



Materials Inspection Report

1. Licensee/Location Inspected:

Curium US LLC
14395 Bergen Boulevard
Noblesville, IN 46060

Report Number(s) 2022-001

2. NRC/Regional Office

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. Docket Number(s)

030-38903 / 030-38841

4. License Number(s)

13-35179-03 / 13-35179-02

5. Date(s) of Inspection

August 23, 2022

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:



1. Based on the inspection findings, no violations were identified.



2. Previous violation(s) closed.



3. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.


A. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.

(Non-cited violation(s) was/were discussed involving the following requirement(s))

B. The following violation(s) is/are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Ryan Craffey	 Digitally signed by Ryan J. Craffey Date: 2022.09.08 16:45:53 -0400
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.09.09 06:42:49 -0500



Materials Inspection Record

1. Licensee Name: Curium US LLC		2. Docket Number(s): 030-38903 / 030-38841		3. License Number(s) 13-35179-03 / 13-35179-02	
4. Report Number(s): 2022-001			5. Date(s) of Inspection: August 23, 2022		
6. Inspector(s): Ryan Craffey		7. Program Code(s): 03210 / 03620		8. Priority: 2 / 5	9. Inspection Guidance Used: IP 87125, 87141
10. Licensee Contact Name(s): Matthew Trusner - RSO Manuel Diaz - RSC Chair		11. Licensee E-mail Address: matthew.trusner@curiumpharma.com manuel.diaz@curiumpharma.com		12. Licensee Telephone Number(s): 217-433-7902 314-225-8628	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		14. Locations Inspected: <input type="checkbox"/> Main Office <input checked="" type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 08/23/2024 / 08/23/2026 <input type="checkbox"/> Normal <input type="checkbox"/> Extended <input checked="" type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

Curium US LLC was a radiopharmaceutical manufacturer in Noblesville, Indiana, authorized by materials license no. 13-35179-03 to use a cyclotron to produce Sr-82 and perform chemical purification of this material for distribution to clients who used the material to manufacture rubidium-82 generators; and by materials license no. 13-35179-02 to perform research and development activities involving radiopharmaceuticals. At the time of the inspection the licensee employed 44 staff, including the RSO and two certified health physicists who supported the RSO's oversight of the radiation safety program. The licensee recently chartered an RSC, which currently met monthly.

The inspector toured the facility in Noblesville. All areas were adequately posted, as confirmed by independent and confirmatory surveys, and all licensed material was adequately secured and accounted for. No evidence of residual contamination was noted via independent surveys in unrestricted areas. The inspector observed ongoing production activities including radiochemistry and dispensing operations, as well as material handling external hot cells. The inspector also discussed waste and target handling and breathing zone and air effluent monitoring methods as well as ongoing and upcoming research and development activities with the licensee's staff and management. Personnel were knowledgeable of radiation protection principles, regulatory requirements, contamination control and ALARA practices, and wore dosimetry, utilized personal protective equipment, and performed contamination checks as required by licensee procedures.

The inspector reviewed a selection of radiation safety program records, including RSC minutes, internal audits, sealed source leak test results and inventories, air sampling results, air effluent monitoring results, and personnel dosimetry results, which recorded maximum occupational doses of 3,310 mrem DDE and 34,925 mrem SDE to extremities in 2021, and 2,911 mrem DDE and 13,598 mrem SDE to extremities in 2022 through May 31. No intakes in excess of 10% of any ALIs or airborne concentrations in excess of 10% of any DACs were noted.

The licensee was previously cited in IR 03038903/2021001(DNMS) for a SLIV violation of LC 19.A after an individual failed to monitor their hands and clothing before leaving the facility's restricted area. The inspector reviewed the licensee's corrective actions, which appeared to be adequate and effective, noted that the violation had not occurred again since, and identified no additional examples of the violation while on-site. Therefore this violation is closed.

No violations of NRC requirements were identified as a result of this inspection. The next inspection date for license no. 13-35179-02 was reduced to synchronize its inspections with those of license no. 13-35179-03, thereby minimizing the number of visits needed to complete routine inspections of both licenses. The reduction was not due to any performance deficiency or compliance issue.