

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:

Mallinckrodt, LLC  
2703 Wagner Place  
Maryland Heights, MO 63043

REPORT NUMBER(S) 2014/001

2. NRC/REGIONAL OFFICE

Region III  
U. S. Nuclear Regulatory Commission  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-38173

4. LICENSE NUMBER(S)

24-04206-02

5. DATE(S) OF INSPECTION

May 12-16, 2014

**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, to exercise discretion, were satisfied.

\_\_\_\_\_ Non-cited violation(s) were discussed involving the following requirement(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 in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.  
(Violations and Corrective Actions)

**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			
NRC INSPECTOR	Ken Lambert / Ryan Craffey	<i>Ken Lambert / Ryan Craffey</i>	5/27/14
BRANCH CHIEF	<i>Thomas T. McCann</i>	<i>[Signature]</i>	5/28/14

**Docket File Information**  
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6. INSPECTION PROCEDURES USED  87125, 87126	7. INSPECTION FOCUS AREAS  03.01 - 03.07
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**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  3210	2. PRIORITY  2	3. LICENSEE CONTACT  Scott Surovi, RSO	4. TELEPHONE NUMBER  (314) 654-7444
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Main Office Inspection                      Next Inspection Date: May 12, 2016  
 Field Office Inspection \_\_\_\_\_  
 Temporary Job Site Inspection \_\_\_\_\_

**PROGRAM SCOPE**

This was a routine inspection at Mallinckrodt who was authorized for the production, possession and handling of radiochemicals for medical use and research. The licensee operates six cyclotrons and primarily produces gallium-67, indium-111, and thalium-201 for use as radiopharmaceuticals for medical use.

**PERFORMANCE OBSERVATIONS**

The inspectors noted that radioactive materials were appropriately secured from unauthorized removal or access. The inspectors discussed/reviewed: (1) radiation safety committee meeting minutes; (2) corrective action program implementation with emphasis to corrective actions to entering the wrong target bunker for maintenance; (3) annual ALARA audit and corrective actions to findings; (4) annual radiation protection program audit and corrective actions to findings; (5) high radiation controls and appropriate posting; (6) personnel bioassay program; and (7) organizational changes since the last inspection.

The inspectors observed: (1) that high radiation areas were properly posted and secured; (2) cyclotron operations staff performing maintenance activities that included cyclotron carbon foil assembly replacement and bunker entry procedures; (3) HP staff performing pre-job radiation surveys and discuss results with operations staff prior to beginning maintenance activities; (4) that personnel were wearing appropriate PPE and required dosimetry; and (5) personnel performing the required personal contamination monitoring.

The inspectors reviewed external dosimetry results and noted maximum doses of 1773 mrem DDE and 9344 mrem SDE for 2013, and 456 mrem DDE and 3920 mrem SDE for 2014 through March.

No violations or regulatory requirements were identified.