

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

EN 45735

1. LICENSEE/LOCATION INSPECTED:

Mallinckrodt, Inc.
2703 and 2600 Wagner Place
Maryland Heights, MO

2. NRC/REGIONAL OFFICE

Region III
2443 Warrenville Rd.
Lisle, IL 60532

REPORT NUMBER(S) 2011-001

3. DOCKET NUMBER(S)

03000001

4. LICENSEE NUMBER(S)

24-04206-01

5. DATE(S) OF INSPECTION

1/10-14/11, in-office review through 1/28/11

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

_____ 1 _____ Non-cited violation(s) were discussed involving the following requirement(s):

10 CFR 20.1601(a): On August 16 and 17, 2010, the licensee failed to ensure that the door to a high radiation area was locked nor did it ensure positive control over the entry when the door was unlocked.

The licensee's corrective actions to prevent a similar violation included retraining its staff on its "Standard Testing Method (STM) 291-116" for verifying that HRA doors are secured by challenging the doors to ensure that they are locked in the closed position before leaving the doors unattended, and increasing communication of the importance of securing HRAs and implementing (STM) 291-116.

- 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

Statement of Corrective Actions

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	Daniel Hoffman		
NRC INSPECTORS	Robert Gattone	<i>Robert D. Gattone, Jr.</i>	2/7/11
	Robert Hays	<i>Robert D. Gattone, Jr. for</i>	2/7/11
Branch Chief	Tamara Bloomer	<i>Tamara Bloomer</i>	2/7/11

Docket File Information
SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE Mallinckrodt, Inc. 2703 and 2600 Wagner Place Maryland Heights, MO		2. NRC/REGIONAL OFFICE Region III 2443 Warrenville Rd. Lisle, IL 60532	
REPORT NUMBER(S) 2011-001			
3. DOCKET NUMBER(S) 03000001		5. LICENSE NUMBER(S) 24-04206-01	
6. INSPECTION PROCEDURES 87125		7. INSPECTION FOCUS AREAS 03.01 -03.07	
5. DATE(S) OF INSPECTION 1/10-14/11, in-office review through 1/28/11 (included receipt and review of information about underground waste pipes)			

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM 03211	2. PRIORITY 2	3. LICENSEE CONTACT Dan Hoffman	4. TELEPHONE NUMBER 314-654-7906
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Main Office Inspection Next Inspection Date: January 2013

Field Office Inspection Temporary Job Site Inspection

PROGRAM SCOPE

The licensee operated 5 cyclotrons to produce thallium-201, gallium-67, and indium-111 for medical use. In addition, the licensee produced several hundred technetium-99m generators per week. The licensee also produced unit dosages of iodine -131 capsules for medical use.

PERFORMANCE OBSERVATIONS

The inspectors observed: (1) that the licensee implemented its Corrective Action Program (CAP) to prevent loss of technetium-99m generators during transit (EN45735); (2) that the licensee replaced sections of underground radioactive waste pipe with double-walled stainless steel pipe in accordance with the Radiation Safety Committee's pre-approval; (3) that the stainless steel radioactive waste pipe combined with the licensee's weekly surveys to detect leakage from the primary pipe wall to the secondary wall and from the secondary pipe wall to the cement encasing it (raceway) provided adequate protection of leakage of waste to the environment; (4) a licensee staff member conduct Class III training; (5) that the licensee implemented actions to prevent the Non-Cited Violation documented in Part 1 of this report; (6) that the licensee conducted adequate audits as required; (7) that the licensee implemented its CAP to prevent Techniscan labeling problems; (8) several High Radiation Area (HRA) doors were secured as required; (9) that selected HRAs were posted as required; (10) the Environmental Compliance Supervisor demonstrate how he would respond to an HRA door malfunction; (11) a Traffic Expeditor demonstrate how the licensee's computer system was used to verify customer authorization to receive radioactive material prior to transfer; (12) authorized staff conduct maintenance activities on a cyclotron using time, distance, and shielding to reduce radiation exposure; (13) a staff member conduct ambient exposure rate surveys of strategic areas prior to conducting cyclotron maintenance in the areas; (14) an ambient exposure rate reading with an NRC survey instrument that was comparable to the licensee's reading with its instrument during a comparative measurement; (15) staff don required personal protection equipment and dosimetry badges, as required; (16) a Day Shift Coordinator conduct quality assurance testing of gallium-67; (17) a Day Shift Coordinator demonstrate how he would respond to a radioactive spill; (18) that the licensee implemented its CAP to prevent the Octreoscan binding problem; (19) training provided to respirator users; (20) a staff member demonstrate how he conducted safety checks prior to using SCBA respirators; (21) a Safety Engineer conduct a respirator fit test; (22) that licensed material was secured as required; (23) I-131 production procedures; (24) animal studies using gallium-67; (25) survey meter and RADOS calibration procedures; (26) receipt of bulk Mo-99; (27) gown dress out training; (28) generator reclamation procedures; (29) packaging and shipment of iodine products; (30) generator column loading; (31) radioactive waste disposals; (32) wipe-test counting; and (33) personnel bioassays.

Max. doses in 2009: 2156 mrem DDE (Distribution Department) and 10086 mrem SDE (I-123 production area).
Max. doses in YTD November 2010: 1570 mrem DDE and 3370 mrem SDE (cyclotron department) due to increased TI-201 production during the Mo-99/Tc-99m shortage