

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) 030-00001	4. LICENSE NUMBER(S) 24-04206-01	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.

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

1. Failure to post two high radiation areas in accordance with 10 CFR 20.1902(b)
2. Failure to label two Molybdenum/Technicium generators for commercial distribution with the correct quantity of radioactivity in accordance with 10 CFR 32.72(a)(4)(i).

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	Scott Surovi		04 JUN 14
NRC INSPECTOR	Ken Lambert / Ryan Craffey		5/27/14
BRANCH CHIEF	Aaron T. McCann		5/28/14

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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)

030-00001

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(Continued)

Two non-cited violations were identified. The first NCV involved the licensee's failure to post two high radiation areas as required by 10 CFR 20.1902(b). The licensee entered each of the high radiation area (HRA) events into its corrective action program, and implemented corrective actions. The first HRA posting issue resulted from leaving a waste container in a room that was posted as a radiation area versus a HRA (room had been previously posted as a HRA). The container measured 180 mrem/hr @ 30 cm. Corrective actions included: moving the waste container to an area posted as a HRA; retraining waste disposal staff on the corrective survey instruments to be used when surveying waste; and training HP staff to perform risk assessments during abnormal processes; and revising the radiological posting procedure to include a step to communicate to effected employees when postings are changed.

The second HRA posting issue involved a filter bank from a hot cell where a new process was being developed for germanium check sources. Germanium being highly volatile resulted in a radiation level measurement of 110 mrem/hr @ 30 cm from the filter bank housing. Corrective actions included: removing the filter with elevated readings and moving to a secured HRA; posting the area as HRA; installing a locked gate at the top of the mezzanine stairs; retraining of staff on the correct distance for measuring radiation levels from containers and sources of radiation; revising the survey procedure to ensure the surveys are being performed at 30 cm from an object; and performing an evaluation of all filter banks to determine if site controls are adequate to prevent or secure filter banks if they exceed HRA levels.

The second NCV involved the licensee's failure to label two Mo/Tc generators for commercial distribution with the correct quantity of activity in accordance with 10 CFR 32.72(a)(4)(i). A generator containing 11 Ci of Mo/Tc was labeled as containing 19 Ci and a generator containing 19 Ci was labeled as containing 11 Ci. This occurred when two generators were removed from the assembly line for sampling and were placed back into the assembly line in the wrong order and the packaging operator did not visually identify the labeling issue. Corrective actions included: Stopping the assembly line after removing a generator for sampling; retrain personnel on the procedure; and adding a bar code reader to the system to read the activity number of the generator and outer casing to ensure they are the same; Adding an automatic stop to the packaging system if the numbers do not match.

The inspectors reviewed corrective actions to a Notice of Violation, dated January 9, 2014, involving entering a cyclotron target bunker before one week of radiation cooling had occurred. The corrective actions included requiring a second operator to verify that the correct bunker has been selected for entry and retraining staff on the new requirement. This violation is closed.

NMED 130592 and 140026 involved two separate reports of lost depleted uranium (DU) shielding in Mo/Tc generators. The inspectors reviewed the circumstances surrounding loss of the DU shielding and the efforts by the licensee to locate the missing DU shields. The licensee contacted the facilities that were shipped the generators containing DU shielding, the contact couriers, the common carriers, and a lead recycling company. The generator reported missing in NMED 140026 was found in the common carriers warehouse and was returned to the licensee. Four of five generators reported missing in NMED 130592 were located at a lead recycling facility and returned to the licensee. In addition, the licensee found an additional three generators, and had reduced the number of missing DU shields from 17 to 9 during its efforts to locate missing generators. The NRC considers these NMED items to be closed.

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

1. PROGRAM CODE(S) 3211	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 of Mallinckrodt, a large medical isotope manufacturing facility authorized for manufacturing, processing and packaging of 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; (2) corrective action program implementation with emphasis on 2 high radiation area posting events and a generator mislabeling event; (3) annual ALARA audit and corrective actions to findings; (4) annual radiation protection program audit and corrective actions to findings; (5) radioactive solid waste handling, surveys for decay in storage, and off site shipments; (6) high radiation controls and appropriate posting; (7) generator DU shielding inventory controls; (8) personnel bioassay program; and (9) 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) cyclotron chemistry; (4) current Mo-99/Tc-99m generator production line; (6) returned Mo-99/Tc-99m generator processing; (7) animal research labs; (8) waste shipment radiological surveys; (9) HP staff perform an audit of the waste shipping process; (10) that personnel were wearing appropriate PPE and required dosimetry; and (11) 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.

Continued on Part 2