

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: Mallinckrodt Inc. Imaging Research and Development P.O. Box 5840 St. Louis, MO 63134		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4351	
REPORT 2005/001			
3. DOCKET NUMBER(S) 030-12559	4. LICENSEE NUMBER(S) 24-17450-01	5. DATE(S) OF INSPECTION 11/7/2005	

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 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	Tony S. Go		11/7/05

NRC FORM 591M PART 3 (10-2003) 10 CFR 2.201		U.S. NUCLEAR REGULATORY COMMISSION	
<i>Docket File Information</i> SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION			
1. LICENSEE Mallinckrodt Inc. Imaging Research and Development REPORT NUMBER(S) 2005/001		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III	
3. DOCKET NUMBER(S) 030-6584 12539	4. LICENSE NUMBER(S) 24-3489-01 17450-01	5. DATE(S) OF INSPECTION 11/07/05	
6. INSPECTION PROCEDURES 87126	7. INSPECTION FOCUS AREAS 03.01 - 03.07		
SUPPLEMENTAL INSPECTION INFORMATION			
1. PROGRAM 3610	2. PRIORITY 3	3. LICENSEE CONTACT Joseph Koch, PhD	4. TELEPHONE NUMBER 314-654-3269
<input checked="checked" type="checkbox"/> Main Office Inspection		Next Inspection Date: 11/08	
<input type="checkbox"/> Field Office		_____	
<input type="checkbox"/> Temporary Job Site		_____	
PROGRAM SCOPE			

NRC FORM 591M PART 3 (10-2003)

The licensee is a broadscope industrial research facility with only two to three active labs remaining. The licensee received only one Mo-99/Tc-99m generator per week for QA and R&D associated with generator research and small animal research studies. The licensee also possessed an instrument calibrator Shepherd Model No. 28-6, containing a nominal activity of Cs-137, this calibrator is currently in storage. The licensee also possessed several other sealed sources that were placed in storage. As of the inspection date, the licensee also used low millicuries quantities of I-125 for iodination binding research activities. Currently there are nine authorized users as approved by the RSC, these individuals were trained in radiation protection through an annual refresher course offered by the RSO through a self-study program that is listed on the licensee's intranet system.

Performance Observations

The inspector toured the facility and was able to observe the storage area, the hot lab and the research floor where Tc-99m used in daily basis. The licensee's staff demonstrated survey procedures for surveying packages containing byproduct materials and waste. No problems were identified during the tour of the facility.