

Draft
ORNL WORK PLAN
Operations, Maintenance and Services



62569

Work Plan Name / Rev: CGMP-ACTD-OP-015 / 0

WORK SCOPE/DESCRIPTION	
Requester (Name/Badge/Division):	Dean, Ian / 03100183 / X073
Location of work (Bldg/Rm/Other):	7920 / 201 /
Work Plan Title:	Actinium-225/Radium-225 Intermediate Consolidation
Description of Service/Work Needed:	
<p>Purpose</p> <p>This procedure describes the process to reclaim and consolidate Ra-225 fractions and any unused purified Ac-225 from a previous Column VI run. These fractions are combined into one vial, labeled as "Ra pool-W2" followed by the associated batch number that contains and is referred to as the Ac-225/Ra-225 intermediate.</p> <p>This work operates under Current Good Manufacturing Practice (CGMP) for Drug Substance Intermediate production.</p>	
<p>1.2 Scope</p> <p>The operations described in this procedure are routinely performed in Lab 201 in Building 7920 at Oak Ridge National Laboratory (ORNL). The scope of this procedure is limited to the CGMP Drug Substance Intermediate production of Ac-225 from Th-229.</p> <p>This procedure applies to the Actinium Production Team (AcPT) and Quality Unit (QU) personnel supporting Ac-225 from Th-229 production.</p>	
Charge Number, if required:	
Work Plan Grade/Worktype:	0 / 0
Author (Name/Badge):	Dean, Ian / 03100183
File Attachments:	
INSTRUCTIONS	
<p>Prerequisites/Precautions:</p> <p>Directions:</p> <p>Post Work Testing:</p> <p>Closeout:</p>	
JOB HAZARD EVALUATION	
HAZARDS	PERMITS / CONTROLS
Radiological Work: Adhere to any applicable RWP's or RCT controls.	<ul style="list-style-type: none"> Radiological Work Permit (Enter RWP no.) Dosimetry Monitoring Requirements Follow radiological posting, entry control & egress requirements Respond to Abnormal Radiological Conditions and Alarms. Radiological alarms include: Continuous Air Monitor (CAM), Area Radiation Monitor (ARM), Electronic Pocket Dosimeter (EPD), Personnel Contamination Monitor (PCM).
Electrical Equipment and Tools	<ul style="list-style-type: none"> Listed by a nationally recognized testing laboratory (NRTL) Not NRTL listed <ul style="list-style-type: none"> Has Equipment Labels or Have made provision for Electrical Equipment Inspector (EEI) review and Electrical Safety Officer (ESO) approval or Equipment poses no or little hazard (see Exhibit)
Ergonomic Conditions (Contact Stress, Vibration, Posture, Force, Repetitive Motion): working within glove boxes will be required and may pose ergonomic strain to workers.	<ul style="list-style-type: none"> Exposure Assessment: Enter or attach justification to classify exposure scenario as low risk, qualitative exposure assessment (QEA), or requirement to conduct quantitative exposure monitoring (QEM) Diversify activities: Implement as feasible. Special Tools (Lifts, etc.): Padded floor mats, step

	<ul style="list-style-type: none"> stools, etc may be used. Stretch breaks/exercises: Implement as needed Worker rotation: Implement as feasible or needed.
Explosives/Shock Sensitive: Nitrated organics are present in the resins before being converted to safe state prior to disposal.	<ul style="list-style-type: none"> Special waste provisions: Nitrated organics are converted to another form prior to disposal to eliminate explosive hazard.
Thermal Sources: Use of a heat sealer and hot plate is required under this procedure.	<ul style="list-style-type: none"> Be aware of hot any hot surfaces or how it may affect material.: Be aware of hot any hot surfaces or how it may affect material. Ensure hot plate does not exceed 230C: Do not store other material on/around hot plate. Ensure hot plate is turned off when not in use
Chemical/Rec ID 1: Nitric Acid / 00275	<ul style="list-style-type: none"> <u>Exposure Assessment:</u> Enter or attach justification to classify exposure scenario as low risk, qualitative exposure assessment (QEA), or requirement to conduct quantitative exposure monitoring (QEM) Aprons: Apron with long sleeves or lab coat when performing hands on work with chemicals Chemical goggles: Required during hands on work where splash or vapor hazard exists. Gloves: Specify. When handling nitric acid outside of containment ensure you are wearing any of the following gloves; Laminate film (barrier gloves, Unsupported neoprene gloves, or Polyvinyl Chloride gloves Lab coats: Required when performing hands on work Eyewash/safety shower: Ensure eyewash/safetyshower is working and readily accessible. If used ensure to rinse for 15 minutes & notify supervision & medical. Ventilation: If working with chemicals in containment, ensure the ventilation is working properly and the system is within its certification period. Suitable shoes: Closed toed shoes are required for general work. Safety toed shoes required when lifting/moving heavy material. Safety glasses: Safety glasses are required throughout the work process when they are not superseded by other PPE. Lab spaces require safety glasses.
Chemical/Rec ID 2: Hydrogen Peroxide / REC ID 00443	<ul style="list-style-type: none"> <u>Exposure Assessment:</u> Enter or attach justification to classify exposure scenario as low risk, qualitative exposure assessment (QEA), or requirement to conduct quantitative exposure monitoring (QEM) Aprons: Apron with long sleeves or lab coat when performing hands on work with chemicals Chemical goggles: Required during hands on work where splash or vapor hazard exists. Gloves: Specify. Gloves required for handling hydrogen peroxide include any of the following: Nitrile, Unsupported neoprene, Polyvinyl chloride, Natrual rubber, neoprene/natrual rubber blend, Viton/butyl . Lab coats: Required when performing hands on work Eyewash/safety shower: Ensure eyewash/safetyshower is working and readily accessible. If used ensure to rinse for 15 minutes & notify supervision & medical. Ventilation: If working with chemicals in containment, ensure the ventilation is working properly and the system is within its certification period. Suitable shoes: Closed toed shoes are required for general work. Safety toed shoes required when lifting/moving heavy material. Safety glasses: Safety glasses are required throughout

the work process when they are not superseded by other PPE. Lab spaces require safety glasses.

DOCUMENTATION REVIEW AUTHORIZATION
(Approvals are certification of hazards assessment)

Reviewer/Approver Roles	Signature	Date
Work Package Concurrence		
Facility Manager		
Operations Supervisor		
Facility Manager Approval To Start Work		
Facility Manager		
Work Start Authorization		
Task Leader		
Work Acknowledged Complete		
Task Leader		
Worker Feedback:		

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PRE-JOB SAFETY REVIEW GUIDE

ID: 62569

Scope of Work: Review work package/plan to ensure all participants understand the work activity.

Hazards: Review the hazards identified in Job Hazard Evaluation (JHE) / work plan (IOP).

- ε Since the work package / plan was written: 1) Have conditions changed? 2) Are there new hazards? Refer to Field Notes and Focus Areas.

Hazard Controls / Permits: Review:

- ε Written permits for the work activity.
- ε Precautions, step warnings, Hold Points ...
- ε Personal Protective Equipment (PPE)

- ε Work instructions for information - e.g., steps where hazards are introduced.
- ε ORNL subject area requirements - e.g., non-permit hazard controls.

Performing Work:

- ε Discuss group/individual responsibilities for safe & effective work.
- ε Follow work instructions & safety procedures.
- ε Availability/location of materials, tools, etc.
- ε Any previous experiences / lessons learned?
- ε Response if work cannot be performed as planned.
- ε What is the worst thing that could happen?
- ε Are there *Potential error traps* with the job? → →
- ε Take a minute before: work start & leaving work area.
- ε Work Hand-off / Turnover - workers & Task Leader

→ **Potential Error Traps:**

- ε Time pressures
- ε Distractive environment
- ε High workload
- ε First time evolution
- ε First day back
- ε Vague guidance
- ε Over confidence
- ε Imprecise communications
- ε Work stress

Abnormal Situation Response:

- | Stop Work: Observe an unsafe act, activity or condition that creates an imminent danger.
- | Emergency Response: Discuss egress paths or other responses if problems are encountered.

Field Notes and Focus Areas: (Use this area as a work space to record notes related to new hazards identified in the field or changed conditions. Record feedback in work package/plan information systems.)

By signing below, I am indicating that I have been briefed on the potential hazards associated with completing this job.

Signature / Badge	Date	Signature / Badge	Date