

INSPECTION RECORD

Region: III

Inspection Report No. 2015002

License No. 21-04206-01

Docket No. 030-00001

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

Locations Inspected: Same as above

Licensee Contact: Manuel Diaz, Radiation Safety Office

Telephone No. 314-654-7661

Program Code: 03211 Priority: 2

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

Last Inspection Date: 09/21/2015 Date of This Inspection: 10/22/2015
Next Inspection Date: 09/21/2016 (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
- () Follow-up on previous violations

Inspectors: Deborah A. Piskura, Senior Health Physicist

/RA/
Signature

Date 11/10/2015

Navid N. Tehrani, Health Physicist

/RA/
Signature

Date 11/10/2015

Approved: Aaron T. McCraw, Chief, MIB

/RA/
Signature

Date 11/12/2015

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>
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No licensing actions had been issued since the previous routine inspection on September 22-25, 2015. On March 31, 2014, the licensee submitted a revised contingency plan (Revision 7), incorporating minor changes and corrections. The revised contingency plan was approved in Amendment No. 89, issued on May 22, 2014.

2. INSPECTION AND ENFORCEMENT HISTORY:

The last routine inspection of this licensee was on September 21-25, 2015; the inspection was ongoing with in office review. No violations of NRC requirements were identified during previous inspections of the licensee's biennial exercises on October 3, 2013, and September 13, 2011.

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:

The licensee operated a Type A broad scope manufacturing and distribution program. The licensee's operations included the manufacture of Moly-Tech generators, I-131, Xe-133 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 dedicated full-time RSO, supported by three health physicists and five health physics technicians. Based on the licensee's possession limit of I-131, the licensee is required by Section 30.32(i) and License Condition 18 to establish and implement a contingency plan. As part of the contingency plan, and Section 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.

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 600 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 and the State of Missouri, Radiological Emergency Preparedness Section. The licensee's post-exercise critique findings identified several means of improving emergency response. The inspectors' findings were consistent with those identified by the licensee.

The exercise scenario involved a fire within the filter bank in Building 600, the iodine production lab. An individual was injured and required decontamination in the scenario. The fire released five curies of I-131. As a result of the accident scenario, the victim suffered injuries and personal contamination. The licensee personnel in the lab instigated 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 assembly points. Licensee emergency response staff promptly responded to the scene of the accident with proper 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 new 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 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, and licensee senior management representatives. The exercise participants provided updates to the required notifications.

Response staff assessed the radiological hazards at the scene and administered first aid care to the victim. Due to the nature and the quantity of the iodine-131 involved in the scenario, the response team 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.

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.

Response staff assessed the radiological hazards at the scene and administered care to the victim. 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.

Licensee staff who participated in the exercise, conducted an 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 noted that the licensee implemented several actions/recommendations from the 2013 exercise such as using RASCAL for its dose assessment, taking field air samples to re-create real-time measurement efforts, and relocating its Emergency Control Center to a larger space.

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 exercise included participation by the City of Maryland Heights Fire Department and the State of Missouri, Emergency Management Agency. The post-exercise critique findings served as a means of improving emergency response, and were consistent with those identified by the inspectors.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

None. Biennial exercise.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

No violations of NRC requirements were identified during this inspection.

5. PERSONNEL CONTACTED:

Manuel Diaz, Health Physics Manager, RSO
Dale Eyman, Site Director
Melissa Fischer, EH&S Associate
Eric Hill, Senior Health Physicist
Shaun Kelly, Principal Health Physicist / Coordinator of this Biennial Exercise
Brad Nelson, Senior Health Physicist, RHP Emergency Manager
Bob Schager, EH&S Manager
Jim Schuh, Radiological Programs Director
Scott Surovi, Director, Transportation Programs

Greg Voss, Radiological Emergency Preparedness Manager, State of Missouri

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

All individuals listed above attended exit meeting on October 22, 2015.