

ENCLOSURE 6 - INSPECTION RECORD

Region: III Inspection Report No. 2019002

License No. 24-04206-01

Docket No. 030-00001

Licensee: Curium US LLC
2703 Wagner Place
Maryland Heights, MO 63043

Location 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: 10/12/2017

Date of This Inspection: 10/17/2019

Next Inspection Date: 10/29/2019*

() Normal

(X) Reduced

Justification for reducing the routine inspection interval:

*During this inspection, the licensee informed the inspector of a significant molybdenum-99 contamination event in August 2019, involving multiple individuals. An individual who performed cleaning tasks on a shipping cask, became contaminated and tracked contamination throughout two buildings and the parking lot of the licensee's plant. Approximately 50 individuals were required to surrender their shoes to the radiation safety office. Based on the significance of this event, the NRC will perform a reactive inspection during the week of October 28, 2019.

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: Deborah A. Piskura, Senior Health Physicist, RIII

/RA/

Signature

Date: 11/8/19

Approved: Robert Ruiz, Acting Chief, MIB, RIII

/RA/

Signature

Date: 11/13/19

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 amendments have been issued related to the licensee's contingency plan.

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 September 21, 2015 and October 12, 2017.

The last routine inspection was conducted on March 18-22, 2019, with continued in-office review through April 11, 2019. The inspectors identified one violation involving the failure to perform surveys on three packages as required by 10 CFR 20.1906(b).

The previous 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 10 CFR 20.1501. The inspectors also identified two NCVs concerning: (1) unauthorized transfers of two depleted uranium shields as required by 10 CFR Section 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 as required by 10 CFR 20.2206.

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, 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 dedicated full-time RSO, supported by two health physicists, one contract health physicist, and five health physics technicians. In addition, the radiation safety program is supplemented by a dedicated radwaste coordinator and four technicians. Based on the licensee's possession limit of iodine-131, the licensee is required by Paragraph 30.32(i) and License Condition 17 to establish and implement a contingency plan. As part of the contingency plan, and Item 30.32(i)(3)(xii), the licensee is required

to conduct biennial exercises. At the time of this inspection, the licensee did not possess or process iodine-131.

The inspector 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 March 18-22, 2019, with continued in-office review through April 11, 2019; one violation of 10 CFR 20.1906(b) was identified. The violation involved the licensee's failure to perform surveys for radioactive contamination and radiation levels on three Yellow II packages, received on November 10, 2018, each containing approximately 1.1 millicuries of thorium-227, within three hours of receipt of these packages. The licensee submitted its reply to the NOV in letter dated June 7, 2019; the licensee's corrective actions included revising its procedures for receiving and surveying incoming radioactive packages and providing instruction to the courier staff. The violation of 10 CFR 20.1906(b) is considered closed.

2. SCOPE OF INSPECTION:

Inspection Procedures Used: 88051 and 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 promptly completed an evacuation of Building 600 and took appropriate emergency response actions in response to the event. Command and control, hazard assessment, and communications were adequate. The exercise was limited to participation by the Maryland Heights Fire Department. The Missouri Department of Health, Radiological/ Chemical Response Program, the Maryland Heights Police Department and other agencies elected not to participate in this exercise. The licensee's post-exercise critique findings identified several means of improving emergency response. The inspector's findings were consistent with those identified by the licensee.

The exercise scenario involved a simulated fire on the loading dock of Building 600, with the fire approaching chemicals and compressed gases. A shipping cask of molybdenum-99 and package containing iodine-123 were located on the dock. Four of the licensee responders were "victims" requiring decontamination in the scenario. The scenario released 1.2 curies of iodine-123; the molybdenum-99 remained contained within the cask contributing no radiological consequences to the scenario. 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.

When the licensee staff contacted the Region III office, the call was transferred to a member outside of the division; this individual was unfamiliar with the licensee's emergency plan and exercise requirements. The licensee recognized that they need to request their notification call to be directed to the Division of Nuclear Materials Safety.

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 molybdenum-99 and iodine-123 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 inspector.

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 was limited to participation by the City of Maryland Heights Fire Department. The post-exercise critique findings served as a means of improving emergency response and were consistent with those identified by the inspector. The licensee entered the exercise critique findings into its Corrective Action Program.

The inspector provided feedback to the licensee on the observations noted during the exercise.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

None for the biennial exercise.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

No violations of NRC requirements were identified during this inspection.

The licensee informed the inspector of a significant personnel contamination incident that occurred in August 2019. An individual was cleaning and preparing a molybdenum shipping cask for return to the vendor. The cask was released from the hot cell and the staff identified residual molybdenum-99 within the inner container. The individual removed the cask lid and started to remove the R2 sleeve (liner) when he recognized that the cask was contaminated. The individual became contaminated and tracked contamination throughout two buildings and the parking lot of the licensee's plant. Approximately 50 individuals were required to surrender their shoes to the radiation safety officer. The licensee determined that the root causes of this incident were attributed to inadequate surveys (by the individual), and the individual's failure to follow the standard operating procedure (SOP) for the task. The licensee's corrective actions included providing training to its personnel, revising SOPs related to casks cleaning/return. The inspector noted that this incident involving elevated residual molybdenum-99 contamination was similar to two previous incidents that occurred in 2015 and 2012. However, these previous incidents did not result in personnel contamination. This contamination incident will be reviewed during a separate inspection.

5. PERSONNEL CONTACTED:

Manuel Diaz, Health Physics Manager, Radiation Safety Officer (#)
Elizabeth Engelmann, Senior Health Physicist (#)
Eric Hill, Senior Health Physicist
Jim Schuh, Consulting Health Physicist / Coordinator of this Biennial Exercise (#)
Mr. Richard Proehl, Vice President, Operations, North America (#)
Steve Reinhart, Chief, Maryland Heights Fire Department

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

(#) Attended exit meeting on October 17, 2019.

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