

**Work scope details:**

Title: Actinium-225/Radium-225 Intermediate Consolidation

Work Scope Summary: - The procedure outlines the process for reclaiming and consolidating Radium-225 fractions and any unused purified Actinium-225 from a previous Column VI run. These fractions are combined into a single vial, labeled with a specific batch number, and referred to as the Ac-225/Ra-225 intermediate. The operations are conducted under Current Good Manufacturing Practice (CGMP) for Drug Substance Intermediate production, specifically within Lab 201 at Oak Ridge National Laboratory.

Key Work Scope Components: - Reclaiming Ra-225 fractions - Consolidating unused purified Ac-225 - Combining fractions into a single vial labeled "Ra pool-W2" - Operating under CGMP for Drug Substance Intermediate production - Involvement of Actinium Production Team (AcPT) and Quality Unit (QU) personnel

**Relevant previous events and lessons learned:**

Event Title	Event Summary	Lessons Learned	Reference link
Unintended Isotope Provided to Argonne National Laboratory	<p>On May 10, 2022, Oak Ridge National Laboratory (ORNL) discovered that a February shipment of radium-223 (Ra-223) to Argonne National Laboratory (ANL) unintentionally contained actinium-227 (Ac-227), which had a potential to expose ANL staff and equipment. ORNL is supporting ANL in evaluating potential impacts to ATLAS staff and equipment. There were no dose or contamination issues during transport and no disruptions at the receiving facility upon receipt.</p> <p>Radium-223 processing and shipments were stopped pending a review of procedures and controls. A critique of the event was conducted on May 12. ORNL management commissioned a formal investigation of the event and is actively investigating the cause of the event which will include a Root Cause Analysis.</p>	<p>The ATR was operating for Cycle 172A-1 at the time. Required actions were completed per the TSRs including establishing a correlation between N16 and a known NL instrument indication. Appropriate levels of BEA management and the DOE Facility Representative were notified of this discovery. Maintenance Work Request 2024-1431 was submitted.</p>	<a href="#">Link</a>

Clothing Contamination in Building 4501	<p>On March 5, 2024, a Radiological Control Technician (RCT) discovered radiological contamination on a Radioisotope Science and Technology Division employee's pant leg in Building 4501 (a contamination area). The employee was working in a hood pouring a solution of Ac-225 and Th-232 into a column. Some of the solution spilled toward the employee after the ring stand holding the column unexpectedly shifted. The employee immediately stopped work, placed the equipment in a safe configuration, and requested RCT support. The isotopic analysis of the contaminated piece of clothing identified Ac-225, Th-232, and Fr-221. The work area was secured pending further surveys. Notifications were made. A critique was conducted on March 6. A causal analysis will be conducted, and corrective actions will be developed and tracked to closure.</p>	<p>The ATR was operating for Cycle 172A-1 at the time. Required actions were completed per the TSRs including establishing a correlation between N16 and a known NL instrument indication. Appropriate levels of BEA management and the DOE Facility Representative were notified of this discovery. Maintenance Work Request 2024-1431 was submitted.</p>	<a href="#">Link</a>
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#### Missing Hazards:

Hazard	Missing or Inadequate Mitigation in Current Work Control Document	Recommended Mitigation for Revision	Reference link	SBMS Link
Thermal Hazards	Inadequate controls for extreme temperature exposure	Implement comprehensive temperature monitoring and control measures, including PPE and administrative controls	<a href="#">HSE Blog</a>	<a href="#">Link</a>
Radiological Contamination	Lack of specific controls for contamination monitoring and prevention	Enhance contamination monitoring protocols and protective measures for workers in radiologically controlled areas	<a href="#">Wikipedia</a>	<a href="#">Link</a>

Unintended Isotope Shipment	No specific controls for isotope shipment safety	Develop detailed procedures for safe handling and transport of isotopes, including emergency response plans	<a href="#">IAEA</a>	<a href="#">Link</a>
Ergonomic Strain	No mention of ergonomic hazard controls	Implement ergonomic assessments and controls to reduce strain, including workstation adjustments and training	<a href="#">OSHA</a>	<a href="#">Link</a>
Inadequate Ventilation	Lack of ventilation assessment and improvement measures	Conduct ventilation assessments and implement engineering controls to ensure adequate airflow and air quality	<a href="#">Weblio</a>	<a href="#">Link</a>
PPE Failure	No specific controls for PPE integrity and failure	Establish regular PPE inspection and maintenance protocols to ensure effectiveness and reliability	<a href="#">Weblio</a>	<a href="#">Link</a>
Procedural Errors	No specific controls for preventing procedural errors	Develop comprehensive training and procedural guidelines to minimize errors and enhance safety practices	<a href="#">CCOHS</a>	<a href="#">Link</a>

**Failure mode analysis:**

Current control	Failure mode of the control	Effect of Failure	Cause of Failure	Recommended action
Written permits for the work activity	Permit not obtained or invalid	Unauthorized work leading to safety hazards	Miscommunication or oversight in permit process	Implement a robust permit verification system and regular audits
Personal Protective Equipment (PPE)	PPE not used or inadequate	Increased risk of injury or contamination	Lack of training or availability	Conduct regular PPE training and ensure availability of appropriate PPE

Work instructions	Instructions not followed or unclear	Unsafe work practices leading to accidents	Vague guidance or lack of understanding	Enhance clarity of instructions and conduct pre-job briefings
Radiological Work Permit	Permit not followed or expired	Exposure to radiological hazards	Failure to update or adhere to permit conditions	Regularly review and update permits; conduct compliance checks
Dosimetry Monitoring Requirements	Monitoring equipment failure	Undetected exposure to radiation	Equipment malfunction or improper use	Regular maintenance and calibration of monitoring equipment
Ventilation system	System failure or inadequate ventilation	Chemical exposure or contamination	Mechanical failure or lack of maintenance	Schedule regular inspections and maintenance of ventilation systems
Safety glasses	Not worn or incorrect type used	Eye injuries from chemical splashes or debris	Non-compliance or incorrect PPE selection	Ensure mandatory use and correct selection of safety glasses
Emergency Response Plan	Plan not followed or inadequate	Ineffective response to emergencies	Lack of training or unclear procedures	Conduct regular emergency drills and update response plans
Eyewash/safety shower	Equipment failure or inaccessible	Delayed response to chemical exposure	Lack of maintenance or improper placement	Regular checks and ensure accessibility of eyewash/safety showers
Ergonomic conditions	Poor ergonomic practices	Musculoskeletal injuries	Lack of ergonomic assessment or training	Implement ergonomic assessments and provide training on safe practices