

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED: <i>Mallinckrodt, LLC</i> <i>2703 Wagner Place</i> <i>Maryland Heights, MO</i>	2. NRC/REGIONAL OFFICE  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
REPORT NUMBER(S) <i>2013-001</i>	

3. DOCKET NUMBER(S) <i>030-00001</i>	4. LICENSE NUMBER(S) <i>24-04206-01</i>	5. DATE(S) OF INSPECTION <i>5/20-24/13</i>
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**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	<i>Ken Lambert/Bill Lin</i>	<i>Ken Lambert</i>	<i>5/24/13</i>
BRANCH CHIEF	<i>Aaron T. McCann</i>	<i>[Signature]</i>	<i>6/4/13</i>

**Docket File Information**  
**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

1. LICENSEE/LOCATION INSPECTED:  Mallinckrodt, LLC 2703 Wagner Place Maryland Heights, MO 63043  REPORT NUMBER(S) 2013-001	2. NRC/REGIONAL OFFICE  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. DOCKET NUMBER(S)  030-00001	4. LICENSE NUMBER(S)  24-04206-01	5. DATE(S) OF INSPECTION  May 20-24, 2013
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6. INSPECTION PROCEDURES USED  87125; TI 2600/017	7. INSPECTION FOCUS AREAS  03.01- 07
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**SUPPLEMENTAL INSPECTION INFORMATION**

1. PROGRAM CODE(S)  3211	2. PRIORITY  2	3. LICENSEE CONTACT  Gary Bosgraaf, RSO	4. TELEPHONE NUMBER  (314) 654-7661
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Main Office Inspection                      Next Inspection Date: May 24, 2015

Field Office Inspection \_\_\_\_\_

Temporary Job Site Inspection \_\_\_\_\_

**PROGRAM SCOPE**

Mallinckrodt is a large medical isotope manufacturing facility authorized for manufacturing, processing and packaging or radiopharmaceuticals and/or radiochemicals. The licensee distributes thallium-201, gallium-67, and indium-111 for medical use. The licensee manufactures over 500 molybdenum-99/technetium-99m (Mo-99/Tc-99m) generators per week. The licensee also produces unit dosages of iodine-123 (I-123) and iodine-131 capsules for diagnostic and therapeutic medical procedures.

**OBSERVATIONS AND FINDINGS**

The inspectors noted that radioactive materials were appropriately secured from unauthorized removal or access. The inspectors discussed/reviewed: (1) radiation safety committee meeting minutes and authorized use approvals; (2) corrective action program implementation with emphasis on; (3) annual ALARA audit and corrective actions to findings; (4) annual radiation protection program audit and corrective actions to findings; (5) decommissioning planning rule and surveys for subsurface contamination; (6) liquid and gaseous effluent controls, analysis and results; (7) high radiation controls and appropriate posting; (8) generator DU shielding inventory controls; (9) personnel bioassay program; and (10) organizational changes since the last inspection. The inspectors observed: (1) that high radiation areas were properly posted and secured; (2) the new generator production facility; (3) I-123 capsule production; (4) Mo-99/Tc-99m generator radionuclide chemical formulation; (5) returned Mo-99/Tc-99m generator processing; package receipt surveys; (6) HP staff perform an audit; (7) that personnel were wearing appropriate PPE and required dosimetry; and (8) personnel performing the required personal contamination monitoring.

The inspectors reviewed external dosimetry results and noted maximum doses of 1518 mrem DDE and 4990 mrem SDE for 2012, and 213 mrem DDE and 2160 mrem SDE for 2013 through March.

No violations or regulatory requirements were identified.