INSPECTION RECORD

Region: III **Inspection Report No.** 2019-001 **License Nos.** 24-04206-01
24-04206-02
24-04206-05MD
Docket Nos. 030-00001
030-38173
030-10801

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

Location 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: February 5-8, 2018 **Date of This Inspection**: March 18-22, 2019, with continued in-office review through April 11, 2019

Next Inspection Date: March 18, 2021 (X) Normal ( ) Reduced
Justification for reducing the routine inspection interval: N/A

Summary of Findings and Actions:

( ) 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
(X) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspectors: Deborah A. Piskura, Senior Health Physicist, Materials Inspection Branch

/RA/ Date ***05/07/2019***
Signature

Bryan A. Parker, Senior Health Physicist, Materials Licensing Branch

/RA by Aaron McCraw for/ Date ***05/09/2019***
Signature

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

/RA/ Date: ***05/09/2019***
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:		
97	9/25/2018	Increase in possession limit and expanded scope of use for thorium-227 (Th-227)
96	08/27/2018	Name change, increase possession limit and expanded scope of use for Th-227, and changes to possession limits for sealed sources with atomic nos. 83-103
For the -02 license:		
08	08/27/2018	Name change
For the -05MD license:		
51	09/25/2018	Add Th-227 distribution authorization; product labeling for Th-227
50	08/27/2018	Name change

2. INSPECTION AND ENFORCEMENT HISTORY:

The last routine inspection was conducted on February 5-8, 2018. The inspectors identified one Noncited Violation (NCV) concerning the failure to monitor the external surfaces of a package, received on January 16, 2018, for removable contamination and for radiation levels, no later than three hours after the package was received as required by 10 CFR 20.1906(c).

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

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 manufacturing of Moly-Tech generators; sodium 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 produced or distributed since November 2017. The licensee recently received authorization to use Th-227, copper-64 and gallium-68 (Ga-68) 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 used its cyclotron units for the production of Ga-68, Ge-68, indium-111, and thallium-201. The licensee added beam ports for the in-house production of copper-64 and research and development on iodine-123.

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 of customer's license; the customer support staff verified 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. The licensee updated its ordering system to prohibit the ordering and distribution of iodine-131, which it had ceased dispensing in November 2017.

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 (HPs) and five HP 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, monthly, and quarterly based on amount of material and frequency of 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. The licensee conducted RSC meetings on an as-needed basis, typically quarterly. 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, incidents and items entered into the corrective action program (CAP), and radiation protection issues. No concerns were noted from review of minutes for 2018 RSC meetings.

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 on February 28, 2018 for the 2017 calendar year. The licensee continued its occupational dose reduction initiative.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 83822, 87102, 87125

Focus Areas Evaluated: All, as applicable

This inspection consisted of interviews with licensee personnel; a review of select records including RSC meeting minutes, program audits, and CAP 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 health physics area surveys in the V4 production line and the Th-227 lab, personnel surveys, security of byproduct material, and use of personnel monitoring.

During the facility tours, the inspectors observed: (1) posting and control of high radiation areas; (2) cyclotron production and chemistry operations; (3) Th-227 production trials; (4) V4 line moly formulation and column loading; (5) radioactive material package receipt and surveys; (6) training facilities; and (7) renovated areas for new production areas for copper-64 and iodine-123. 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 in accordance with ALARA principles to handle the material and measure the vial in the dose calibrator. The inspectors also toured the proposed laboratory (including the ventilation system in the penthouse) for future use/production of two anticipated new products.

The inspectors reviewed selected customer licenses for product distributed from the previous V4 generator production run. The inspectors noted that approximately one-third of this sampling of licenses appeared to be out of date or under timely renewal for an extended time (i.e., four years). Discussions with the licensee revealed that they relied on the customer to provide its most current license for the files. The inspectors prompted the licensee staff to implement a mechanism to periodically confirm or request the most current version of each customer's license.

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

Year	TEDE	SDE
2018	1,185	9,590
YTD 2019	266	2,559

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspectors performed independent surveys using a Canberra Model MRAD213 survey meter (NRC Tag No 33569G), calibration date 07/27/2018. 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 these 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 25-30 µR/hr.

The TLD badge data for the 2018 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 of 25 millirem which is below the NRC's annual limit of 100 millirem. 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). 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 results of the licensee's evaluation for 2018 demonstrated that the dose from air effluents (0.54 millirem) was less than applicable annual 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. In 2018, the licensee entered 95 incidents into its CAP. The majority of these events were categorized as Level 3 and 4 incidents. These incidents involved low level contamination of personnel protective clothing or shoe covers as a result of spills or improper de-gowning techniques.

Since the previous inspection, the licensee entered five events at the Category 2 investigation level into its CAP. These events involved an unsecured space in the penthouse posted as a high radiation area (however the actual radiation levels in this area was determined to be indistinguishable from background); a generator shipment to a hospital in excess of the maximum quantity authorized by the customer's Agreement State license; and the shipment of two packages with damaged/missing DOT labels. A fifth event (Incident No.18-137) that represented radiological and regulatory significance involved the failure to perform surveys of three packages within three hours of receipt as required by 10 CFR 20.1906(c).

On Saturday, November 10, 2018, at approximately 5:10 p.m., the licensee received a total of four packages containing licensed material, three packages, each containing approximately 1.1 millicuries of Th-227 in normal form and one package containing 2.8 curies of iodine-123, also in normal form. All four packages were labeled as "Radioactive Yellow II." Typically, the licensee received packages containing Th-227 on Mondays. However, the driver observed that these Th-227 packages were addressed to the licensee and included them with another package he was scheduled to retrieve from Chicago-O'Hare airport. When the driver arrived at the licensee's facility, he stated the contents of this load to the security guard. The driver declared the package of iodine-123 as a "radioactive" package and stated that he did not know the contents of the three remaining packages. The licensee staff interpreted that these other three packages (containing Th-227) were not "radioactive" and characterized these packages as "miscellaneous". Licensee staff at the loading dock of Building 600 granted access to the driver who placed all the packages in the licensee's receiving area. Licensee production staff retrieved and surveyed the package containing iodine-123; the contents were processed that evening into customer product. The three packages containing Th-227 remained in the receiving area for approximately 38 hours.

At approximately 7:30 a.m. on November 12, 2018, a HP technician walked by the receiving area and noticed the Th-227 packages on the floor. The technician informed a member of the HP staff of these packages. At approximately 7:30 a.m., a member of the

HP staff identified that these packages had been delivered, unexpectedly early, and performed the required 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 three hours after receipt of the package if it is received during the licensee's normal working hours, or not later than three 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 three Yellow II packages, each containing approximately 1.1 millicuries of Th-227, within three hours after receipt of these packages is a violation of 10 CFR 20.1906(c).

The licensee identified this incident and entered it into the CAP. The licensee attributed the root cause of the late package surveys to a miscommunication between the licensee's security staff and the courier. The licensee's corrective actions included changing drivers, changing the day of the week for delivery of Th-227 packages, creating a monthly calendar listing all expected package deliveries, and changing its procedure and process for package surveys. The inspectors noted that this incident was similar to another instance, involving a failure to timely survey a package, entered into the licensee's CAP (Incident No.18-008) and described in Inspection Report 03000001/2018001(DNMS).

The inspectors identified multiple causes of the violation. Based on the inspectors' assessment of this incident, the licensee staff may have misinterpreted the driver's statements that he did not know what the three packages contained as meaning that these packages were not radioactive. The inspectors were unable to determine how these packages were believed to be not radioactive when these boxes were labeled as "Radioactive Yellow II" and delivered with the iodine-123 package, also labeled as "Radioactive Yellow II." The Th-227 packages remained in the Building 600 receiving area in plain view of the licensee staff who intermittently entered the area. According to the staff, no one asked questions about or investigated these packages until the morning of November 12, 2018.

The inspectors also noted that unlike other packages/shipments that the licensee regularly received, there was no real-time tracking information on the Th-227 packages. The licensee was aware when the packages were shipped and the expected arrival date at Maryland Heights. However, there was no mechanism for tracking changes to inform the licensee that these Th-227 packages would be delivered ahead of the scheduled date. In addition, the inspectors noted that the "owners" of these packages were not on duty at the time of delivery to prompt the receiving staff of their receipt.

The inspectors also believed that the licensee's investigation into this incident was misdirected by focusing on the actions and apparent statements made by the driver. The inspectors reminded the licensee of its responsibility for identifying and surveying all radioactive packages in a timely manner.

5. PERSONNEL CONTACTED:

Lori Bloomfield, Supervisor, Production and Manufacturing
Gary Burlison, Supervisor, V4 Production
#Matt Cochran, Director, Cyclotron Hot Products
^*#Manuel Diaz, Radiation Safety Officer/Health Physics Manager
Mike DiChristina, Customer Service Rep IV
*#Janet Dohm, Administrative Coordinator
*#Elizabeth Engelmann, Senior Health Physicist
Jennifer Eyman, Ph.D., Technical Transfer Chemist
#Leoul Hagoss, Senior HP Technician
*#Eric Hill, Senior Health Physicist
*Gary Hosna, Vice President, Compliance
*#Reonda Hunt, HP Technician
*#Natalie Jones, HP Technician
#Steve King, HP Technician
*#Tony Kinney, Associate General Counsel
*#Corey Lamb, EHS Specialist
Tracy Lore, Transportation Compliance Specialist
#Nhi (Lily) Ma, HP Technician
#Thomas McCormack, Distribution Manger
*#Brad Nelson, Senior Production Health Physicist/Emergency Manager
*#Richard C. Proehl, Vice President, Operations, North America
John Schmitc, Senior Process Engineer
Tom Scifflett, Ph.D., Director, Analytical Chemistry, R&D
Jim Spieker, Director, Quality Control
Barry Todd, Manufacturing/Engineering Tech III
Shawn Voican, Manufacturing/Engineering Tech IV
Kenneth Wamhoff, Waste Management Technician
*Kimberly Weber, Quality System Manager

*Individuals at entrance meeting
#Individuals who attended on-site exit meeting on 3/22/2019
^Individual contacted by telephone on 4/11/2019 for final exit teleconference

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

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