

INSPECTION RECORD

Region: III

Inspection Report No. 2015001

License No. 24-04206-01

Docket No. 030-00001

Licensee: Mallinckrodt, LLC  
2703 Wagner Place  
Maryland Heights, MO 63043

Locations Inspected: same as above

Licensee Contact: Manuel Diaz, RSO Telephone No. 314-654-7661

Program Code: 03211 Priority: 2

Type of Inspection: ( ) Initial (X) Routine (X) Announced  
( ) Special ( ) Unannounced

Last Inspection Date: 5/12-16/2014

Date of This Inspection: 9/21-25/2015, with continued in office review through 12/21/2015 to review two elevated personnel extremity exposures and one high radiation area event entered into the licensee's corrective action program.

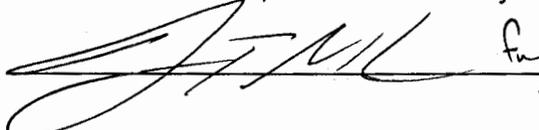
Next Inspection Date: 1/2016 ( ) Normal (X) Reduced

Justification for reducing the routine inspection interval: Additional inspection necessary to perform additional review of elevated exposure events.

Summary of Findings and Actions:

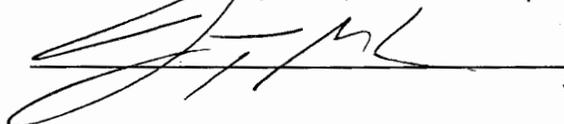
- (X) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- ( ) Non-cited violations (NCVs)
- ( ) Violation(s), Form 591 issued
- ( ) Violation(s), regional letter issued
- ( ) Follow-up on previous violations

Inspector: Deborah A. Piskura, Senior Health Physicist

  
Signature

Date: 12/31/15

Approved: Aaron T. McCraw, Chief, Materials Inspection Branch

  
Signature

Date: 12/31/15

Enclosure

**PART I – LICENSE, INSPECTION, INCIDENT/EVENT AND ENFORCEMENT HISTORY**

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

| <u>AMENDMENT #</u> | <u>DATE</u> | <u>SUBJECT</u>  |
|--------------------|-------------|---|
| 91                 | 4/2/2015    | possession limit increases; new production process  |
| 90                 | 11/13/2014  | new RSO   |
| 89                 | 5/22/2014   | changes to contingency plan; changes/clarifications on source model numbers and possession limits |

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations of NRC requirements were identified during the previous inspections on May 12-16, 2014; October 3, 2013; and May 20-24, 2013.

3. INCIDENT/EVENT HISTORY:

Since the previous inspection, the licensee reported three separate events involving lost material during shipping.

**NMED 150155:** On March 19, 2015, the licensee reported the loss of a spent molybdenum-99 (Mo-99)/technetium-99m (Tc-99m) generator (also containing 8.1 millicuries (mCi) depleted uranium (DU)) during shipment from a customer on or about January 19, 2014. The licensee's investigation included contacts with the customer and the courier. The courier searched its facility but could not locate the missing generator. During shipments, the courier consolidated multiple packages destined to the licensee's facility. The licensee believed that the missing generator remains in possession of the courier at its warehouse and will eventually be returned.

**NMED 150263:** On May 7, 2015, the licensee reported the loss of a package containing indium-111 (In-111) during shipment to a customer on or about April 7, 2015. The courier sorted and consolidated multiple packages destined to the same locality as the customer. A search of the licensee's facility, the courier's warehouse, sorting station, and vehicles could not locate the missing package. The licensee believed that the missing package remains at either the courier's warehouse or the sorting facility.

**NMED 150366:** On June 29, 2015, the licensee reported the loss of a package containing iodine-123 (I-123) during shipment to a customer on or about June 8, 2015. The courier sorted and consolidated multiple packages destined to the same locality as the customer. At the completion of the delivery of multiple packages to the customer's facility, the courier discovered that the individual package was missing. A search of the licensee's facility, the courier's warehouse, sorting station, and the vehicle could not locate the missing package. The licensee believed that the missing package remains at either the courier's warehouse or the sorting facility.

The licensee described its corrective actions in response to these multiple lost package event. The licensee proposed to implement a package tracking system to improve transport tracking/status and proof of delivery. These events are considered closed.

## PART II – INSPECTION DOCUMENTATION

### 1. ORGANIZATION AND SCOPE OF PROGRAM:

The licensee operated a Type A broad scope manufacturing and distribution program. The licensee's operations included the manufacture of Mo/Tc generators; sodium iodide-131 (I-131) and I-123; In-111; and other cyclotron-produced products, and cold products/kits for compounding radiopharmaceuticals. The licensee was in the process of reactivating its manufacture and distribution activities for xenon-133 (Xe-133), pending FDA approval. The licensee established a radiation safety committee to review its uses, users, and facilities. All licensed activities were performed at the Maryland Heights complex. The licensee employed approximately 300 individuals at its site. The radiation safety program was managed by a dedicated full-time Radiation Safety Officer (RSO), supported by three health physicists and five health physics technicians. The radiation safety office staff audited all areas of use and storage at frequencies based on the amount of material processed/used. The radiation safety program also performed confirmatory surveys (daily, weekly, and quarterly based on amount of material and use) of these areas to ensure compliance with its NRC license and regulations.

### 2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 83822, 87125

Focus Areas Evaluated: All

This inspection consisted of interviews with licensee personnel; a review of select records including radiation safety committee meeting minutes, program audits, and corrective action program implementation with emphasis on three events involving elevated exposures to licensee personnel; tours of the reactor hot products and cyclotron hot products production areas; shipping and receiving and waste handling; and independent measurements. The inspector observed licensee personnel perform health physics audits and area surveys, personnel surveys, inventory of sealed sources, security of byproduct material, and use of personnel monitoring.

At the time of this inspection, the licensee initiated use of the new generator production line (V 4 Line); the licensee anticipated that the V 4 Line would be in full production by the end of the year and would cease its older V 3 production line. During the facility tours, the inspector observed: (1) posting and security of high radiation areas; (2) the new V 4 production line; (3) current V 3 production line; (4) the I-131 compounding and proposed Xe-133 dispensing lines; (5) product holding and distribution; (6) product return and reclamation; and (7) waste storage. The inspector accompanied health physics personnel while they performed laboratory audits and confirmatory surveys. The inspector noted personnel wore their assigned dosimetry and PPE and performed personal surveys upon exiting the production labs as required.

The following table summarizes the maximum total effective dose equivalent (TEDE) and the shallow dose equivalent (SDE) to personnel in millirem (mrem):

| <u>Year</u> | <u>TEDE</u> | <u>SDE</u> |
|-------------|-------------|------------|
| 2014        | 1,865       | 37,633*    |
| YTD 2015    | 1,869       | 7,729      |

\*elevated extremity exposure attributed to a needle stick incident previously reviewed during the last inspection.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector performed direct radiation measurements in and around the licensee's use and storage areas and the calibration lab which indicated similar results as noted in the licensee's survey records. Radiation levels in the unrestricted areas outside the production suites and the waste storage buildings were indistinguishable from background. All survey measurements in the restricted areas were comparable to the licensee's survey results. The inspector concluded that these radiation levels within the facility complied with Part 20 limits.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Condition 19. of License No. 24-04206-01 requires, in part, that the licensee maintain a corrective action program (CAP) to identify and correct deficiencies associated with radiation safety. The licensee established four investigation levels for incidents/items entered into its CAP. Since the previous inspection, the licensee entered three events at the severity II investigation level into its CAP. These events involved two elevated extremity exposures to personnel and one elevated exposure rate in the waste handling area.

**Incident No. 14-0122:** On December 8, 2014, an individual directly handled a 7.5-curie Mo-99/Tc-99m generator column during generator rework efforts in the generator production line. The rework area involved minor repairs to generators that failed QA/QC tests. The individual was tasked with labeling columns, recovering canisters and removing labeling from rejected generators. The individual did not routinely work in the production line was accustomed to working on returned product that decayed to background levels and treated as "cold." The individual retrieved a generator from the shielded storage bunker and placed it on a workspace to remove the labels and the canister. The individual removed the generator hood for preparation to transfer the generator into the hot cell for reprocessing; removal of the hood exposed the inlet needles. A coworker questioned the individual about the exposed inlet needles and expressed concern about a potential unsafe condition. The individual proceeded to disassemble the generator and reverted to familiar tasks used during his usual job duties of handling "cold" or decayed generators. Using needle-nose pliers in his left hand, the individual removed the shielded plug (with the generator column attached) causing his electronic dosimeter to alarm. The individual grabbed the column from the needle-nose pliers with the thumb and forefinger of his right hand and placed the column in a "sharps" container (unshielded). The licensee evacuated the immediate area and notified the health physics office. Health physics staff responded to the incident and secured the unshielded sharps vessel contained the generator column within the hot cell. The production lab resumed operations. The licensee held the generator column for decay

within the hot cell. The individual handled the generator column for approximately 3.8 seconds. Based on the licensee's re-enactment and dose assessment, the licensee assigned an extremity exposure of 7,413 mrem; the licensee determined that the individual received a whole body exposure of 22 mrem from this incident. The licensee determined that the root causes of this incident included lack of training, fatigue, limited standard operating procedure (SOP) guidance on the task the individual was assigned and multi-tasking. The licensee's corrective actions included providing training to its personnel, revising SOPs related to rejected generators, and improved supervision and work schedules.

**Incident No. 15-0025:** On February 28, 2015, an individual was cleaning and preparing a shipping cask for return to the vendor. The cask was released from the hot cell and the staff failed to identify residual Mo-99 within the R2 container. The individual removed the cask lid and started to remove the R2 sleeve (liner) when his electronic dosimeter alarmed. The individual proceeded to remove the plug and the sleeve, placing the sleeve in a bucket and replaced the plug within the cask with the lid secured. The individual notified the supervisor of the alarming dosimeter because he believed that the cask was contaminated. The licensee staff surveyed the cask and the sleeve and determined that the sleeve was reading approximately 70 Roentgen per hour (R/hr) at an unspecified distance. The licensee secured the sleeve within an overpack and placed it in a secured waste storage area for decay. The licensee determined that the root causes of this incident were attributed to an inadequate surveys (by the individual), lack of training, limited SOP guidance on the task the individual was assigned. The licensee's corrective actions included providing training to its personnel, revising SOPs related to casks cleaning/return. The licensee noted that this incident was similar to a previous incident that occurred in 2012 (Incident No. 12-0070). Corrective actions for the 2012 incident included the development of a "retrieval tool" for use by the hot cell staff to remove the R2 container from the cask. The production staff were also instructed to visually inspect the interior of the R2 container for residual liquid (Mo-99) prior to releasing a cask from the hot cell. According to the licensee's investigation, the whereabouts of the "retrieval tool" was unknown.

**Incident No. 15-0037:** On April 29, 2015, during a review of dosimetry reports, the licensee identified that an individual received an extremity exposure of 4,765 mrem for the March 2015 monitoring period. The licensee staff determined that the individual performed target rebuild work on a scatter plate used for the production of germanium-68/gallium-68 generators. Although this target was stored for decay in a bunker for nine months, germanium-68 (half-life 271 days) is a positron emitter with a long-lived energetic shallow dose contribution. The individual initially surveyed the scatter plate with a telescoping radiation survey meter (gamma radiation only) and measured that the plate was indistinguishable from background. The individual proceeded to rebuild the target for re-introduction into the cyclotron unit for production. These target rebuild efforts required more time than originally anticipated. As a result, the individual received an elevated extremity exposure. The licensee determined that the root causes of this incident included lack of awareness of the radiological properties of germanium-68. The licensee's corrective actions included providing training to its personnel and survey instrumentation with beta-radiation measuring capabilities.

The licensee applied its corrective actions from this incident to a planned hot cell remediation effort (germanium-68 contamination) in April 2015. In this remediation effort (Incident No. 15-0038), the licensee anticipated that four employees could receive

elevated extremity exposures. During this remediation effort, the licensee staff conducted surveys for gamma and beta radiation in order to properly characterize any adverse radiation safety conditions. As a result, the personnel received extremity exposures significantly less than the previous incident with results ranging from 272-886 mrem.

The incidents described above, which were reported in the licensee's CAP, are being reviewed further by NRC and are characterized as open items. The NRC will continue to review these incidents and will notify the licensee via separate correspondence of the outcome of the review.

5. PERSONNEL CONTACTED:

Eric Berry, Vice President, Environmental Law  
\*#Manuel Diaz, Radiation Safety Officer/Health Physics Manager  
Keith A. Edwards, Senior EHS Specialist  
\*Dale Eyman, Site Director  
Gerald Fuller, Human Resources Manager  
\*Eric Hill, Senior Health Physicist  
Reonda Hurt, Health Physics Technician  
\*Shaun Kelly, Principal Health Physicist  
Edward Keppel, Performance Excellence Manger  
Corey Lamb, Health Physics Tech Coordinator /EHS Specialist  
Bryan Lowery, Operations Manager  
Dustin Martin, Health Physics Technician  
Thomas McCormack, Distribution Manger  
Charles McCullum, Senior Health Physics Technician  
\*Brad Nelson, Senior Production Health Physicist/Emergency Manager  
\*#Jim Schuh, Director EHS-Nuclear Operations  
Kevin White, RHP Production Manager

\*Individuals at entrance meeting

All individuals listed above attended exit meeting on 9/25/2015

#Individuals contacted on 12/21/2015 for final telephonic exit meeting

Numerous production, transportation, support staff members were also contacted as part of this inspection.

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