UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

December 15, 2021

EN 55326
NMED No. 210271 (closed)

Mr. Matthew Trusner
Radiation Safety Officer
Curium US LLC
111 Westport Plaza Dr.
Ste. 800
St. Louis, MO 63146

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03038903/2021001(DNMS) AND NOTICE OF VIOLATION – CURIUM US LLC

Dear Mr. Trusner:

From June 25, 2021 through December 10, 2021, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection of activities at your facility in Noblesville, Indiana. The purpose of the inspection was to review the circumstances surrounding a contamination event that you reported to the NRC Operations Center on June 24, 2021. While you eventually determined that the event was not reportable under NRC requirements, the NRC chose to perform a reactive inspection based on the information you had initially provided. Mr. Geoffrey Warren of my staff conducted a final exit meeting by telephone with you on December 10, 2021, to discuss the inspection findings. The enclosed inspection report presents the results of the inspection.

During this inspection, the inspector examined activities conducted under your license related to public health and safety. Additionally, the inspector examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation concerned the failure for an individual to monitor their hands and clothing before leaving the restricted area, as required by License Condition No. 19.A. of your license and your written procedure on safe use of radioactive materials. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the enclosed Notice because it was determined to be self-revealing through the contamination event even though the event itself did not require reporting.

The inspector determined that the root cause of the violation was individual error. As corrective actions to restore compliance and to prevent recurrence, you have installed a portal monitor to

prevent personnel from leaving the restricted area without performing required surveys and trained staff on its use.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter and in the enclosed inspection report. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and any response you provide will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, any response should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Mr. Warren of my staff if you have any questions regarding this inspection. Mr. Warren can be reached at 630-829-9742.

Sincerely,

Michael A. Kunowski Signed by Kunowski, Michael on 12/15/21

Michael A. Kunowski, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-38903
License No. 13-35179-03

Enclosure:
1. Notice of Violation
2. Inspection Report No. 03038903/2021001(DNMS)

cc w/encl: Ryan Wallace, Site Director
State of Indiana

Letter to Matthew Trusner from Michael A. Kunowski, dated December 15, 2021.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03038903/2021001(DNMS) AND NOTICE OF VIOLATION – CURIUM US LLC.

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OFFICE	RIII-DNMS		RIII-DNMS					
NAME	GWarren:brt		MKunowski					
DATE	12/15/21		12/15/21					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Curium US LLC
Noblesville, IN

License No. 13-35179-03
Docket No. 030-38903

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted from June 25 through December 10, 2021, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> License Condition No. 19.A. to NRC License No. 13-35179-03 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated January 25, 2016.
>
> Section 10.F. of the application dated January 25, 2016, states that the licensee has developed, and will implement and maintain, written procedures for the safe handling and use of radioactive materials.
>
> The licensee's procedure titled "General Rules for the Safe Use of Radioactive Materials," Item 1.1.3, states that "Hands and clothing will be monitored with a low-level radiation detection instrument (e.g., G-M survey meter) for contamination after each RAM procedure or before leaving the restricted area."
>
> Contrary to the above, on June 24, 2021, a license employee failed to monitor their hands and clothing with a low-level radiation detection instrument for contamination before leaving the restricted area.

This is a Severity Level IV violation (Enforcement Policy Section 6.3, Example d.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the letter transmitting this notice and in the enclosed inspection report. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, IR 03038903/2021001(DNMS)" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 15th day of December 2021.

U.S. Nuclear Regulatory Commission
Region III

Docket No.	030-38903
License No.	13-35179-03
Report No.	03038903/2021001(DNMS)
EN No. / NMED No.	55326 / 210271
Licensee:	Curium US LLC
Facility:	14395 Bergen Blvd. Noblesville, IN
Inspection Dates:	June 25, 2021 - December 10, 2021
Exit Meeting Date:	December 10, 2021
Inspector:	Geoffrey M. Warren, Sr. Health Physicist
Approved By:	Michael A. Kunowski, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Curium US LLC
NRC Inspection Report 03038903/2021001(DNMS)

This inspection was performed in response to the report of a potential contamination event received by the U.S. Nuclear Regulatory Commission (NRC) on June 24, 2021. A chemist handled radioactive material, left the restricted area without monitoring his hands and clothing for contamination, washed his hands, and left the licensee's facility in Noblesville, Indiana. The RSO and licensee staff surveyed the licensee's facility, as well as the chemist's car and home, for contamination. Contamination at the facility was cleaned up by licensee staff, and no contamination was found in the chemist's car and home. The RSO's explanation for the lack of contamination in the car and in the home was that despite the chemist's failure to survey his hands he had washed his hands sufficiently to remove any easily removable contamination. Contamination on the chemist's hands was cleaned to the extent practical, and the chemist's clothing was placed into decay in storage pending return.

Exposure calculations, including urine bioassay, showed no exposures to the chemist exceeding any regulatory limits from contamination, uptake, or handling the radioactive materials directly, and dosimetry records supported the licensee's calculations of extremity exposure to the chemist.

The inspector identified one violation of License Condition No. 19.A. of NRC License No. 13-35179-03 concerning the chemist's failure to monitor his hands and clothing for contamination before leaving the restricted area. The inspector determined that the root cause of the violation was individual error. As corrective action for the violation, the licensee has installed a portal monitor at the exit to the controlled area and placed it so that it must be used to exit the area except under emergency conditions. Licensee personnel were trained on the use of the portal monitor. In addition, the licensee updated their written procedures to make clear that no handling of unshielded radioactive material is allowed and trained personnel handling radioactive material on the revision. Because of this event and other issues, the licensee terminated the chemist's employment.

REPORT DETAILS

1 Program Overview and Inspection History

Curium US LLC (formerly Curium US PET LLC) is authorized under NRC Materials License No. 13-35179-03 to use a cyclotron to produce strontium-82 (Sr-82) and perform chemical purification of the material for distribution at a site in Noblesville, Indiana. The licensee employs 29 personnel on site, of whom around 20 support this manufacturing process. Additional personnel at the site work under NRC License No. 13-35179-02, which authorizes certain research and development activities. The Sr-82 produced at this site is distributed to two client companies who use the Sr-82 to manufacture rubidium-82 generators for distribution to hospitals.

As a result of the combined routine/reactive inspection begun in July 2020, the licensee received a Severity Level IV violation for the failure to report an unplanned explosion within 24 hours as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 30.50(b)(4) and 10 CFR 30.50(c)(1). The violation was closed during the next inspection, begun in October 2020 in response to another reported event; no violations were cited in this inspection.

The licensee has identified certain information about its manufacturing process that it considers to be proprietary. As this information is not necessary to support any findings in this report, it was not included.

2 Circumstances Surrounding the Potential Contamination Event

2.1 Inspection Scope

The inspector reviewed the events prior to and following a contamination event that occurred on June 24, 2021, by interviewing staff involved in the event and the follow-up to the event, and by reviewing a variety of records about the event including logs, exposure calculations, and dosimetry information.

2.2 Observations and Findings

On June 24, 2021, licensee staff were performing routine activities involving the chemical purification of Sr-82 produced in the licensee's cyclotron. At around 6 pm ET, a chemist was attempting to perform an operation using a vial containing Sr-82 but was unable to do so using the remote handling tools in the hot cell. The chemist then went behind the hot cell, opened the back door into the hot cell, and tried this operation using his hands, handling the vial directly. This was still unsuccessful, so the chemist closed the door into the hot cell, returned to the front, tried again using the remote handling tools, and cracked the vial. He then left the restricted area surrounding the hot cells without first surveying his hands and clothing for contamination, washed his hands in the employee washroom, and went home.

License Condition No. 19.A. to NRC License No. 13-35179-03 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated January 25, 2016. Section 10.F. of that application states that the licensee has developed, and will implement and maintain, written procedures for the safe handling and use of radioactive materials.

The licensee's procedure titled "General Rules for the Safe Use of Radioactive Materials" requires that hands and clothing be monitored with a low-level radiation detection instrument (e.g., G-M survey meter) for contamination after each RAM procedure or before leaving the restricted area. The chemist's failure to monitor his hands and clothing before leaving the restricted area is a violation of License Condition 19.A. to NRC License No. 13-35179-03.

Another individual working in the area who had observed the chemist's actions contacted the licensee's radiation safety officer (RSO), who directed a radiation safety technician to perform surveys around the facility. The technician found contamination in two areas. The first area was behind the hot cell; licensee staff were able to quickly decontaminate this area. The second area was on some paperwork the chemist had handled; instead of decontaminating the paperwork, licensee staff photographed the paperwork and placed the originals into radioactive waste. No contamination was found in other areas where the chemist had gone.

The contamination on the paperwork prompted the RSO to contact the chemist to ensure he was not contaminated. At this time, the chemist had been home for about 45 minutes. The RSO had him drive in the same car he had previously driven to meet half-way between the office and the chemist's home. The RSO found contamination on the chemist's hands and clothing but none in his car; they then returned to the licensee's facility for a full survey and decontamination. Through this survey, the RSO identified contamination on the chemist's hands, up to 34 thousand counts per minute (kcpm), and on his clothes, up to 600 kcpm. The clothes were placed into decay in storage. The RSO decontaminated the chemist's hands as much as practical to below 4.2 kcpm.

The chemist and RSO then went to the chemist's house, where the RSO surveyed all the places the chemist had gone after getting home and found no contamination. The RSO's explanation for the lack of contamination in the car and in the home was that despite the chemist's failure to survey his hands he had washed his hands sufficiently to remove any easily removable contamination. At this point, the RSO considered the situation under control because all potential contaminated areas had been surveyed and all removable contamination had been cleaned up.

The next morning, licensee radiation staff worked on a dose assessment for the chemist. Based on the skin and clothing contamination levels, they estimated 80 millirem (mrem) to the hands, 640 mrem shallow dose to the torso, and 13 mrem whole body deep dose. Based on the handling of the dose vial, they estimated 1200 mrem to the extremities. A 24-hour urine bioassay showed no evidence of any uptake.

The licensee chose to not stop work because they considered that the contamination and any other consequences were the result of the chemist working outside their standard process without approval. The chemist's dosimetry was sent to the dosimetry provider to attempt to verify the licensee's exposure calculations; ring dosimeters showed exposures of between 1.6 and 1.7 rem for each hand, consistent with the licensee's calculations and supporting the licensee's determination that no regulatory exposure limits were exceeded.

The licensee's analysis determined that the root cause of the violation was individual failure to follow licensee procedures and protocols. As corrective action for the violation, the licensee has installed a portal monitor at the exit to the restricted area and placed it so that it must be used to exit the area except under emergency conditions. Licensee personnel were trained on the use of the portal monitor and received refresher training

on donning and doffing protective equipment and clothing. The licensee updated their written procedures to make clear that no handling of unshielded radioactive material is allowed and trained personnel handling radioactive material on the revision. The chemist was immediately placed on administrative leave and was later terminated because of this event and other circumstances.

2.3 Conclusions

The inspector identified a violation of License Condition No. 19.A. to NRC License No. 13-35179-03 and the licensee's procedure for the safe use of radioactive materials concerning an individual's failure to monitor their hands and clothing for contamination before leaving the restricted area. The licensee took corrective action to reduce the likelihood of recurrence for this violation or similar violations.

3 Reporting of Potential Event to the NRC

3.1 Inspection Scope

The inspector reviewed the licensee's activities concerning reporting of this potentially-reportable event to the NRC's Operations Center by reviewing relevant documents and interviewing the licensee's RSO.

3.2 Observations and Findings

The licensee's RSO contacted the NRC's Operations Center by telephone the evening of June 24. He had not yet met with the chemist or surveyed his home, but he chose to report this situation proactively in case he found contamination sufficient to require reporting under 10 CFR 30.50(a). The licensee later determined, in communication with NRC staff, that the event was not reportable. Based on this determination, on July 20, prior to the written report being required, the RSO contacted the NRC's Operations Center to retract the initial report. As such, no written report was required or submitted to the NRC.

3.3 Conclusions

The inspector identified no violations concerning the licensee's reporting of this event to the NRC's Operations Center.

4 Exit Meeting Summary

The NRC inspector presented preliminary inspection findings following the inspection on December 10, 2021. The licensee acknowledged the findings presented.

PARTIAL LIST OF PERSONNEL CONTACTED

Matthew Trusner, Radiation Safety Officer

Attended exit meeting on December 10, 2021.

INSPECTION PROCEDURES USED

IP 87103: Inspection of Materials Licensees Involved in an Incident or Bankruptcy Filing
IP 87125: Materials Processor/Manufacturer Programs