



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2056 WESTINGS AVENUE, SUITE 400
NAPERVILLE, IL 60563-2657

September 25, 2025

EAF-RIII-2025-0146
EN 57657
NMED No. 250143 (closed)

Jason Tilly
Vice President and General Counsel
Curium US, LLC
111 Westport Plaza Drive, Suite 800
St. Louis, MO 63146

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03038841/2025002(DRSS) –
CURIUM US, LLC

Dear Mr. Tilly:

This letter refers to reactive inspection activities conducted by the U.S. Nuclear Regulatory Commission (NRC) on April 11 and 17, 2025, at your facility in Noblesville, Indiana, and to a Special Inspection conducted there the week of May 19, 2025, with continued in-office review through July 17, 2025.

The purpose of the reactive inspection was to assess the immediate impact of an incident involving a loss of control over licensed activities on April 8, 2025, which potentially resulted in an occupational exposure to radiation above regulatory limits, and to observe and evaluate your efforts to restore full control over licensed activities. The purpose of the Special Inspection was to conduct a thorough and systematic evaluation of this incident, and to collect, analyze, and document information and evidence sufficient to determine its causes, conditions, and circumstances. The in-office review included an independent assessment of occupational exposures from the incident, an independent root cause analysis, and an evaluation of the significance of inspection findings. The enclosed inspection report presents the results of these inspection activities.

The inspection examined activities conducted under your license as they relate to safety and compliance with the NRC's rules and regulations and with the conditions in the facility's NRC licenses. Within these areas, the inspection consisted of an examination of selected procedures and records, observations of activities, evaluations of facilities and equipment, and interviews with personnel.

Based on the results of the inspection, six apparent violations of NRC requirements were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy, available on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

The apparent violations concerned the failure to: (1) limit annual occupational doses to two individuals below the limits in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20.1201(a); (2) follow radioactive waste handling procedures, as required by Condition 23.O of

NRC License No. 13-35179-02; (3) use available engineering controls to optimize occupational doses, as required by 10 CFR 20.1101(b); (4) perform adequate radiological surveys, as required by 10 CFR 20.1501(a)(2); (5) adequately label containers of liquid radioactive waste, as required by 10 CFR 20.1904(a); and (6) adequately audit the facility's radiation protection program, as required by Condition 23.P of NRC License No. 13-35179-02.

The circumstances surrounding the apparent violations, their significant safety consequences, and the need for lasting and effective corrective action were discussed with members of your staff at the inspection exit meeting conducted by the inspection team on August 20, 2025.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) request a Pre-decisional Enforcement Conference (PEC), or (2) request Alternative Dispute Resolution (ADR). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. **Please contact Rhex Edwards at (630) 829-9722 or Rhex.Edwards@nrc.gov within 10 days of the date of this letter to notify the NRC of your intended response or request.** A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a pre-decisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the information notice on the NRC website at: <https://www.nrc.gov/docs/ML0310/ML031060071.pdf>.

You may also request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third-party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral party (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. **Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. In addition, if you choose ADR, please also contact Rhex Edwards at the telephone number or email address listed above.**

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with the NRC's "Agency Rules of Practice and Procedure" in 10 CFR 2.390, a copy of this letter, its enclosure, and your response, if you choose to provide one, 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 Ryan Craffey of my staff if you have any questions regarding this inspection. Ryan can be reached at 630-829-9655 or ryan.craffey@nrc.gov.

Sincerely,



Signed by Heck, Jared
on 09/25/25

Jared Heck, Acting Director
Division of Radiological Safety and Security

Docket No. 030-38841
License No. 13-35179-02

Enclosures:

- (1) Inspection Report No.
03038841/2025002(DRSS)
- (2) Addendum to Inspection Report –
Fault Tree Analysis

cc (w/encl): M. Diaz
J. Portwood
D. Coffman,
Indiana Department of Homeland Security
C. Eckstein,
Indiana State Liaison Officer

Letter to J. Tilly from J. Heck, dated September 25, 2025.

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03038841/2025002(DRSS) –
CURIUM US LLC

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

Docket No. 030-38841

License No. 13-35179-02

Report No. 03038841/2025002(DRSS)

EA No. EAF-RIII-2025-0146

EN No./NMED No. 57657 / 250143 (closed)

Licensee: Curium US LLC

Facility: 14395 Bergen Boulevard
Noblesville, Indiana

Inspection Dates: April 11 and 17, 2025
May 19 through 23, 2025

Exit Meeting Date: August 20, 2025

Inspectors: Ryan Craffey, Senior Health Physicist
Randolph Ragland, Senior Health Physicist
Daisy Coffman, Health Physicist Specialist, State of
Indiana Department of Homeland Security

Approved By: Rhex Edwards, Chief
Materials Inspection Branch
Division of Radiological Safety and Security

EXECUTIVE SUMMARY

Curium US LLC NRC Special Inspection Report 03038841/2025002(DRSS)

Beginning on April 11, 2025, NRC Region III conducted a series of inspections in response to a notification by Curium US LLC (the licensee) that a loss of control over licensed activities on April 8, 2025, potentially resulted in an occupational exposure to radiation above regulatory limits. This included reactive inspections on April 11 and 17, 2025, to assess the immediate impact of the incident and to evaluate and observe the licensee's recovery efforts. It included a Special Inspection the week of May 19, 2025, to conduct a timely, thorough, and systematic review of this incident, and to collect, analyze, and document information and evidence sufficient to determine its causes, conditions, and circumstances. It also included an in-office review to conduct an independent assessment of occupational exposures from the incident, an independent root cause analysis, and an evaluation of the significance of inspection findings.

The NRC concluded that one individual received 18.4 rem total effective dose equivalent (TEDE) and 56 rem shallow dose equivalent (SDE) to the lower extremities from the incident, and that another individual received 9.5 rem TEDE and did not receive more than the annual limit on SDE to the lower extremities from the incident. No immediate effects from this exposure were reported by either individual. The NRC concluded that the root cause of the incident was the failure to implement and maintain an effective radiation safety program, due to insufficient management oversight and accountability. Contributing factors included inadequate recognition and mitigation of hazards; deficiencies in planning and execution of radiological activities; insufficient training and failure to ensure personnel competency in radiation safety procedures; and a deficient safety culture that failed to prioritize radiological risk, procedural compliance, and effective management of operational changes.

As a result of the inspection, six apparent violations were identified: (1) the failure to limit annual occupational doses to two individuals below the limits in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20.1201(a); (2) the failure to follow radioactive waste handling procedures, as required by Condition 23.O of NRC License No. 13-35179-02; (3) the failure to use available engineering controls to optimize occupational doses, as required by 10 CFR 20.1101(b); (4) the failure to perform adequate radiological surveys, as required by 10 CFR 20.1501(a)(2); (5) the failure to adequately label containers of liquid radioactive waste, as required by 10 CFR 20.1904(a); and (6) the failure to adequately audit the facility's radiation protection program, as required by Condition 23.P of NRC License No. 13-35179-02.

The licensee performed an independent investigation into the incident, including its own assessment of occupational exposures and root cause analysis. The licensee concluded that one individual received 12.4 rem TEDE and 240 rem SDE to the lower extremities from the incident, and that a second individual received 9.6 rem TEDE and did not receive more than the annual limit on SDE to the lower extremities from the incident. The licensee concluded that the root cause of the incident was a breakdown in the implementation and oversight of the site's radiological control program, including inadequate pre-job planning, ineffective radiological work controls, insufficient training on high-radiation waste handling procedures, and weak safety culture and oversight.

The licensee's investigation recommended extensive corrective actions. The licensee committed to implementing all actions recommended by the investigation, and any additional actions recommended by its Radiation Safety Committee from its review of the investigation.

REPORT DETAILS

1 Program Overview and Inspection History

Curium US LLC (the licensee) is authorized by NRC Materials License Nos. 13-35179-02 (a broad-scope manufacturing and distribution license) and 13-35179-03 (a radionuclide production license) to produce radiochemicals and radiopharmaceuticals at a facility in Noblesville, Indiana. The licensee operates an IBA Cyclone 70 cyclotron to produce strontium-82 (Sr-82) from metallic rubidium targets for clients who use the material to produce rubidium-82 generators and infusion machines for cardiac stress tests via positron emission tomography. The licensee also manufactures therapeutic radiopharmaceuticals containing lutetium-177 at this facility.

The radiation protection program is overseen by a Site Radiation Safety Officer (RSO), who reports to the North American RSO in Maryland Heights, Missouri. The Site RSO is principally supported in their radiation protection duties by a principal health physicist and a lead radiation safety technician.

The NRC last inspected the Noblesville facility on January 15, 2025, and before that on August 13, 2022. No violations of NRC requirements were identified during either routine inspection.

2 Sequence of Events

2.1 Inspection Scope

The inspectors toured the facility in Noblesville, interviewed involved personnel, and reviewed a selection of records to establish and assess a sequence of events from April 8, 2025.

2.2 Observations and Findings

On April 8, 2025, in preparation for Sr-82 production activities to be performed the following week, the licensee tasked personnel with routine radioactive waste handling and collection activities for the two banks of hot cells used to handle irradiated targets and extract Sr-82. These activities required entering confined spaces below each bank of hot cells, known as the “west basement” and “east basement” respectively.

Liquid waste was received in these basements from the primary production process via tubing connected to the hot cells above. Solid waste was received from one of two chutes, also connected to the hot cells. Containers receiving waste were kept in barrels lined with either concrete, two inches of lead shielding, or three inches of lead shielding, depending on expected contents. Production personnel manually tracked the volume of liquid waste added to each container, as well as the number of production runs' worth of solid waste. Once the containers were full, the licensee's radioactive waste handling procedure (EHS.0028) stated that personnel were to swap the barrel with the full container for a barrel with a new container, to leave the full container in the barrel in the basement for six months to decay, then move the barrel to the waste collection area known as the “north pit” for another six months of decay. According to the licensee's waste disposal procedure (EHS.0080), containers were not to be removed from barrels

or an approved storage area for disposal through an authorized waste broker if dose rates on contact with the container exceeded 200 millirem per hour (mrem/hr).

By April 8, 2025, one solid waste container in the west basement was full, one liquid waste container in the east basement was full, one solid waste chute in each basement was clogged, and a liquid waste line in the west basement needed repair. Production of Sr-82 could not resume until these matters had all been addressed.

The licensee held a pre-job briefing at around 8:30 am (this and all subsequent times Eastern) to prepare for the waste handling and collection activities to be performed later in the day. The licensee's two manufacturing chemists attended the briefing, as they were normally tasked with this work. However, due to other production-related work that were priorities for the chemists, the licensee enlisted a manufacturing specialist and an Environmental Health and Safety (EHS) specialist (the assigned personnel) to perform the work instead. Both attended the briefing, along with another manufacturing specialist who would assist from the ground floor above, two health physicists (one of whom would also assist from the ground floor), and the Site RSO. No concerns or objections were raised about the plan during the briefing.

At around 2:00 pm that afternoon, the licensee began the planned waste handling and collection activities in the west basement. The attending health physicist performed confined space oxygen monitoring and started (but never completed) a Confined Space Permit and a Radiation Work Permit (RWP) for the work. One of the two assigned personnel then entered the basement and performed radiation surveys with a Thermo Fisher Scientific RadEye B20-ER gamma/beta survey meter, noting 0.2 Roentgen/hr (R/hr) at the entrance and 0.3-0.4 R/hr on liquid waste lines feeding the barrel. The other then entered, and both proceeded to unclog the solid waste chute and repair the liquid waste line. Both individuals also wore Mirion DMC3000 electronic dosimeters (EDs) on their chest under the hood of their respirators.

Knowing that the solid waste container was to be replaced as well, the assigned personnel performed an additional survey on contact with the container inside the barrel after removing the chute to unclog it. They reported to personnel above that the reading on contact with the container through the opening of the barrel's lid was 0.7 R/hr. The attending health physicist acknowledged this, and the assigned personnel proceeded to replace the container. They positioned the barrel at the entrance to the basement with a pallet jack, removed the lid with an overhead crane, and swapped the container for a new one. As had been done before during previous waste handling activities, including on November 5, 2024, (or shortly thereafter) and on December 3, 2024, the assigned personnel handed the container of solid waste up to the health physicist, who took it to a designated room in the restricted area (the "iodine room," named after its previous intended purpose) for decay in storage.

Work in the west basement lasted approximately 30 minutes and was completed without complication. Each assigned personnel received around 0.025 rem of dose per their EDs by the time they left the west basement. Personnel above received negligible dose.

Around 2:40 pm, the assigned personnel then entered the east basement. They performed radiation surveys upon entering, noting 0.175 R/hr at the entrance, 0.5 R/hr on contact with the high-level liquid radioactive waste barrel, which was lined with three

inches of lead shielding, and a few tenths of an R/hr on liquid waste lines feeding the barrel.

Knowing that the liquid waste container was to be replaced, the assigned personnel continued surveying to find a maximum reading on contact with the barrel. They noted 0.93 R/hr at a small opening at the interface between the lid and a removable shielding plug for liquid waste line access and reported the reading to the workers above. The readings were considered unremarkable based on the apparent similarity to readings in the west basement, and work proceeded. The assigned personnel first inspected the clogged solid waste chute. They found an evaporation flask, wrapped in tubing and stuck inside, and removed it.

The assigned personnel then proceeded to replace the liquid radioactive waste container. They first removed the shielding plug from the lid of the barrel and disconnected liquid waste lines from fittings on the lid of the liquid waste container. One of the lines was reportedly brittle and broke from the ceiling when handled. The assigned personnel passed the broken line to the personnel above, reporting that it had come from the E2 hot cell. They then positioned the barrel at the entrance to the basement, removed the lid with an overhead crane, and one of them removed the container from the barrel, by hand.

Dosimeter data logs later confirmed that at this time (2:44 pm), both individuals' EDs started alarming within seconds of each other for exceeding the dose set point of 0.1 R. However, neither individual recalled hearing an alarm for dose from either ED at that time, and only recalled hearing the EDs alarm repeatedly during their time in the basement for exceeding the dose rate set point of 0.1 R/hr. Neither individual acted in response to the alarms they heard, as dose rates throughout the basement were expected to exceed this set point.

The individual who removed the container carried it at chest level and placed it on the floor of the basement next to three other containers that had been removed from barrels during prior entries on May 14, 2024, October 14, 2024, and December 3, 2024.

Upon completing the swap and returning the barrel to its position under the hot cells, the assigned personnel checked the adjacent solid waste chute for additional blockage. While doing so, they noticed a second liquid waste line had also broken away from the ceiling. At around 2:50 pm, the assigned personnel both returned to the entrance to the basement to discuss replacing the lines with the personnel above.

The personnel above opened the E2 hot cell and performed radiation surveys of the interior using the RadEye that the assigned personnel had been using in the basement earlier. The personnel above noted 1-5 R/hr inside the hot cell, as would be expected a few days post-production. One of them attempted to lift a shielding plate inside the E2 hot cell to permit replacement of the broken liquid waste lines from above, but it was too heavy to lift by hand. The assigned personnel offered that they might be able to lift the plate from the basement by reconnecting the solid waste chute to the plate, the chute to the barrel, and lift the barrel (and everything above) using the pallet jack below.

Without apparent consideration for whether the new plan remained within the scope of the RWP, the personnel above agreed to the plan, and at around 2:55 pm, the assigned personnel returned to the barrels to reposition and reconnect equipment.

Within two minutes they began raising the pallet jack, standing now in very close proximity to the unshielded waste containers, while the personnel above monitored movement of the plate. For the next five minutes, no movement of the E2 shielding plate was reported, despite the barrel and chute continuing to rise. In fact, the assigned personnel had misidentified the order of the hot cells from the onset of the work and were raising the solid waste cask under hot cell E4, not E2.

Upon reaching the height limit of the pallet jack without any apparent success, the assigned personnel left the basement by 3:05 pm to discuss a new plan to replace the waste lines with the personnel above. The assigned personnel removed their respirators, and noticed that the EDs they were wearing underneath their respirators reported unexpectedly high readings: one read 4.399 rem and the other read 2.924 rem. The work was not expected to exceed 0.1 rem.

Based on the sequence of events of April 8, 2025, violations of two requirements were apparent:

- A. Condition 23.O of NRC License No. 13-35179-02, Amendment No. 11, dated August 14, 2023, states in part that, except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the letter dated June 29, 2022.

In Attachment C to the letter dated June 29, 2022, the licensee stated that it developed an implements written waste disposal procedures for radioactive material that meet the requirements of the applicable sections of 10 CFR 20, Subpart K.

Section 2 of revision A.02 to EHS.0028, Radioactive Waste Management, effective November 1, 2023, provides, in part, the following instructions for liquid production waste:

- 2.3 Once low/high level liquid waste has reached capacity, trained employees must go into the East/West basement and disconnect low/high level liquid waste barrels from hot cell liquid waste tubes
- 2.4 Employees will move the disconnected waste barrel into either the east or west basement. To remain there for a minimum of six months
- 2.5 Liquid waste barrels are to be moved to the north pit after a minimum of six months has elapsed, or if deemed necessary by RSO or designee.

Contrary to the above, on multiple occasions between at least May 14, 2024, and April 8, 2025, Curium US LLC did not conduct its program in accordance with its radioactive waste management procedures described in the letter dated June 29, 2022. Specifically:

- (1) On at least four occasions, the licensee removed containers of liquid waste from shielded waste barrels and left the unshielded containers in the basements to decay.

- (2) On at least three occasions, the licensee removed containers of low-level liquid waste and solid waste from waste barrels and transferred them to the iodine room to decay.

This is an apparent violation of Condition 23.O of NRC License No. 13-35179-02 and is being considered for escalated enforcement in accordance with the NRC's Enforcement Policy.

- B. 10 CFR 20.1101(b) states that the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

Contrary to the above, on multiple occasions between at least May 14, 2024, and April 8, 2025, Curium US LLC did not use, to the extent practicable, engineering controls based upon sound radiation protection principles to achieve occupational doses that were ALARA. Specifically, licensee personnel on several occasions did not use any appreciable shielding while handling and working in the vicinity of containers of radioactive waste and placed the unshielded containers in the east basement for decay, resulting in occupational exposures that were not ALARA, as these elevated exposures were neither necessary nor optimized for the task.

This is an apparent violation of 10 CFR 20.1101(b) and is being considered for escalated enforcement in accordance with the NRC's Enforcement Policy.

2.3 Conclusions

Violations of Condition 23.O of NRC License No 13-35179-02 and 10 CFR 20.1101(b) were apparent.

3 **Licensee Response**

3.1 Inspection Scope

The inspectors toured the facility in Noblesville, interviewed involved personnel, and reviewed a selection of records to assess the licensee's response to the events of April 8, 2025.

3.2 Observations and Findings

A. Immediate Actions

At around 3:15 pm, after realizing that they had received unexpectedly excessive doses, personnel contacted the Site RSO who was present at the facility, responded immediately, and ordered the attending health physicist to perform a survey of the east basement with a Ludlum Model 3078 stretch scope survey meter. The attending health physicist entered the basement and noted 2 R/hr at the entrance, 25 R/hr in the area where the assigned personnel had stood while attempting to lift the shielding plate, and over 999 R/hr (the upper limit of the instrument) near the base of

the liquid waste container that had been removed from shielding. Upon exiting the basement, the health physicist's ED read 0.456 rem.

The Site RSO notified the Director of the Radiation Safety Office, who had been on-site that day and returned around 4:00 pm. The Site RSO instituted a facility-wide stop-work order around this time, and rescinded access to restricted areas for all personnel involved.

After exiting the restricted area, one of the assigned personnel found around 25,000 disintegrations per minute (dpm) of contamination on their left hand while using a portal monitor to exit the restricted area. This was, however, on the skin of their hand and under the layers of personal protective equipment that they had been wearing and was not likely associated with entry into the basement. Regardless, the licensee had the individual perform bioassay via urinalysis. Preliminary results did not identify any counts above background levels, suggesting no intake.

The Site RSO then directed all four personnel involved in the work to provide written statements, while the Director had the Site RSO enter the east basement and conduct additional physical and radiological assessments. Using the Ludlum Model 3078 stretch scope survey meter, the Site RSO noted dose rates of 35 R/hr at about a meter from the liquid waste container that the workers had removed from shielding and 580 R/hr on contact with the midline of the container. The RSO also reported that the container was "easily moveable and [I] felt a solid rattle inside." Based on this, the Site RSO initially suspected that the elevated exposure rates may have been the result of a discrete source of radioactive material in an otherwise empty bucket. The Site RSO further hypothesized that if true, the only discrete source in the facility that could cause the levels of radiation observed would be an irradiated, unprocessed target. After exiting the basement, the Site RSO's ED recorded 0.644 rem.

Based on the dose rates subsequently measured in the east basement on April 8, 2025, and ensuing ED readings, an additional violation was apparent:

10 CFR 20.1501(a)(2) states that each licensee shall make or cause to be made, surveys of areas, including the subsurface, that are reasonable under the circumstances to evaluate—

- (i) The magnitude and extent of radiation levels; and
- (ii) Concentrations or quantities of residual radioactivity; and
- (iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

Contrary to the above, on April 8, 2025, Curium US LLC made surveys of areas of its facility in Noblesville, Indiana, that were inadequate under the circumstances to evaluate the magnitude and extent of radiation levels, and the potential radiological hazards of the radiation levels. Specifically, the licensee did not perform surveys to evaluate a significant change in radiation levels in an area occupied by two individuals for 20 minutes after they removed a container of radioactive waste from a shielded barrel.

This is an apparent violation of 10 CFR 20.1501(a)(2) and is being considered for escalated enforcement in accordance with the NRC's Enforcement Policy.

Meanwhile, the Director of the Radiation Safety Office reviewed ED data for the workers. By about 4:30 pm, the Director realized that, based on previous exposures, that one of the assigned individuals may have exceeded the regulatory limit of 5 rem Total Effective Dose Equivalent (TEDE) in 10 CFR 20.1201. The licensee recognized that this individual's electronic dosimeter had been assigned a calibration factor of 1.2 (i.e., the measured doses were 20% higher than actual) based on deviations observed previously between ED readings and passive dosimeter readings for the cyclotron operations group, of which the individual was a member. Regardless, the licensee considered this indication of a potential overexposure and reported it to the NRC the following day, pursuant to 10 CFR 20.2203(a)(2)(i), and sent in all passive dosimetry worn during the incident for emergency processing.

The licensee received results of this monitoring on April 11, 2025. Based on passive dosimetry, the assigned workers received 3.387 rem and 2.584 rem during the month of April, and 4.743 rem and 2.946 rem respectively during 2025. The licensee recognized that, given the variability of the work in close proximity to the source of exposure, additional modeling and evaluation would be needed to confirm the validity of the passive dosimeter measurements. The licensee thereafter contracted an independent third party to estimate the true dose to both individuals.

The following week, the licensee began drafting a remediation plan (Radiological Work Permit No. NBL-EHS-02), as well as modeling dose rates for the leading exposure theory (i.e., an irradiated, unprocessed target).

On April 16, 2025, the Director of the Radiation Safety Office completed the remediation plan, and the licensee's Radiation Safety Committee (RSC) approved it at an ad-hoc meeting. The Site RSO began preparing a training area at the facility with a mock-up of the basement to conduct dry runs of the recovery plan.

On April 17, 2025, the licensee performed gamma spectroscopy analysis of the container using a Canberra GC3020 high purity germanium (HPGe) detector that was ISOCS (in-situ counting system) characterized to enable activity estimates. The detector was placed on the ground floor of the main facility and measurements were adjusted for counting from the floor above through the ceiling of the basement (consisting of 60 centimeters of concrete). The assay detected over 165 curies (Ci) of rubidium radionuclides and over 188 Ci of strontium radionuclides. Metallic radionuclides such as manganese-52, cobalt-56, and vanadium-48, which would be expected from irradiation of Inconel (the material used as the rubidium target shell), were not detected. This cast some doubt on the leading theory, but not enough to deter the licensee from proceeding with its remediation plan.

It was later determined that the strontium detected in this assay was from a trivial amount of contamination on the floor of the facility. The activity of this material was grossly overestimated as the assay was calculated assuming all exposure had been measured through a significant amount of concrete and from a much greater distance.

B. Recovery

Based on the leading theory, the licensee had eight-foot aluminum tongs fabricated to permit lifting the waste container back into its shielded barrel from a distance. Placing additional shielding in the east basement was considered; however, due to limited space in the basement, no meaningful additional shielding was readily available that would not likely impede recovery efforts. The licensee therefore chose to rely primarily on control of time and distance to ensure that the workers would not exceed an operational dose goal of 1 rem per person.

The licensee recruited personnel from the company's facility in Maryland Heights, Missouri, to enter the basement and perform the recovery. Two were selected for their experience performing hot work (such as recovering dropped targets), and for having low year-to-date doses of record.

On the morning of April 17, 2025, the approved remediation plan was reviewed with personnel who would participate in the recovery. The entry team practiced the evolution multiple times, discussing hold points and possible unexpected conditions with the Site RSO and Director of the Radiation Safety Office. At around 1:00 pm, the licensee commenced with the recovery plan. The entry team entered the east basement and attempted to lift the container using the tongs provided. They found, however, that the container was far too heavy to lift using the tongs at any distance. The licensee conducted additional surveys and evaluations and concluded that if personnel could lift the bucket into the barrel by hand quickly enough (i.e., within a few minutes), they would remain well within the recovery operation's dose goal. Both individuals were comfortable with the new plan, so they returned to the basement, and under intense scrutiny of the licensee to ensure strict adherence to time (the remaining ALARA measure), they lifted the container into the barrel in a matter of seconds.

The lid was placed back on the barrel, and the barrel lifted out of the basement, and moved into the north pit for extended decay. A maximum dose rate on contact with the barrel of around 550 mrem/hr was noted as it was moved. Upon exiting the basement, the entry team's EDs read 0.666 rem and 0.263 rem, respectively. The east basement was thereafter surveyed; dose rates were confirmed to have returned to expected levels. The recruited personnel's passive dosimeters, provided specifically for the recovery operation, were promptly sent for emergency processing, recording 0.377 rem and 0.166 rem, respectively.

On April 21, the licensee again performed HPGe gamma spectroscopy analysis of the container, this time on contact with the barrel. The licensee concluded that it had contained approximately 210 Ci of various rubidium radionuclides (Rb-83, -84, and -86) on April 8, 2025. No strontium or metallic radionuclides were again detected. The licensee concluded that the total activities of the radionuclides and their relative ratios were consistent with several months' worth of incidentally activated rubidium generated during routine Sr-82 production activities.

C. Investigation

Per the licensee's corrective action program (EHS.0044), the incident was classified as a Category 1, prompting formation of an investigation team to review the

circumstances of the incident, establish a root cause, and propose corrective actions in accordance with the licensee's incident investigation procedure (EHS.0045). The Director of the Radiation Safety Office recruited four senior managers (three from Maryland Heights and one from Noblesville who was not involved in the incident or recovery) as well as an independent consultant to serve on the team.

During the week of April 21, 2025, the investigation team visited the Noblesville facility, collected data and records, and conducted interviews with the personnel involved in the incident. In a preliminary report dated May 9, 2025, the investigation team concluded that the direct cause of the potential overexposures was the removal of a container of highly radioactive liquid waste from shielding and the continuation of work in its vicinity with no knowledge or recognition of the radiological hazard. The investigation concluded that the root cause was a breakdown in the implementation and oversight of the site's radiation protection program, characterized by inadequate pre-job planning, ineffective radiological controls, insufficient training, and weak safety culture and oversight.

The licensee's investigation team identified several potential violations of regulatory and administrative requirements from their review and proposed an extensive corrective action plan. These included but were not limited to:

- Heightened oversight of radiological work permitting, including an overhaul of radiological work permitting procedure and revisions to RWP templates.
- Development and implementation of training in pre-job planning, including detector selection and operation, for all signatories on an RWP.
- Changing electronic dosimeter set points on RWPs to be more relevant to each task.
- Performing an engineering assessment of waste area equipment to reduce the potential for chute clogs and line breaks.
- Labeling all existing radioactive waste and completing a new inventory of it.
- Performing an assessment of decay-in-storage times and purchasing additional shielded barrels if necessary.
- Combining EHS.0028 and EHS.0080 to create a single procedure for waste management and provide training on it.
- Reviewing all relevant procedures to clarify any ambiguous language.
- Performing an audit of processes against approved procedures to identify any additional deviations of practice from procedure.
- Ensuring that all employees involved in waste management activities receive proper training.
- Adding classroom and/or on-the-job training for radioactive waste handling procedures.
- Performing an audit of the radiological training curriculum to ensure that it is comprehensive of all site procedures

- Establishing a continuous audit plan to ensure that waste handling activities are performed according to approved procedures and that training in these activities is effective.
- Performing a comprehensive audit of safety culture, identify weaknesses, and develop a continuous improvement plan to strengthen safety culture.
- Developing a case study on this event and folding it into safety culture training at Noblesville and across the broader manufacturing network.
- Conducting periodic safety standdowns to focus on safety culture principles.

In a final report dated June 9, 2025, the consultant contracted by the licensee to assess radiation exposure to personnel concluded that the individual who operated the pallet jack in an attempt to lifting the shielding plate received 12.4 rem TEDE and 240 rem to the skin of the lower extremities, and that the other individual, who removed the container from its shielded barrel, received 9.6 rem TEDE and did not exceed the annual limit on SDE to the lower extremities.

The consultant estimated a total exposure rate from 6.7 gallons of liquid radioactive waste in the container of 107 R/hr at one meter and modeled individual exposure to this bucket with consideration for position relative to the container. Since the individuals' torsos would have provided substantial shielding to their passive dosimeters with the container at their backs, the consultant recommended multiplying 89% of their passive dosimeter readings by 4 and 11% of their dosimeter readings by 1, based on MicroShield modeling for the factor and the fraction of time spent in the vicinity of the container for the percentage. The consultant also conservatively estimated that the individual who received the 240 rem SDE dose was standing "a few inches" from the container, receiving a dose to the skin of their lower extremities of 1,000 R/hr for 15 minutes, in the absence of definitive evidence to the contrary.

The consultant also reviewed raw bioassay and air sample data from the day of the event and concluded that assigned personnel received no more than 7 mrem from the intake of rubidium radionuclides that day and that they likely received no more than 2 mrem from the intake from low levels of airborne strontium, rubidium, cobalt and europium radionuclides present in the air sample taken from the ground floor of the main facility.

The licensee considered the consultant's estimate of skin dose to the first individual to be conservative but nevertheless accepted the consultant's conclusions in full and stated that it would assign personnel these values in their doses of record for 2025.

Based on these conclusions, an additional violation was apparent:

10 CFR 20.1201(a)(1)(i) states, in part, that the licensee shall control the occupational dose to individual adults to an annual total effective dose equivalent being equal to 5 rems (0.05 Sv).

10 CFR 20.1201(a)(2)(ii) states, in part, that the licensee shall control the occupational dose to individual adults to an annual shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

Contrary to the above, during calendar year 2025, the licensee did not limit the annual occupational dose to two adult individuals to 5 rem, total effective dose equivalent (TEDE), and did not limit the annual occupational exposure to one of those two individuals to 50 rem, shallow dose equivalent (SDE) to the skin of the lower extremities. Specifically, the licensee concluded that one individual received 13.8 rem TEDE and 240 rem SDE to the skin of the lower extremities between January 1 and April 8, 2025, and another individual received 9.9 rem TEDE between January 1 and April 8, 2025.

This is an apparent violation of 10 CFR 20.1201(a) and is being considered for escalated enforcement in accordance with the NRC's Enforcement Policy.

3.3 Conclusions

Violations of 10 CFR 20.1201(a) and 10 CFR 20.1501(a)(2) were apparent.

4 Notifications and Reporting

4.1 Inspection Scope

The inspectors interviewed involved personnel and reviewed a selection of records to assess the licensee's compliance with notification and reporting requirements.

4.2 Observations and Findings

A. Initial Notification

The incident occurred between 2:40 pm and 3:10 pm on April 8, 2025. The Site RSO was notified of the incident at 3:15 pm the same day. The Director of the Radiation Safety Office recognized that a worker may have exceeded occupational limits for radiation exposure by about 4:30 pm.

At around 9:55 am on April 9, 2025, the Site RSO notified the NRC's Headquarters Operations Center (HOC) by telephone and email to report the event under 10 CFR 20.2202(b)(1). This notification resulted in Event Number 57657 and was recorded in the Nuclear Materials Events Database under item number 250143.

Although actual radiological conditions and the degree of loss of control over licensed activities were potentially more significant than was first realized, the inspectors found it reasonable that the licensee reported this incident under 10 CFR 20.2202(b)(1) rather than 20.2202(a)(1), given the information available within 24 hours of the incident.

B. Written Report

On May 9, 2025, the licensee submitted a preliminary written report to NRC Region III, pursuant to 10 CFR 20.2203(a)(1). The report was timely and contained all information required by 10 CFR 20.2203(b)(1). On September 2, 2025, the licensee supplemented this with a final written report which also contained the information required by 10 CFR 20.2203(b)(2).

4.3 Conclusions

There were no findings in this area.

5 **Special Inspection**

5.1 Inspection Scope

A special inspection was chartered (ML25113A262) in response to the event and the initial residual uncertainty to its cause. The inspectors were tasked with the following inspection objectives:

1. Develop a clear understanding of the circumstances leading to the exposure incident through a review of records, performing observations of licensed activities, and conducting interviews.
2. Assess the initial response to the exposure incident, including its efforts to identify the cause of the potential overexposure and an assessment of immediate actions to prevent recurrence.
3. Evaluate the licensee's radiation dose monitoring and assessment methods.
4. Evaluate the licensee's material control and accountability measures.
5. Evaluate the licensee's radiation protection program for contributing causes to the exposure incident. This will include an assessment of compliance with applicable NRC requirements; operability and adequacy of radiation safety equipment; safety culture; and the effectiveness of oversight activities.

5.2 Observations and Findings

A. Objective 1 – Develop a clear understanding of the circumstances

The inspectors observed rubidium target processing and Sr-82 dispensing and packaging activities, interviewed all personnel involved in the waste handling activities on April 8, 2025, obtained time and motion information from the assigned individuals who entered the east basement, and reviewed an extensive selection of records, including all radiation-safety related EHS procedures, operational records for Sr-82 production, quality control, and waste handling activities, ED and passive dosimetry records, personnel training records, a selection of area survey records, inventory and accountability records for sealed sources, targets, and waste, corrective action program documentation for recent radiation-related category 1 and 2 incidents, and radiation protection program audits.

The inspectors' best understanding of the circumstances, based on written statements, interviews, and the licensee's chronology in its written report, are described above in Section 2.2

The inspectors also reviewed other recent waste handling activities. Although containers of waste had been prematurely removed from barrels before, personnel dosimetry data indicated that exposures from these prior instances had been well

below regulatory limits. The inspectors considered this plausible based on the circumstances of prior instances which were different from those on April 8, 2025, including that more time had passed between the production run and waste handling activities, resulting in additional time for waste to decay; placement of waste containers well away from the immediate work area; and/or fewer tasks to complete in the basement than were necessary on April 8, 2025.

The inspectors found that it had become an accepted practice for licensee personnel to remove containers of radioactive waste from barrels since, in most cases, contact dose rates on these containers were below 200 mR/hr. Personnel considered this threshold acceptable because the licensee's waste disposal procedure (EHS.0080) stated that containers of radioactive waste must remain in shielding containers or an approved storage area if contact dose rates are above 200 mR/hr. However, this threshold was established to ensure compliance with USDOT limits for dose rates on outgoing packages of radioactive waste. It did not explicitly permit the premature removal of radioactive waste containers below this threshold from shielding, nor had the licensee explicitly approved the basements as an approved storage area for unshielded containers.

B. Objective 2 – Assess the initial response to the exposure incident

On April 11, 2025, a Region III inspector responded to the site to assess radiological conditions on-site and to gather additional information.

The inspector found that the licensee had secured and posted the east basement as a very high radiation area for dose rates above 500 rads/hr, as required. Neither of the exposed individuals had reported any symptoms of acute radiation syndrome or cutaneous radiation injury. The inspector interviewed licensee management and the site RSO, reviewed operational records and ED data associated with the work. The licensee had taken timely action to collect written statements from the involved personnel, to perform its own assessment of conditions, to initiate corrective action and investigation procedures, and begin developing a remediation plan to restore control over licensed activities based on the leading theory. No operational pressure to restore control was noted; the next production run was scheduled for April 16, 2025, but the licensee was prepared to delay as long as necessary to ensure a successful recovery.

On April 16, 2025, the licensee provided the inspector with a copy of its remediation plan that it had submitted to the RSC for approval. The inspector reviewed the plan and had no concerns.

On April 17, 2025, the inspector returned to the site to observe the licensee's preparation for and execution of recovery operations.

The licensee's preparations were thorough and extensive, and the operation was closely monitored. All involved personnel were knowledgeable of the circumstances and potential hazards involved and wore personnel dosimetry and EDs as assigned. The licensee maintained a strong focus on ALARA, even as unexpected challenges were encountered. Personnel were comfortable and confident with the alternative recovery method and executed it as planned and well within the licensee's ALARA goal for the operation.

No residual contamination was noted and dose rates in the vicinity of the east basement returned to expected levels. The liquid waste container, now appropriately shielded, was handled appropriately and placed in the north pit to decay.

During the week of May 19, 2025, the inspectors asked the exposed individuals if the licensee had discussed the potential consequences of their dose or options for monitoring for effects through REACT/S. Both workers reported that the licensee had yet to discuss any of this with them.

C. Objective 3 – Evaluate radiation dose monitoring and assessment methods

The inspectors evaluated available radiation detection and measuring instrumentation on-site, observed the use of this instrumentation during licensed activities, interviewed staff about selection and use of instruments, and reviewed calibration records. The inspectors also reviewed the licensee's methods and measures for periodically evaluating and optimizing occupational dose received by workers and reviewed occupational exposure records.

The licensee used optically stimulated luminescent (OSL) dosimeters, exchanged monthly through an NVLAP-approved processor, to passively monitor beta, gamma, and neutron dose for all radiation workers. These were supplemented by Mirion DMC 3000 EDs, worn by any radiation worker or visitor who entered a restricted area, with dose and dose rate setpoints set at 0.1 R and 0.1 R/hr, respectively. These were the factory default settings for the device. Although for most radiological work activities the inspectors found these setpoints adequate, for work in the hot cell basements (where dose rates were reportedly no less than 0.175 R/hr) the dose rate setpoint provided little meaningful value to workers in monitoring the magnitude and extent of radiation levels in the basement, as it would alarm continuously there.

The Site RSO reviewed electronic dosimeter data at least weekly and actively compared dosimeter readings to OSL reports. Personnel were administratively limited by the licensee's radiation monitoring procedure (EHS.0014) to 3.6 rem DDE, 40 rem SDE to extremities, 6 rem lens dose equivalent, and 20 rem committed effective dose equivalent to other organs in a year. If personnel exceeded any of these limits, the licensee rescinded the individual's access to restricted areas for the remainder of the calendar year.

The inspectors noted that the individual who exceeded regulatory limits on DDE and SDE to the lower extremities previously had their access rescinded after exceeding the licensee's administrative limit (but not the NRC's regulatory limit) on DDE in 2023 and in 2024. The licensee attributed the individual's exceedances to their unique skillset and job duties involving cyclotron maintenance. No other individuals had exceeded administrative limits during this time.

The licensee had several calibrated Thermo Fisher RadEye B20-ER gamma/beta survey meters available for exposure rate measurements in the restricted area. These instruments could read up to 10 R/hr. These instruments were adequate for monitoring radiation levels typically encountered by personnel during normal operations performed in accordance with approved procedures, including radioactive waste handling activities. However, for the activities performed on April 8, 2025 (i.e., removing liquid waste containers from shielding), the instruments could not evaluate

the true magnitude and extent of radiation levels that were created. The licensee had two calibrated Ludlum 3078 extended reach gamma survey meters on-site which could read higher (up to 1,000 R/hr), but personnel did not use these instruments until after the excessive exposures had already occurred. Moreover, staff reported no formal training on selection and use of survey instrumentation.

The licensee also uses airborne contamination monitoring equipment, multi-channel analyzers for facility/package contamination checks, and hand/foot and whole-body portal monitors for personnel leaving restricted areas.

Based on the evaluation of the licensee's radiation dose monitoring methods, additional examples of an apparent violation of 10 CFR 20.1501(a) were identified:

10 CFR 20.1501(a)(2) states that each licensee shall make or cause to be made, surveys of areas, including the subsurface, that are reasonable under the circumstances to evaluate—

- (iv) The magnitude and extent of radiation levels; and
- (v) Concentrations or quantities of residual radioactivity; and
- (vi) The potential radiological hazards of the radiation levels and residual radioactivity detected.

Contrary to the above, on April 8, 2025, Curium US LLC made surveys of areas of its facility in Noblesville, Indiana, that were inadequate under the circumstances to evaluate the magnitude and extent of radiation levels, and the potential radiological hazards of the radiation levels. Specifically:

- (1) The licensee provided personnel with electronic dosimeters for monitoring radiation levels but left the dose rate alarm at 0.1 R/hr. This alarm did not provide the workers with a meaningful evaluation of radiation levels as levels throughout the work area were consistently above 0.1 R/hr, even before they removed a container of radioactive waste from shielding.
- (2) The licensee provided personnel with an instrument for monitoring radiation levels with an upper limit of 10 R/hr when radiation levels well above 999 R/hr were present after they removed a container of radioactive waste from shielding.

D. Objective 4 – Evaluate material control and accountability measures

The inspectors verified that all sealed sources on the licensee's most recent inventory were authorized, secured, and accounted for. The licensee possessed these sources primarily for calibration and evaluation of radiation detection and quantification instruments used in the facility.

The inspectors also reviewed the licensee's control and accountability of rubidium targets, Sr-82 product, and radioactive waste.

Rubidium targets, upon irradiation, were remotely lifted from the cyclotron target vault to a hot cell on the roof of the vault. There each target was kept for a period to allow for decay of short-lived nuclides generated during irradiation. From there, the

targets were transferred via cask to either the east or west bank of hot cells for extraction of Sr-82. After processing, empty target shells remained in the hot cells for extended decay.

Sr-82 product, once isolated from the targets, was kept in the hot cell banks until dispensing. Vials of product were measured with a dose calibrator inside the banks, then loaded into lead pigs for shipping. Aliquots of product were also dispensed at this time and transferred to the Quality Assurance laboratory for analysis.

Radioactive waste was generated throughout restricted areas of the facility. Potentially contaminated personnel protective equipment and other dry materials were disposed of in designated containers lined with plastic bags printed with the radiation trefoil and the words "CAUTION: RADIOACTIVE MATERIALS". Low-level liquid waste generated in the Quality Assurance laboratory was collected in jugs kept in similar bags. All such containers, when full, were taken to the north pit or the iodine room for decay in storage. Activated cyclotron components were handled in a similar manner.

Radioactive waste generated from the hot cell banks was handled as described in Section 2.2 of the report.

The inspectors found that the licensee did not routinely label the containers of waste generated in the hot cell banks with information on their actual or expected contents, until the waste was eventually characterized and prepared for disposal via a waste broker. The only labeling the licensee provided for the containers while in the basements was via plastic bags as previously described.

Based on this evaluation of waste accountability and handling measures, an additional violation was apparent:

10 CFR 20.1904(a) states that the licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

Contrary to the above, as of April 8, 2025, Curium US LLC did not ensure that each container of licensed material bears a durable, clearly visible label providing sufficient information to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures. Specifically, the licensee did not routinely label containers of liquid radioactive waste with sufficient information on its contents of its hazards to permit workers handling and working in the vicinity of these containers to take precautions commensurate with the quantities of radioactivity and radiation levels present.

This is an apparent violation of 10 CFR 20.1904(a) and is being considered for escalated enforcement in accordance with the NRC's Enforcement Policy.

The inspectors also found it difficult to fully reconcile the licensee's inventory of material other than sealed sources possessed under the license, especially its inventory of radioactive waste. For example, multiple bags of discarded personnel protective equipment, three containers of germanium-68 from 2016-2017, and a box labeled to contain strontium-85 and germanium-68 were not accounted for on the licensee's waste inventory records.

E. Objective 5 – Evaluate the radiation protection program for contributing causes

The inspectors interviewed licensee personnel and management on the implementation of the licensee's radiation protection program and reviewed a selection of records including all radiation-related procedures, all corrective action program entries for category 1 and 2 radiation-related incidents in Noblesville, audits of the radiation protection program in Noblesville, and documentation of radiation-related training and routine health physics duties, including tracking mechanisms.

The licensee's radiation protection program was adequately staffed at the time by individuals who were knowledgeable of radiation protection principles, licensee operations and procedures, and regulatory requirements.

Previous radiation-related incidents were identified and investigated promptly and per procedure. Radiation-related procedures were generally clear and provided adequate administrative control of radiological risk, when followed. One notable exception, however, was the radiological work permit procedure (EHS.0003), which only required an initial evaluation of radiological conditions during work, and did not address the potential for changes in those conditions.

During a review of tracking and documentation of radiation-related training and routine duties, several gaps were identified, suggesting less than rigorous oversight of these matters. It was unclear, for example, whether a scheduled area survey selected for review had been performed, as full documentation could not be located. In addition, several individuals' records of training (read and sign) on procedures were incomplete. Notably, the individual who exceeded the annual limit on DDE (but not SDE to the lower extremities) did not sign off on having read and understood the licensee's radioactive waste handling procedure (EHS.0028).

The licensee last audited its radiation protection program on November 28, 2022, December 28, 2023, and November 25, 2024. The inspectors found these audits to be cursory relative to the scope of licensed activities, with limited and repetitive reviews of day-to-day operations and deficient relative to commitments made as part of the licensee's broad scope application in 2023, with no review of radioactive waste management, no documentation of independent or confirmatory surveys, and no documented review of ALARA principles or their application.

Based on this evaluation, an additional apparent violation was identified:

Condition 23.P of NRC License No. 030-38841, Amendment no. 11, dated August 14, 2023, states in part that, except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the letter dated June 7, 2023.

In the letter dated June 7, 2023, the licensee stated, in part, that it “follows the audit model provided in Appendix F of NUREG-1556, Volume 11, Revision 1. Curium performs in-depth audits of the program elements included in the audit model. The audits include reviews of the day-to-day operations to determine compliance risks and gaps with NRC regulations, the terms and conditions of the NRC license, the requirements of the RSC- or RSO-approved permits (as appropriate) as well as application of good health physics practices and ALARA principles.”

Appendix F of NUREG-1556, Volume 11, Revision 1 includes Radioactive Waste Management and Independent and Confirmatory Measurements as program elements in the audit model.

Contrary to the above, between December 28, 2023, and November 25, 2024, Curium did not conduct its program in accordance with the statements, representations, and procedures contained in the letter dated June 7, 2023. Specifically:

- (1) The licensee did not perform in-depth audits of the program elements Radioactive Waste Management and Independent and Confirmatory Measurements in its 2023 and 2024 audits.
- (2) The 2023 and 2024 audits did not include any evaluation of the licensee’s application of ALARA principles.

This is an apparent violation of Condition 23.P of NRC License No. 13-35179-02 and is being considered for escalated enforcement in accordance with Section 6.3 and 6.7 of the NRC’s Enforcement Policy.

5.3 Conclusions

A violation of 10 CFR 20.1904(a) was apparent, as were additional examples of a violation of 10 CFR 20.1501(a)(2). A violation of License Condition 23.P was also identified.

6 Additional NRC Assessments

6.1 Inspection Scope

The inspectors obtained an independent assessment of occupational exposures from the incident and performed independent root cause analysis using information obtained during the on-site inspection.

6.2 Observations and Findings

A. Assessment of Radiation Exposures

The inspectors collected passive dosimeters readings for 2025 and electronic dosimeter logs from April 8, 2025, for those involved in the incident. The inspectors confirmed the source term and dimensions, and had the assigned workers perform timed reenactments of activities in the basement to estimate time, distance, and orientation to the unshielded container of liquid radioactive waste. The inspectors

assembled this information into a minute-by-minute integrated event timeline and collated it with personnel actions derived from written statements, interviews, and the licensee's chronology in its written report.

The NRC then contracted an independent consultant to perform a dose reconstruction for the exposed workers using the information obtained from the inspection. The consultant developed modifying factors for buildup and attenuation for various standoff distances and positions to calculate per-minute effective dose equivalents and used VARSKIN+ to calculate skin dose and, along with Phantom with Moving Arms and Legs (PiMAL) code, to validate effective dose equivalent estimates. The consultant calculated a maximum dose rate on contact with the container of liquid radioactive waste to be 5,500 R/hr (around 1.5 R/s) and concluded that one individual received 18.4 rem TEDE and 56 rem SDE to the skin of the lower extremities as a result of the incident. The consultant concluded that the other individual received 9.5 rem TEDE.

The inspectors considered the estimate provided by the licensee's consultant of 240 rem SDE to the lower extremities of one of the assigned workers to be exceedingly conservative. The inspectors found reasonable assurance that this worker was standing in close but variable proximity from the container for no more than 5 minutes, rather than in extremely close proximity for the full duration of the work (20 minutes) after the bucket was removed, as assumed by the consultant in the absence of evidence beyond reasonable doubt to the contrary. The NRC's consultant determined that the worker's SDE could not have exceeded 100 rem, and the inspectors independently determined that it could not have exceeded 135 rem.

B. Root Cause Analysis

The inspectors performed a root cause analysis for the incident using fault tree analysis, supplemented by barrier analysis and the five whys technique. The inspectors concluded that the direct cause of the exposures above limits was the removal of the waste container, and the 210 curies of rubidium radionuclides inside, from shielding at the beginning of work in the east basement.

The inspectors concluded that the root cause of the incident was the licensee's failure to implement and maintain an effective radiation safety program, due to insufficient management oversight and accountability.

The inspectors also noted the following contributing factors: Inadequate recognition and mitigation of hazards, deficiencies in planning and execution of radiological activities, insufficient training and failure to ensure personnel competency in radiation safety procedures, and a deficient safety culture that failed to prioritize radiological risk and procedural compliance and failed to effectively manage operational changes (see the Addendum to this report for more detail).

The inspectors noted that the root cause analysis performed by the licensee's internal investigation team was thorough and of high quality and was generally consistent in its conclusions.

C. Safety Culture Assessment

The inspectors identified inadequate safety culture as a contributing factor to the exposures. Specifically, the inspectors noted deficiencies in the following traits, which are defined by the NRC's Safety Culture Policy Statement (76 FR 34772 dated June 14, 2011, available at <https://www.nrc.gov/about-nrc/safety-culture/sc-policy-statement.html>):

Leadership Safety Values and Actions: The licensee's leadership permitted (or did not notice) a relaxed approach to procedural compliance and ALARA as well as a cavalier attitude to occupational exposure.

Problem Identification and Resolution: Discrepancies between procedure and practice had been identified in prior radiation protection program audits but were inadequately evaluated (assumed to be the result of outdated procedures rather than a misunderstanding of them) and had yet to be resolved.

Work Processes: Radiological conditions were poorly assessed and controlled during the conduct of waste handling activities, as departures from approved procedures were allowed to persist and proliferate. The established radiological work permitting procedure did not address the potential for changing conditions.

Questioning Attitude: Complacency permeated the conduct of waste handling activities. Departures from approved procedures were not questioned by involved personnel or management, revealing an underlying pattern of inadequate change management.

6.3 Conclusions

The inspectors concluded that one of the licensee's workers received 18.4 rem TEDE and 56 rem SDE to the skin of the lower extremities, and another received 9.5 rem TEDE. The root cause of these exposures was the licensee's failure to implement and maintain an effective radiation safety program, due to insufficient management oversight and accountability.

7 **Exit Meeting Summary**

The NRC inspectors presented preliminary inspection findings at the conclusion of the Special Inspection and presented final inspection findings by teleconference on August 20, 2025, following completion of the in-office review. The licensee acknowledged the findings presented and committed to continuing the implementation of comprehensive corrective actions. The inspectors also acknowledged, in response to questions from the licensee, the particularly close relationship between the two apparent violations described in Section 2.2 of this report, and agreed that the licensee's existing EHS procedures would have been adequate if implemented as written.

LIST OF PERSONNEL CONTACTED

Curium (Noblesville Facility)

Courtney Chambers – Director, Operations
Danielle Donnelly – Principal Health Physicist
David Furusho – Site Director
Brandon Gilmore – Senior EHS Specialist
Maxim Kiselev – Vice President, R&D Process Improvement
Wesley Klaasen – Principal Manufacturing Chemist
Nicholas Menne – Manager, Production
Nicholas Schwalm – Principal Manufacturing Production Technician
Audra Seifert – Senior Manufacturing Chemist
Franco Storino – Principal Manufacturing Technician
Paul Talbott – Lead Radiation Safety and EHS Technician
Matthew Trusner – Manager, Health Physics and EHS (Site RSO)

Curium (Maryland Heights Facility)

Manuel Diaz – Director, North American Radiation Safety Office
Nhi Ma – Senior Health Physicist
J. Matthew Milton – Senior Director, Continuous Improvement
James Portwood – Vice President, Operations
Ryan Spillers
Daniel Szatkowski – Manager, Health Physics and EHS (Site RSO)
Jason Tilly – Vice President and General Counsel
Ethan Wilson

NV5 Training Academy

Brett Rosenberg – Senior Health Physicist

Attended exit meeting on August 20, 2025.

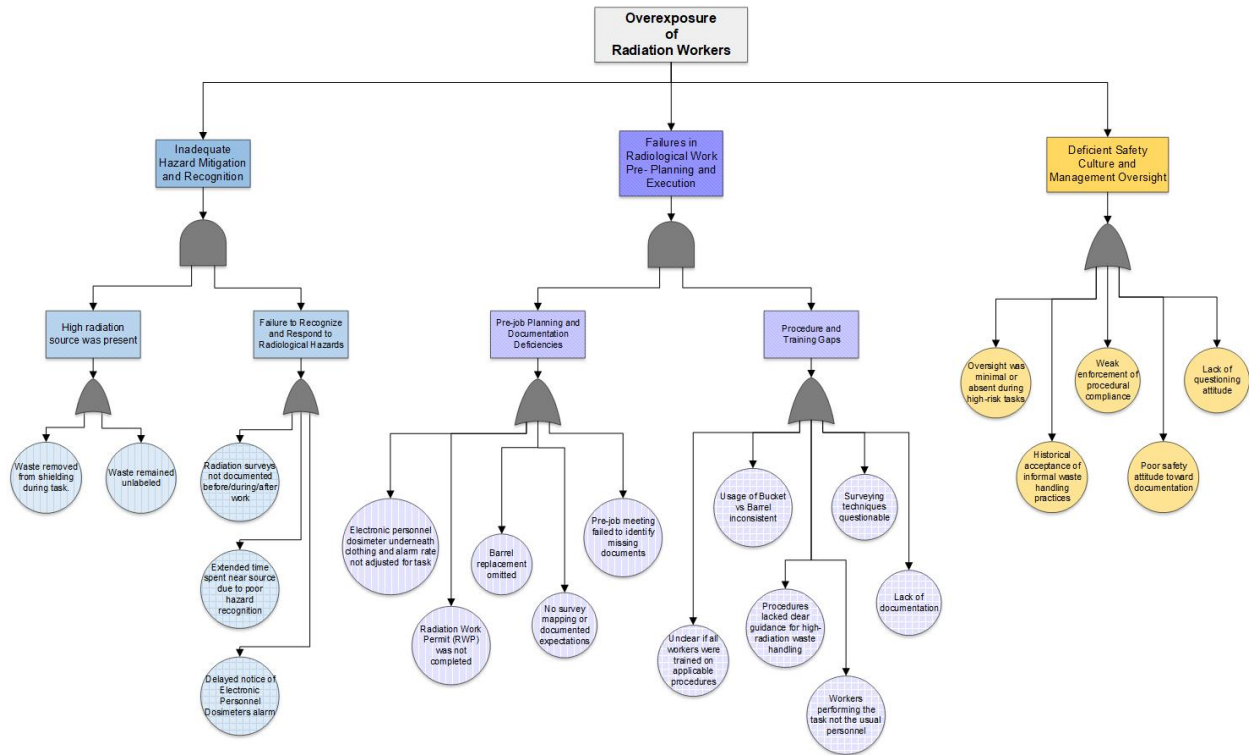
INSPECTION GUIDANCE USED

IP 87103 Inspection of Nuclear Material Licensees Involved in an Incident or Bankruptcy Filing

IP 93812 Special Inspections

Addendum to IR 03038841/2025002(DRSS) Fault Tree Analysis

Courtesy of Candace Krout, U.S.NRC Region I



Gate 1: Inadequate Hazard Mitigation and Recognition (AND gate)

- Gate 1.1: High radiation source was present (OR gate)
 - 1.1.1: Waste removed from shielding during task.
 - 1.1.2: Waste remained unlabeled
- Gate 1.2: Failure to Recognize and Respond to Radiological Hazards (OR gate)
 - 1.2.1: Radiation surveys not documented before/during/after work.
 - 1.2.2: Extended time spent near high radiation source due to poor hazard recognition
 - 1.2.3: Delayed notice of Electronic Personnel Dosimeters alarm

Gate 2: Failures in Radiological Work/Pre- Planning and Execution (AND gate) (Failure in pre-planning)

- Gate 2.1: Pre-job Planning and Documentation Deficiencies (OR gate)
 - 2.1.1: Radiation Work Permit (RWP) was not completed

- 2.1.2: Electronic personnel dosimeter underneath clothing and alarm rate not adjusted for high radiation area
- 2.1.3: Pre-job meeting failed to identify missing documents (RWP)
- 2.1.4: Barrell replacement omitted
- 2.1.5: No survey mapping or documented expectations
- Gate 2.2: Procedure and Training Gaps (OR gate)
 - 2.2.1: Procedures lacked clear guidance for high-radiation waste handling
 - 2.2.2: Unclear if all workers were trained on applicable procedures
 - 2.2.3: Lack of documentation
 - 2.2.4: Surveying techniques questionable
 - 2.2.5: Usage of Bucket vs Barrel inconsistent
 - 2.2.6: Lack of documentation
 - 2.2.7: Workers performing the task were not usual personnel

Gate 3: Deficient Safety Culture and Management Oversight (OR Gate)

- 3.1: Oversight was minimal or absent during high-risk tasks
- 3.2: Historical acceptance of informal waste handling practices
- 3.3: Weak enforcement of procedural compliance
- 3.4: Poor safety attitude toward documentation
- 3.5: Lack of questioning attitude