008001

2. NRC/REGIONAL OFFICE

U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road
Suite 210
Lisle, Illinois 60532-4351

3. DOCKET NUMBER(S)

03050262

4. LICENSEE NUMBER(S)

24-04206-11MD

5. DATE(S) OF INSPECTION

Apr 1 29, 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	G. P. Parker	[Signature]	4/27/08

Docket File Information
SAFETY INSPECTION REPORT
AND COMPLIANCE INSPECTION

1. LICENSEE Mallinckrodt Pharmacy REPORT NUMBER(S) 2008-001		2. NRC/REGIONAL OFFICE Region III	
3. DOCKET NUMBER(S) 030-30262	4. LICENSE NUMBER(S) 24-04206-11MD	5. DATE(S) OF INSPECTION 04/29/2006	
6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 3/01-07		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 2500	2. PRIORITY 2	3. LICENSEE CONTACT Joseph Blair	4. TELEPHONE NUMBER 989/799-7669
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<input checked="" type="checkbox"/> Main Office Inspection	Next Inspection Date: 04/10
<input type="checkbox"/> Field Office	
<input type="checkbox"/> Temporary Job Site	

PROGRAM SCOPE

Program Scope

87127

The licensee is a regional division of the Mallinckrodt chain located in Saginaw, MI. This radiopharmacy employs one pharmacist, one pharmacy tech and approximately five drivers from a commercial firm. Currently the licensee has approximately 150+ customers located in the north eastern Michigan area. The pharmacy serves its customers from approximately 4:00am to 3:00pm daily including Saturdays and Sundays. Licensee's first run starts about 4:30am and continues throughout the day. This pharmacy receives Mo99/Tc99m generators each week for the preparation of unit doses to be distributed to clients.

Performance Observations

During the inspection, the inspector toured the facility and observed the preparation of unit doses destined for clients. The inspector observed shipping procedures being performed and interviewed the staff concerning their roles in the process. The inspector determined that they possessed an adequate level of knowledge of shipping requirements. The inspector performed confirmatory surveys of the restricted area and the results were similar to those of the licensee. Conversations between the inspector and licensee staff provided assurances that licensee staff had an adequate knowledge of radiation safety.

Independent surveys performed by the inspector did not detect any unusual or unexpected readings. No abnormal conditions were detected.