INSPECTION RECORD

Region: III **Inspection Report No.** 2018001 **License Nos.** 24-04206-01
24-04206-02
24-04206-05MD

Docket Nos. 030-00001
030-38173
030-10801

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

Locations Inspected: Same as above

Licensee Contact: Manuel Diaz, RSO **Telephone No**. 314-595-3732

Program Codes: 03211/03210/02511 **Priorities**: 2/2/5

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

Last Inspection Date: 1/23-27/2017, with continued in office review through 5/22/2017

Date of This Inspection: 2/05-08/2018

Next Inspection Date: 2/5/2020 (X) Normal ( ) Reduced*

Summary of Findings and Actions:

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

Inspectors: Deborah A. Piskura, Senior Health Physicist, MIB, RIII

/RA by Aaron McCraw for/ Date: ***03/07/2018***
Signature

Bryan Parker, Senior Health Physicist, MLB, RIII

/RA/ received via email Date: ***03/06/2018***
Signature

Approved: Aaron T. McCraw, Chief, MIB, RIII

/RA/ Date: ***03/07/2018***
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
For the -01 license:		
95	11/14/2017	new radionuclides of use
94	07/05/2017	new RSC chairman
93	04/28/2017	completion of change of ownership transaction
For the -02 license:		
07	04/28/2017	completion of change of ownership transaction
For the -05MD license:		
49	04/28/2017	completion of change of ownership transaction

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations of NRC requirements were identified during previous inspection of the licensee's biennial exercise on October 12, 2017.

The last routine inspection was conducted on January 23-27, 2017, with continued in-office review through May 22, 2017. The inspectors identified one violation involving the failure to conduct adequate surveys, as required by Title 10 of the *Code of Federal Regulations* (CFR) 20.1501. The corrective actions for this violation were reviewed during the inspection of the biennial exercise. The violation was closed. The inspectors also issued two NCVs for licensee-identified and corrected issues concerning: (1) the licensee's unauthorized transfers of two depleted uranium shields as required by 10 CFR 40.51(a) and 40.51(b)(5), and (2) the licensee's failure to timely submit an annual report or the results of individual monitoring for each individual for whom monitoring, as required by 10 CFR 20.2206.

3. INCIDENT/EVENT HISTORY:

No events had been reported by the licensee since the previous inspection

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The licensee operated a Type A broadscope manufacturing and distribution program under its -01 license. The licensee's operations included the manufacture of molybdenum-99/technetium-99m (Mo-99/Tc-99m) generators, sodium iodide-131 and iodide-123, indium-111, thallium-201, germanium-68 (Ge-68), and other cyclotron-produced products, and cold products/kits for compounding radiopharmaceuticals. No iodine-131 had been distributed since November 2017 due to availability of supply. The licensee was in the process of reactivating its manufacture and distribution activities for xenon-133, pending FDA approval. The licensee recently received authorization to use

thorium-227 for product development. The licensee possessed six cyclotron units used for the production of various materials under its -02 license; at the time of this inspection, five units were in operation for the production of isotopes. The licensee's medical distribution activities were authorized under its -05MD license. The licensee used a software-based system for its distribution of radiopharmaceuticals to customers. The licensee also maintained an electronic copy of each customer's license to verify the customer's request against the customer's license authorizations. If the customer was not authorized to receive a radionuclide or quantity, the licensee's ordering system displayed an alert, prompting additional review of the order by the staff.

All licensed activities were performed at the Maryland Heights complex. The licensee employed approximately 300+ individuals at the site. The radiation safety program was managed by a dedicated full-time RSO, supported by three health physicists and five health physics technicians. The radiation safety program staff audited all areas of use and storage at frequencies based on the amount of material processed/used. The radiation safety program staff 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.

The licensee established a radiation safety committee (RSC) to review its uses, users, and facilities. The membership of the committee included staff from various manufacturing groups. In mid-2017, the licensee reorganized its RSC with the addition of several new members. The licensee conducted RSC meetings on a quarterly basis. The licensee established a quorum for each RSC meeting and documented its business in meeting minutes. The meeting topics included approval of new uses and users; dose reduction initiatives, items entered into the corrective action program (CAP), and radiation protection issues.

The licensee reviewed the content of its radiation protection program annually. The licensee documented the results of its annual reviews and presented the audit findings and recommendations to the RSC (last January 2018). The licensee continued its dose reduction initiative. In 2017, the licensee replaced previously contaminated ductwork for its hot cells in the cyclotron chemistry lab. This dose reduction initiative had resulted in a decrease in personnel exposures by 11 percent in 2016 and 39 percent in 2017.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 83822, 87125

Focus Areas Evaluated: 03.01, 03.02, 03.03, 03.04, 03.05, 03.06, & 03.07 and 03.08(for IP 83822)

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; tours of selected reactor hot products and cyclotron hot products production areas; shipping and receiving; and independent measurements. The inspectors observed licensee personnel perform area surveys in the xenon/iodine lab, personnel surveys, security of byproduct material, and use of personnel monitoring.

During the facility tours, the inspectors observed: (1) posting and security of high radiation areas; (2) cyclotron chemistry operations; (3) xenon production trials and validations; (4) radioactive materials receipt and package surveys; and (5) product holding, surveys, labeling, and distribution. The inspectors toured the proposed laboratory for future use/production of an anticipated new product. The inspectors noted personnel wore their assigned dosimetry and personal protective equipment and performed personal surveys upon exiting the production labs as required. The inspectors observed hot cell operations for the preparation of a bulk quantity of Ge-68 in the cyclotron chemistry lab. The technician used time, distance and shielding to handle the material and measure the vial in the dose calibrator.

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

Year	TEDE	SDE
1/1/2017-11/30/2017	2,240	10,506

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspectors performed independent surveys using two Canberra Model MRAD213 survey meters (NRC Tag No 33571G and 33575G), calibration dates, 06/16/2017 and 10/6/2017, respectively. The inspectors performed direct radiation measurements in and around the licensee's use and storage areas and the spent target bunker adjacent to Building 800, 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 inspectors concluded that the radiation levels within the facility complied with Part 20 limits. The inspectors' survey results were within -/+ 20 percent of the licensee's survey readings. At the property fence line (approximately 80 feet from the target bunker) the inspectors measured a maximum of 50-60 microRoentgen per hour.

The TLD badge data for the 2017 monitoring period showed the maximum dosimetry data detected at the fence line near Building 800. By applying the assigned occupancy factor, the inspectors noted that the maximally exposed member of the public would be expected to receive an annual dose 39.3 millirem, which is below the NRC's annual limit of 100 millirem. The area where the licensee detected the highest dose was approximately 200 feet from the fence line (location of the TLD badge). The licensee evaluated the public dose from its air effluents by determining the actual quantities used at the plant, as well as air sampling data, and applying appropriate release fractions. The result of the licensee's evaluation for 2017 showed that the dose from air effluents (0.6 millirem) was less than the applicable NRC constraint of 10 millirem.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

Condition 19 of License No. 24-04206-01 requires, in part, that the licensee maintain a 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 four events at the category II investigation level into its CAP. These events involved an unmonitored release of approximately 2 millicuries of Mo-99/Tc-99m into the sanitary sewer system, an unauthorized transfer

of a depleted uranium generator to a Canadian customer, and the receipt of a package from a European customer incorrectly labeled as an empty package containing vials of Ge-68. A fourth event (Incident No.18-008) that represented radiological and regulatory significance involved the failure to perform surveys of a package within 3 hours of receipt, as required by 10 CFR 20.1906(c).

On January 16, 2018, at approximately 10:30 a.m., the licensee received a package containing approximately 3,000 curies of Mo-99 (labeled as Yellow III) from its sister plant in Petten, Holland. Typically, the licensee received these packages of bulk Mo-99 in the evening. However, due to production and shipping schedules at Petten, this shipment arrived approximately 9 hours early. When the courier arrived at the licensee's facility, he did not declare the contents of this load to the security guard. The courier placed the package in the licensee's receiving area and secured the door. Opening the roll up door activated a blue flashing light providing visible alert to the staff of deliveries. The package remained in the receiving area for approximately 5 hours. Condensation had formed on the window possibly obstructing the view of the alarm light. At approximately 3:00 p.m., the RSO walked by the receiving area and noticed the blue flashing light, indicating that the roll up door to the receiving area had been opened. The RSO requested the radiation safety program staff to confirm if a package had been received. At approximately 3:15 p.m., member of the radiation safety program staff identified that a package had been delivered, unexpectedly early, and performed surveys for radioactive contamination and radiation levels.

Title 10 CFR 20.1906(b) requires each licensee to monitor the external surfaces packages labeled with a Radioactive White 1, Yellow II, or Yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4; and (2) radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Appendix A to Part 71.

Title 10 CFR 20.1906(c) requires licensees to perform the monitoring required by paragraph (b) above, as soon as practicable, but not later than 3 hours after receipt of the package if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

The licensee's failure to perform surveys for radioactive contamination and radiation levels on a Yellow III package containing 3,000 curies of Mo-99 within 3 hours after receipt of the package is a violation of 10 CFR 20.1906(c).

The licensee attributed the root cause of the late package surveys to a miscommunication between the licensee's security staff and the courier. As a result, the security staff, in turn, did not notify the radiation safety program staff of the arrival of the package to prompt the radiation safety program staff to perform the required surveys of the package. The licensee also identified that the courier knew the location of the key that operated the rollup door and proceeded to place the package in the receiving area without the knowledge of the staff. The licensee's corrective actions included securing the keys to the rollup door, reviewing site access procedures for contractors and couriers, and directing the wiring connection for the blue alarm light to the radiation safety program office to alert the staff of any package receipts.

The licensee identified this incident and entered it into the CAP. This non-repetitive, licensee-identified, and corrected violation is being treated as a Non-Cited Violation, in accordance with Section 2.3.2.b of the NRC Enforcement Policy.

5. PERSONNEL CONTACTED:

*Todd Barnes, Production Manager
*#Manuel Diaz, Radiation Safety Officer/Health Physics Manager
*#Janet Dohm, Admin
*#Eric Hill, Senior Health Physicist
*Gary Hosna, Vice President, Compliance
#Sarah Jaeger, Materials Manager
*#Shaun Kelly, Principal Health Physicist
*#Tony Kinney, Associate General Counsel
*#Corey Lamb, Health Physics Tech Coordinator /EHS Specialist
*#Thomas McCormack, Distribution Manger
*#Brad Nelson, Senior Production Health Physicist/Emergency Manager
*#Richard Proehl, Site Director
#Trisha Thompson, HR Generalist
#Sumit Verma, Chief Operating Officer
*Kurt White, RHP Production Manager
*#Mike Witte, Plant Sourcing Manager & Chairman, Radiation Safety Committee

*Individuals at entrance meeting
#Individuals listed above attended exit meeting on 2/8/2018

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

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