



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

April 13, 2021

EN 54959
NMED No. 200417 (closed)

Mr. Matthew Trusner
Radiation Safety Officer
Curium US PET LLC
14395 Bergen Blvd.
Noblesville, IN 46060

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03038903/2020002(DNMS) –
CURIUM US PET LLC

Dear Mr. Trusner:

On October 21, 2020, with continued in-office review through March 24, 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 events surrounding an explosion that occurred in a hot cell that contained radioactive materials and the response to the explosion. The in-office review included a review of written information, survey reports, pictures, and procedures that you provided after the onsite inspection. The enclosed inspection report presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff 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 records, observations of activities, and interviews with personnel.

Based on the results of this inspection, no violation was identified. Mr. Geoffrey Warren of my staff conducted a final exit meeting by telephone with you on March 24, 2021, to discuss the inspection findings.

In Inspection Report 03038903/2020001(DNMS), issued on September 25, 2020, Curium US PET LLC was cited for the failure to report a similar event to the NRC Operations Center 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). Based on the timely reporting of the current event and the completion of the corrective actions described in that report, the violation for the earlier event is closed.

You are not required to respond to this letter or the enclosed report unless you disagree with the information or positions described therein. In this case, or if you choose to respond, clearly mark your response as a "Reply to IR 03038903/2020002(DNMS)" and send it to the NRC's Document Control Desk, Washington, DC 20555-0001, with a copy mailed to the NRC Region III Office, 2443 Warrenville Road, Suite 210, Lisle, Illinois 60532, within 30 days of the date of this letter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, 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 Kunowski, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

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

Enclosure:
Inspection Report No. 03038903/2020002(DNMS)

cc w/encl: State of Indiana

Letter to Matthew Trusner from Michael Kunowski, dated April 13, 2021.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03038903/2020002(DNMS) –
CURIUM US PET LLC

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OFFICE	RIII-DNMS		RIII-DNMS			
NAME	GWarren:brt		MKunowski			
DATE	04/13/21		04/13/21			

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**U.S. Nuclear Regulatory Commission
Region III**

Docket No.	030-38903
License No.	13-35179-03
Report No.	03038903/2020002(DNMS)
EN / NMED No.	54959 / 200417
Licensee:	Curium US PET LLC
Facility:	14395 Bergen Blvd. Noblesville, Indiana
Inspection Dates:	October 21, 2020 - March 24, 2021
Exit Meeting Date:	March 24, 2021
Inspector:	Geoffrey Warren, Sr. Health Physicist
Approved By:	Michael Kunowski, Chief Materials Inspection Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Curium US PET LLC NRC Inspection Report 03038903/2020002(DNMS)

This reactive inspection was performed in response to a reported unplanned explosion in a hot cell at the Curium US PET LLC facility in Noblesville, Indiana, on October 20, 2020. A previous explosion had occurred on May 13, 2020, in the same hot cell. This previous explosion was reviewed in IR 03038903/2020001(DNMS), issued September 25, 2020.

At approximately 10:00 a.m. Eastern Time on October 20, 2020, licensee staff were working with more than a curie of strontium-82 (Sr-82) inside a hot cell when an explosion occurred, forcing open the back door to the hot cell and damaging its latch. Licensee staff performed surveys to confirm that no material had been released, including bioassay of personnel present at the time of the event. The Sr-82 material remained stable in a glass vessel. The licensee took corrective actions to prevent recurrence of the explosion. The licensee followed its procedures in the events leading up to and following the explosion, and the inspector identified no violations concerning the explosion. The inspector identified no concerns with the licensee's actions in reporting the event to the NRC.

For the previous event, the licensee was cited for the failure to report the event to the NRC Operations Center 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). Based on the timely reporting of this event and the licensee's completion of the corrective actions described in the previous report, this violation is closed.

REPORT DETAILS

1 Program Overview and Inspection History

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 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 previous inspection begun in July 2020 in response to another event, the licensee received a Severity Level IV violation for the failure to report an unplanned explosion damaging equipment containing more than a curie of Sr-82 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 is closed as described in Section 3.2 of this report.

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 Unplanned Explosion Event

2.1 Inspection Scope

The inspector reviewed the events prior to and following an explosion in the hot cell that occurred on October 20, 2020, by interviewing staff involved in the event and the follow-up to the event, performing confirmatory surveys, and by reviewing a variety of records of the event.

2.2 Observations and Findings

On October 20, 2020, at approximately 10:00 a.m. Eastern Time (ET), a chemical explosion occurred in a hot cell during the chemical purification of strontium at the licensee's facility in Noblesville, Indiana. Based on the licensee's reconstruction, a spark from a frayed electrical connection caused explosive vapors from an uncapped bottle of cleaning solution to explode, in the presence of oxygen from normal air flow through the cell and from compressed air. This was the same hot cell involved in a previous explosion at the site. At the time of this most recent explosion, more than a curie of Sr-82 was present in a glass vessel inside the hot cell. The pressure from the explosion forced the back door of the hot cell to open, damaging the door latch. The glass vessel containing the licensed material remained intact; no licensed material was released in the explosion. The chemist operating the hot cell activated the fire suppression system to fill the hot cell with argon gas and extinguish the fire, closed the hot cell door, turned off certain equipment to stop the manufacturing process, and evacuated the production area. Another staff member who was present immediately notified the licensee's radiation safety officer (RSO).

The RSO and a health physics technician, who were onsite at the time of the explosion, immediately restricted access to the area to prevent any other employees from entering. They performed ambient radiation surveys and wipe tests of the area surrounding the hot cell and of personnel in the area. These surveys showed no evidence of contamination. Ventilation monitors showed no indication of any release. Nasal swabs of the chemist who was present at the hot cell at the time of the event showed no radioactive material. The RSO observed that radiation alarms placed around the area did not sound at the time of the event. Based on these observations, the licensee determined that no licensed material was released. The chemist reentered the area to chemically stabilize the Sr-82 in the glass vessel to prevent any further reaction. The RSO and chemist verified visually that the glass vessel was undamaged and that the Sr-82 appeared to be in good condition.

Licensee site management personnel arrived onsite and began a preliminary evaluation of the event. They noted that there was an uncapped bottle of a cleaning solution in the hot cell, and that combustible paper material in the cell showed signs of burning. The bottle of cleaning solution was kept uncapped in the cell for ease of access and to limit radiation exposure from opening the hot cell to place it when needed. They further noted that electrical wires for equipment in the hot cell showed signs of physical damage. Based on this, they preliminarily proposed that the explosion was the result of vapor from the flammable cleaning solution being ignited by an electrical spark.

Following this analysis, licensee staff reported the explosion that evening by telephone to the NRC's Operations Center under 10 CFR 30.50(b)(4) and contacted an NRC inspector by telephone to provide additional information.

On the following morning, October 21, a second NRC inspector who was in the general vicinity of the facility on another inspection, visited the site to verify the information provided by the licensee. The inspector walked through the timeline of the explosion with licensee staff. She verified that there was no evidence of contamination as a result of the explosion event and that there was no indication that any individual received any exposure as a result of the event. She also observed the replaced door latch to the hot cell that the licensee stated that they had replaced by this point. In this inspector's presence, licensee staff performed additional wipe tests in the production area and in surrounding areas at the facility; these wipe tests showed results consistent with the licensee's routine surveys.

At this time, licensee staff began a formal root cause analysis of the event in accordance with their procedures. Based on this analysis, they determined that the explosion and fire were the result of an explosive atmosphere from the fumes of the cleaning solution, exposed and loose electrical wires, a rupture of a compressed air line, and the presence of combustible paper materials. The root cause of the event was a lack of preventive maintenance for the hot cells. A contributing factor was the presence of the uncovered cleaning solution in the hot cell; as noted above, it was kept there uncapped during the production process to minimize hot cell entry post-production in order to keep radiation exposure low.

As short-term corrective action for the event, the licensee (1) performed repairs on the electrical systems, fixing potential loose electrical connections; (2) began using argon gas to provide a nonreactive atmosphere throughout the manufacturing process; and (3) removed the cleaning solution and all combustible materials from the hot cell during

production. In addition, the licensee used another hot cell, which they verified showed no indications of electrical issues prior to using, until all these corrective actions were completed; the licensee had previously alternated between these cells weekly. As part of their review, licensee staff performed a full job safety analysis of the production process to identify any other potential safety issues. Long-term corrective actions included (1) establishing and implementing a preventive maintenance program for the hot cells, including electrical connections, (2) conducting an independent process hazard assessment for the entire manufacturing process, (3) replacing the use of compressed air with argon gas to limit oxygen in the hot cell, (4) using a portable oxygen monitor in the hot cell until the operation of the hardwired oxygen monitor in the hot cell can be verified, (5) maintaining argon blanket mode throughout the process, and (6) inspecting conditions of hot cell gas lines and exhaust line repair issues.

2.3 Conclusions

The inspector identified no findings concerning the circumstances prior to and following the explosion event at the licensee's facility in Noblesville, Indiana.

3 **Reporting of Event to the NRC**

3.1 Inspection Scope

The inspector reviewed the licensee's notification to the NRC Operations Center concerning the event described above through reviewing NRC and licensee records and interviewing licensee staff involved in making the report.

3.2 Observations and Findings

The explosion event occurred at approximately 10:00 a.m. ET on October 20, 2020. Under 10 CFR 30.50(b)(4), the licensee was required to report this event within 24 hours. The licensee reported this event telephonically to the NRC Operations Center the evening of the same day, within the required period.

Under 10 CFR 30.50(c)(2), the licensee was further required to submit a written report within 30 days of the initial report. This report was provided by email to an NRC inspector on November 17, 2020, which was within 30 days of the initial report. The written report contained all required information.

In Inspection Report 03038903/2020001, issued September 25, 2020, the licensee was cited under 10 CFR 30.50(b)(4) and 10 CFR 30.50(c)(1) for the failure to notify the NRC within 24 hours after the discovery of a previous unplanned explosion. Based on the licensee's timely reporting of this similar event and the completion of the corrective actions described in the report for the previous event, the violation is closed.

3.3 Conclusions

The inspector identified no findings concerning the licensee's reporting of an event involving an unplanned explosion. The previous violation for the failure to report a similar event timely is closed.

4 Exit Meeting Summary

The NRC inspector presented inspection findings with licensee staff in a telephonic exit meeting on March 24, 2021. The licensee acknowledged the findings presented.

PARTIAL LIST OF PERSONNEL CONTACTED

- # Matthew Trusner, Radiation Safety Officer
- # Participated in the telephonic exit meeting on March 24, 2021
Other individuals were also contacted as part of this inspection effort who are not listed here.

INSPECTION PROCEDURES USED

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