INSPECTION RECORD

Region: III **Inspection Report No.** 2017002 **License No.** 24-04206-01
Docket No. 030-00001

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

Locations Inspected: Same as above

Licensee Contact: Manuel Diaz, Radiation Safety Officer **Telephone No**. 314-654-7661

Program Code: 03211 **Priority**: 2

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

Last Inspection Date: 10/22/2015 **Date of This Inspection**: 10/12/2017

Next Inspection Date: No change (X) Normal ( ) Reduced

Justification for reducing the routine inspection interval: N/A

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
(X) Follow-up on previous violations

Inspector(s) Deborah A. Piskura, Senior Health Physicist, RIII

/RA/ Date 11/07/2017
Signature

Jason VonEhr, Health Physicist, RIV

/RA/ via email Date 11/02/2017
Signature

Approved Aaron T. McCraw, Chief, MIB, RIII

/RA/ Date 11/08/2017
Signature

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

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

AMENDMENT #	DATE	SUBJECT
94	July 5, 2017	new RSC chair
93	April 28, 2017	change of control, organizational changes

On September 20, 2017, the licensee provided a revised contingency plan (Revision 8), incorporating minor changes to internal phone numbers. The licensee intended to submit a revised contingency plan to the NRC to be incorporated into its license.

2. INSPECTION AND ENFORCEMENT HISTORY:

No violations of NRC requirements were identified during previous inspections of the licensee's biennial exercises on October 3, 2013, and October 22, 2015.

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) Section 20.1501. The inspectors also identified two non-cited violations (NCVs) concerning: (1) unauthorized transfers of two depleted uranium shields, as required by 10 CFR 40.51(a) and 40.51(b)(5), and (2) the failure to timely submit an annual report or the results of individual monitoring for each individual for whom monitoring is required, as required by 10 CFR 20.2206.

A special inspection on January 12-15, 2016, with continued in-office review through February 19, 2016, was conducted to review open items identified during the previous routine inspection on September 21 to 25, 2015, with continued in-office review through December 21, 2015. The inspectors identified four NCVs involving two failures to implement a procedure and one failure to maintain a procedure, as required by License Condition 20. The fourth NCV concerned the failure conduct adequate radiation surveys to evaluate the potential radiological conditions before performing work on a contaminated component, as required by 10 CFR 20.1501.

3. INCIDENT/EVENT HISTORY:

No open items or events involving the licensee's emergency plan have been reported since the previous inspection of licensee's biennial exercise.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Mallinckrodt Nuclear Medicine LLC (licensee) operated a Type A broadscope manufacturing and distribution program. The licensee's operations included the manufacture of Moly-Tech generators, iodine-131, xenon-133, numerous isotopes from its cyclotron production, including germanium-68, and cold products/kits for compounding radiopharmaceuticals. 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 full-time Radiation Safety Officer, supported by three health physicists and five health physics technicians. In addition, the radiation safety program is supplemented by a dedicated radwaste coordinator and five technicians. Based on the licensee's possession limit of iodine-131, the licensee is required by 10 CFR 30.32(i) and License Condition 17 to establish and implement a contingency plan. As part of the contingency plan, and 10 CFR 30.32(i)(3)(xii), the licensee is required to conduct biennial exercises.

The inspectors observed the licensee's required biennial exercise of its Emergency Plan. Observations included the pre-exercise brief, response to the exercise scenario by the licensee staff, and the post-exercise critique.

This inspection included a review of the licensee's corrective actions taken in response to the violation identified during the previous routine inspection. The last routine inspection was conducted on January 23-27, 2017, with continued in-office review through May 22, 2017; one violation of 10 CFR 20.1501 was identified. The violation involved the licensee's failure to conduct an adequate radiation survey to evaluate the potential radiological conditions (personal contamination from a spill involving germanium-68) before exiting a restricted area. The inspectors attributed the cause of the spread of the contamination to the employee's failure to conduct reasonable personal surveys, including surveys of materials carried out of the laboratory where he had just handled radioactive materials. The licensee submitted its reply to the Notice of Violation in a letter dated July 31, 2017; the licensee's corrective actions included revising its procedures for conducting personnel surveys and providing instruction to the staff. The inspectors discussed this event and the corrective actions, and re-emphasized the need to ensure that events entered into the corrective action program contain specific details of the events to provide institutional knowledge from the events. This violation is considered closed.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 88051

Focus Areas Evaluated: 02.01, 02.02, and 02.03

This was an announced inspection to observe and evaluate licensee personnel demonstrate their ability to implement its Contingency Plan during the required biennial exercise. The exercise of the Contingency Plan adequately tested the licensee's capability to respond to a radiological accident. The licensee staff completed an evacuation of building 700 and took appropriate emergency response actions in response to the event in a timely manner. Command and control, hazard assessment, and communications were adequate. The exercise included participation by the Maryland Heights Fire Department, the Missouri Department of Health, Radiological/ Chemical Response Program, and other agencies.

The exercise scenario involved a fire resulting from a chemical spill within a hot cell that spread up to the filter bank in cyclotron chemistry lab in Building 700. The scenario released one curie of germanium-68. As a result of the accident scenario, the "victim" suffered injuries and personal contamination. The licensee personnel in the lab initiated

the response by pulling the fire alarm. This initiated the activation of the Emergency Response Team and an audible alarm signaling all personnel to evacuate the buildings and meet at the designated muster/assembly points. Licensee emergency response staff promptly responded to the scene of the accident with decontamination and protective equipment. The Emergency Response Manager arrived at the scene of the accident within several minutes while the Emergency Coordinator and staff arrived and assembled at the licensee's Emergency Control Center within minutes.

The Emergency Coordinator, following communication with the Emergency Response Manager, initially classified the event as an "Alert." The Emergency Coordinator obtained a dose assessment (using RASCAL) to confirm this classification using default source term values. The licensee collected air samples from strategically determined locations in order to obtain data for dose modeling. As survey results and air sampling data became available, the Emergency Coordinator elevated the classification to a "Site Area Emergency." Exercise participants monitored staff evacuation and assembly at the designated points and noted the accountability of all individuals. Exercise participants in the Emergency Control Center made required notifications to the State of Missouri, the NRC's HOO and Region III, and licensee senior management representatives. The exercise participants provided updates to the required notifications.

Licensee staff coordinated their response to the fire by pulling the automatic alarm to the Maryland Heights Fire Department. Licensee response staff, supervised by the Emergency Response Manager used decontamination stations and performed radiation surveys to assess and mitigate the radiological hazards associated with the event. The licensee dispatched four separate survey teams to the accident, addressing radiological contamination issues, and collecting radiological data. Due to the nature and the quantity of the germanium-68 involved in the scenario, the response team assessed the radiological hazards and moved the individual to a safe location while attending to his injuries/medical condition. The responders determined the victim's medical condition required treatment at the hospital. Response staff assessed the radiological hazards at the scene and collected field air sampling data.

Licensee staff who participated in the exercise, conducted a post-exercise critique. The licensee staff discussed the positive and negative findings associated with the emergency plan, facilities, equipment, licensee staff training, and overall event response effectiveness. The critique findings were used as an effective means of improving emergency response and they were consistent with those identified by the inspectors.

The inspectors determined that the exercise of the Contingency Plan adequately tested the licensee's capability to respond to a radiological accident. Licensee staff completed its evacuation and took appropriate emergency response actions in response to the event in a timely manner. Command and control, hazard assessment, and communications were adequate. The post-exercise critique findings served as a means of improving emergency response, and were consistent with those identified by the inspectors. The licensee entered the exercise critique findings into its Corrective Action Program.

The inspectors provided feedback to the licensee on their observations noted during the exercise with the following areas for improvement:

(1) Survey technique of the victim and fire fighters was too fast (for adequate response from the survey meter) and too far from the surfaces to be able to adequately detect contamination.
(2) One fire fighter was seen exiting Building 800 and chewing gum (note that the individual did not enter a restricted area).
(3) Some radio communications did not specify “this is a drill” or “this is an exercise”.
(4) During the notification call to the HOO and Region III, the licensee referred to themselves as “Curium” the name of the new company rather than “Mallinckrodt” the name on the license. The licensee informed the inspectors that they will be changing their name in the near future as there is limited time they will be permitted to refer to themselves as “Mallinckrodt” according to the transaction of sale.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

None for the biennial exercise.

In follow up to the public dose data previously reported by the licensee, the inspectors performed independent surveys of the spent target bunker adjacent to Building 800 using a Canberra Model MRAD213 survey meter (NRC Tag No 33571G), calibration date, 02/17/2017. The inspectors’ survey results were within 20 percent of the licensee’s survey readings. The maximum readings were found at the surface of the building, 200-300 microRoentgen per hour (µR/hr), with an average reading of 100 µR/hr. The immediate area at the bunker, in the driveway, measured 50-70 µR/hr. The maximum reading at the access road guard rail (approximately 30 feet away above grade) was 200 µR/hr, with an average of 50-100 µR/hr. At the property fence line (approximately 80 feet from the target bunker), the inspectors measured an average of 50-60 µR/hr.

In IR 03000001/2017001(DNMS), the inspectors noted that the exposures recorded on the licensee’s TLD badges to evaluate doses to members of the public from Building 800 were trending higher for the years 2015 and 2016 at the fence line due to a higher contribution from waste material stored in the spent target bunker. The licensee determined occupancy factors for these ten stations based on the fraction of the workweek during which the space beyond the fence line was potentially occupied. The licensee determined occupancy factors of either 0.03 (3 percent) and 0.30 (30 percent) for its fence line area. The licensee based these occupancy factors on data collected through observations of activities and contacts with the adjacent businesses. The licensee determined by calculation, applying the occupancy factors of each respective fence line TLD recorded dose, that the TEDE to the individual member of the public did not exceed NRC’s annual dose limit of 100 mrems per year. Although the TLD badge data for the YTD 2017 monitoring period showed dosimetry data higher than reported for 2016, 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 below NRC’s annual limit of 100 millirems. The closest receptor/member of the public to this area where the licensee detected the highest dose would be approximately 200 feet from the fence line (location of the TLD badge).

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

No violations of NRC requirements were identified during this inspection.

5. PERSONNEL CONTACTED:

#Eric Barry, Vice President, Environmental Law
#Manuel Diaz, Health Physics Manager, Radiation Safety Officer
Eric Hill, Senior Health Physicist
#Gary Hosna, Vice President Compliance
Shaun Kelly, Principal Health Physicist / Coordinator of this Biennial Exercise
Corey Lamb, EHS Specialist
Brad Nelson, Senior Health Physicist, RHP Emergency Manager
#Richard Proehl, Site Director
#Dale Simpson, Senior Director, Logistics and Transportation

Keith Henke, Manager Radiological/Chemical Response Program, State of Missouri
Steve Reinhart, Assistant Chief, Maryland Heights Fire Department

Numerous players in the biennial exercise were also contacted as part of this inspection

Attended exit meeting on October 12, 2017.