NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Curium US LLC	030-00001, -10801, and -38173	24-04206-01, -05MD and -02

4. Report Number(s):	5. Date(s) of Inspection:
2022-001 (all three)	February 14-18, 2022; exit March 16, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Craffey (-01), Warren (-05MD), Nieves (-02)	03211 02511 03210	2, 5, 2	IP 87125, 87126, 87127

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Scott Surovi - RSO Manuel Diaz - Chair, RSC	scott.surovi@curiumpharma.com manuel.diaz@curiumpharma.com	314-595-3732 314-654-7661

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☑ Routine ☑ Announced ☐ Non-Routine ☐ Unannounced	☑ Main Office ☑ Field Office ☐ Temporary Job Site ☐ Remote	02/14/2024 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

Curium US is a broad scope radiochemical and radiopharmaceutical manufacturer in Maryland Heights, Missouri. The licensee operates five cyclotrons under its -02 license to produce isotopes of In-111, Tl-201, Cu-64, Ga-67, Ge-68 and I-123 that it then transferred to its -01 license for synthesis into various radiochemicals and radiopharmaceuticals. Curium also received bulk quantities of Mo-99 for the manufacturing of Mo-99/Tc-99m generators, as well as I-123, Xe-133 and Th-227 for preparation and distribution of other radiopharamceuticals. All products were then distributed under its -05MD license. The licensee also possesses two J.L. Shepherd instrument calibrators containing curie-quantity sources of Cs-137 and performs some research and development under its -01 license involving current and future products. The licensee's RSO was assisted in his oversight of the radiation safety program by an RSC, which met quarterly, as well as a staff of five health physicists.

The inspectors toured the licensee's facilities at 2600 and 2703 Wagner Place in Maryland Heights. All locations were adequately posted, and all licensed material was adequately secured. The inspectors conducted independent and confirmatory surveys throughout the inspection; no evidence of residual contamination or exposures in excess of regulatory limits to members of the public were noted in unrestricted areas. The inspectors observed cyclotron operations including target reclamation and rebuilding, chemical synthesis of Cu-64, Ge-68, and In-111 products, generator production and reclamation, packaging and shipping of finished products, receipt of bulk quantities of Mo-99 and I-123, waste collection and handling, HP duties including air sampling, area surveys, instrument calibrations, and process audits, and demonstrations of Th-227 product synthesis and research and development activities. The inspectors interviewed production staff, health physics staff, and licensee management; all were knowledgeable, implemented appropriate ALARA practices, personal protective equipment, and personnel dosimetry, and used calibrated and operable radiation detection instrumentation effectively.

The inspectors reviewed the licensee's continued implementation of its Corrective Action Program, and confirmed that all conditions adverse to radiation safety were promptly identified, documented, and corrected. The licensee investigated all conditions deemed significant, and for each identified the root cause and corrective actions which appeared adequate to preclude repetition of the conditions. The inspectors also reviewed program audits, RSC meeting minutes, personnel dosimetry reports, bioassay measurements and uptake calculations, air and sewer effluent monitoring results, and various other records associated with the activities observed during the inspection.

The inspectors also verified that corrective actions were implemented for a violation identified during the previous inspection regarding a failure to monitor incoming packages containing radioactive material as required by 10 CFR 20.1906. This violation is closed.

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The inspectors also reviewed EN 55702, NMED 220035, and the licensee's 30-day report for two packages of short-lived material that were lost by a courier in New Jersey following shipment via common carrier. The licensee took appropriate actions regarding packaging, shipment, notification and attempts at recovery; no violations were noted and the NMED item is closed. No other violations of NRC requirements were identified during these inspections.