

Work scope details:

Title: Actinium-225/Radium-225 Intermediate Consolidation

Work Scope Summary: This work plan outlines the procedure for reclaiming and consolidating Ra-225 fractions and unused purified Ac-225 from a previous Column VI run. The fractions will be combined into a single vial labeled as "Ra pool -W2," adhering to Current Good Manufacturing Practice (CGMP) for Drug Substance Intermediate production.

Key Work Scope Components:

- Reclamation and consolidation of Ra-225 and Ac-225 fractions
- Use of glove boxes for handling radioactive materials
- Application of CGMP standards in a laboratory setting
- Involvement of Actinium Production Team (AcPT) and Quality Unit (QU) personnel
- Use of specialized equipment such as heat sealers and hot plates

Relevant previous events and lessons learned:

Event Title	Event Summary	Lessons Learned	Reference Link
Radiological Contamination Incident at ORNL	A radiological contamination incident occurred due to improper handling of radioactive materials, leading to personnel exposure.	Importance of strict adherence to radiological work permits and continuous monitoring of radiological alarms.	NRC Event Notification
Equipment Failure During Chemical Handling	A chemical fume hood failed during a nitric acid operation, leading to potential exposure.	Regular maintenance and testing of safety equipment are critical to prevent exposure incidents.	OSHA Chemical Safety
Ergonomic Strain in Laboratory Work	Laboratory workers reported musculoskeletal injuries due to repetitive motions and awkward postures while working in confined spaces.	Implementing ergonomic assessments and providing adjustable workstations can mitigate injury risks.	NIOSH Ergonomics
Chemical Spill in Laboratory	A spill of hydrogen peroxide occurred due to improper storage and handling, leading to a hazardous situation.	Proper labeling, storage, and training on chemical handling are essential to prevent spills.	EPA Chemical Safety
Inadequate PPE Use During Radiological Work	An incident where workers did not use appropriate PPE while handling radioactive materials resulted in contamination.	Regular training and audits on PPE usage can enhance compliance and safety.	OSHA PPE Standards

Missing Hazards:

Hazard	Missing or Inadequate Mitigation in Current Work Control Document	Recommended Mitigation for Revision	Reference Link	SBMS Link
Material Handling	Not addressed	Implement mechanical aids for lifting and moving heavy materials.	N/A	N/A
Confined Space Work	Not addressed	Conduct a confined space entry assessment and provide training for workers.	N/A	N/A
Electrical Hazards	Inadequate mitigation	Ensure all electrical equipment is inspected and labeled by a qualified electrician.	N/A	N/A
Ergonomic Strain	Not addressed	Conduct ergonomic assessments and provide adjustable workstations.	N/A	N/A
Chemical Exposure	Inadequate PPE guidance	Specify required PPE for each chemical and ensure availability in the work area.	N/A	N/A
Thermal Burns	Not addressed	Implement a hot surface warning system and training on safe handling of hot equipment.	N/A	N/A
Radiological Exposure	Inadequate monitoring	Ensure continuous monitoring of radiological levels and provide immediate response training.	N/A	N/A
Noise Exposure	Not addressed	Assess noise levels and provide hearing protection if necessary.	N/A	N/A
Time Pressures	Not addressed	Implement a work schedule that allows adequate time for tasks without rushing.	N/A	N/A
Vague Guidance	Not addressed	Develop clear, detailed work instructions and provide training on task execution.	N/A	N/A
Overconfidence	Not addressed	Conduct regular safety briefings to reinforce the importance of following procedures.	N/A	N/A

Hazard	Missing or Inadequate Mitigation in Current Work Control Document	Recommended Mitigation for Revision	Reference Link	SBMS Link
Communication Issues	Not addressed	Establish a clear communication protocol for all team members involved in the work.	N/A	N/A

Failure mode analysis:

Current Control	Failure Mode of the Control	Effect of Failure	Cause of Failure	Recommended Action
Radiological Work Permit	Permit not obtained or expired	Potential exposure to radiation	Lack of awareness or oversight	Implement a tracking system for permit renewals and approvals.
PPE Requirements	PPE not used or inadequate	Increased risk of chemical exposure	Lack of training or enforcement	Conduct regular training sessions and audits on PPE usage.
Work Instructions	Instructions not followed	Increased risk of accidents or exposure	Vague or unclear instructions	Review and revise work instructions for clarity and detail.
Emergency Response Procedures	Emergency procedures not understood	Delayed response to incidents	Lack of training or drills	Conduct regular emergency response drills and training sessions.
Equipment Inspection	Equipment not inspected regularly	Increased risk of equipment failure	Inadequate maintenance schedule	Establish a routine inspection and maintenance program for all equipment.

Current Control	Failure Mode of the Control	Effect of Failure	Cause of Failure	Recommended Action
Chemical Handling Procedures	Procedures not followed	Potential spills or exposure	Lack of awareness or training	Provide comprehensive training on chemical handling and storage.
Communication Protocol	Poor communication among team members	Increased risk of errors	Lack of established communication channels	Develop and implement a clear communication protocol for all team members.
Ergonomic Assessments	No ergonomic assessments conducted	Increased risk of musculoskeletal injuries	Lack of awareness of ergonomic risks	Conduct regular ergonomic assessments and implement recommended changes.
Ventilation Systems	Ventilation not functioning properly	Increased exposure to hazardous fumes	Lack of maintenance or inspection	Schedule regular maintenance and inspections of ventilation systems.
Training and Competency Verification	Inadequate training for personnel	Increased risk of accidents	Lack of structured training programs	Develop and implement a comprehensive training program for all personnel.
Tool Availability	Tools not readily available	Delays in work and increased risk of improvisation	Poor inventory management	Maintain an inventory management system to ensure tool availability.
Work Schedule	Inadequate time allocated for tasks	Increased risk of rushing and errors	Poor planning	Review and adjust work schedules to allow adequate time for tasks.

This risk assessment report provides a comprehensive overview of the potential hazards associated with the Actinium-225/Radium-225 Intermediate Consolidation work plan, along with relevant historical events, missing hazards, and failure modes of current controls. Implementing the recommended actions will enhance safety and

compliance with applicable regulations.