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. Imaging Research and Development P. O. Box 5840 St. Louis, MO 63134 REPORT NUMBER(S)	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
030-12559	24-17450-01	September 26, 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	Robert P. Hays	Robert P. Hays	9/26/08

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

Docket File Information

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE	2. NRC/REGIONAL OFFICE
Mallinckrodt, Inc. REPORT NUMBER(S) **2008-01**	**Region III** **2443 Warrenville Road, Suite 210** **Lisle, IL 60532**

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
03012559	**24-17450-01**	**September 26, 2008**

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87134 (9/28/05)	**03.01-03.07**

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
03610	**3**	**John Snider, RSO**	**314-654-8563**

[X] Main Office Inspection — Next Inspection Date: **September 2011**

[ ] Field Office

[ ] Temporary Job Site Inspection

PROGRAM SCOPE

The licensee was authorized for any byproduct material with atomic numbers 1-83 and other specified isotopes, to be used for research and development, including animal studies and instrument calibration. The majority of research involves using Mo-99/Tc-99m generators. Any *in vivo* protocols used rodents. Research protocols were restricted to one building on the Covidien campus and almost all research staff were employees with numerous years of employment with Mallinckrodt. The RSO has two additional staff who assist with ordering, receiving, dosimetry, surveys/wipe tests, and waste handling. Liquid waste was held for decay-in-storage (DIS) and then sewered. Inspector area surveys of the waste storage areas and research lab areas did not reveal any contamination or elevated readings.

Performance Observations

During the inspection, the RSO and research staff demonstrated/discussed: (1) survey meter use; (2) package ordering, receiving, and check-in procedures; (3) wipe test counting; (4) dosimetry; (5) research waste handling and storage procedures; (6) isotope inventory control; (7) security of licensed material; (8) radiation safety committee meetings, including approvals for research investigators and protocols; (9) radiation safety program audits; (10) contamination events; and (11) staff training. No violations or concerns identified during the inspection.