



Creating Materials & Energy Solutions
U.S. DEPARTMENT OF ENERGY

Contact Person [Kevin Dennis](#)
Document Procedure 10200.010

Revision 15.1
Effective Date 10/01/2016
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READINESS REVIEW

This procedure shall be used to direct the identification, hazard categorization, and safety readiness review of activities. This procedure shall be utilized by group leaders, program directors/department managers, the Environment, Safety, Health and Assurance (ESH&A) Office, and the Safety Review Committee (SRC) for the review of all activities performed by Ames Laboratory employees.

1.0 APPROVAL RECORD

Reviewed by: Training & Documents, QA Coordinator (Molly Granseth)
Reviewed by: Facilities & Engineering Services Assistant Manager (Terry Herrman)
Reviewed by: Facilities & Engineering Services Engineer (Mike Vaclav)
Reviewed by: Associate Scientist (Igor Slowing)
Reviewed by: Associate Scientist (Pratik Ray)
Reviewed by: Assistant Manager, ESH&A (Shawn Nelson)
Approved by: Manager, ESH&A (Sean Whalen)
Approved by: Deputy Director (Tom Lograsso)

The official approval record for this document is maintained by Training & Documents.

2.0 REVISION/REVIEW INFORMATION

In accordance with the Ames Laboratory Document Control program, this procedure will be reviewed no less than every three years. The revision description for this document is available from and maintained by the author.

3.0 PURPOSE AND SCOPE

The procedure for readiness review of activities has been developed to ensure an appropriate level of rigor, commensurate to the hazards associated with an activity, is applied to the activity's safety review. This procedure shall be utilized by group leaders and Division Directors/Department Managers for all activities. The interaction of the ESH&A Office, Facilities & Engineering Services, Occupational Medicine, and the SRC in the review of activities is also directed by this procedure. All new or significantly modified activities must undergo review prior to commencement of the activity. All existing activities are subject to periodic review (at intervals not to exceed five years) to ensure the activities are being performed within the authorized safety envelope.

4.0 DEFINITIONS

Activity Description (scope of work): One or several action(s), process(es), and/or piece(s) of equipment, coordinated to perform a task. Activity description on the Readiness Review Approval Form must be written with sufficient detail to adequately understand the scope of the activity. Additionally, the description should be written so users know when they have approached or exceeded the intended scope of work. See definition of "Significantly Modified Activity" for additional information.

Activity Supervisor: A person designated by the group leader with responsibility for supervision and coordination of the development and/or operation of an activity.



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Group Leader: A person who reports directly to a division director and has line management responsibility for space, equipment, activities, and employees. The group leader is responsible for the overall management of group activities and shall ensure proper identification and categorization of activities (e.g. new, significantly modified, discontinued, dormant, etc.) in accordance with this procedure. Group leaders are encouraged to have discussions with activity users for feedback and continuous improvement. This also includes financial responsibilities.

Developmental Review: The part of this procedure applicable to new or significantly modified activities and to activities that have been halted due to a stop work order. The developmental review will include a site visit and may require submission of a test plan before developmental approval is given. During the developmental review, the ESH&A lead specialist and the activity supervisor/group leader shall determine a mutually acceptable schedule for completion of the developmental phase and an approximate date for seeking final operational approval.

Dormant Activity: An activity for which a readiness review has been postponed due to the temporary suspension of work or research in a particular area. These activities may be reactivated following completion of an operational readiness review. Failure to reactivate a dormant activity before a second scheduled 5-year readiness review will result in the classification of this activity as discontinued.

Discontinued Activity: An activity that is no longer performed by the responsible group. Reactivation of a discontinued activity requires a developmental readiness review. Discontinued activities may require decommissioning that involves determination of the status and ownership of chemicals, materials, and equipment used in the activity.

ESH&A: The Environment, Safety, Health & Assurance Office at the Ames Laboratory.

ESH&A Lead Specialist: Staff member whom, along with others in the ESH&A Office, is designated to lead the safety aspects of a readiness review.

Hazard Management Statement: Hazard management statements must describe the discrete tasks with specific hazards and the controls implemented to ensure safety of the activity users. The hazard management statement defines the magnitude of hazards and the controls utilized to minimize the risks associated with the hazard. Ambiguous statements such as “when necessary” or “where necessary” are to be avoided; instead they need to specify when and where controls are necessary. The level of detail of the hazard management statement shall be commensurate with the scope and magnitude of the hazard and the associated risk. Hazard management shall be based on the hierarchy of 1) hazard elimination, 2) engineering controls, 3) administrative controls, and 4) personal protective equipment.

New Activities: Planned, funded activities undergoing initial startup as defined by the group leader.

Operational Review: The part of this procedure applicable to activities that have been previously reviewed or which have received developmental approval. The operational review may be restricted to a review of the documentation referenced in section 7.0 Post Performance Activity. A site visit will be documented and work process observed.

Reassigned: An activity in which the approved processes have been combined or merged with another activity or transferred to another activity.

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Safety Analysis Document: The safety analysis document is a report that systematically identifies the hazards of ESH&A designated Level III activities (see appendix A), describes and analyzes the adequacy of the measures taken to eliminate, control, or mitigate risks associated with the identified hazards, and analyzes and evaluates the potential for and the impact of accidents.

Safety Coordinator: An individual designated by the division director/program manager to assist with the implementation of safety-related procedures and to serve as a liaison between the division director and ESH&A. This role is not part of line management responsibility and does not alleviate any responsibilities from the division directors or program managers.

Significantly Modified Activity: An activity in which a modification introduces new hazards or increases the risk of existing hazards. A new hazard usually means an additional item(s) on the [Readiness Review Hazard Identification Checklist](#) are checked. Most often, an increase in risk will also result in checking a new entry. However, if no new hazards are identified but the risk is increased, a developmental readiness review shall be conducted. An increased risk involves work that exceeds the previously authorized safety envelope. Examples of modifications that increase risk without introducing new hazards might be an increase in operating pressure for a high pressure apparatus, or an activity in which toxic or carcinogenic chemicals with different physical properties are used. It is the responsibility of Group Leaders to consult with their SRC facilitator or ESHA Specialist if assistance is needed to determine if a risk is increased. If modification of an activity results in significant reduction of hazards, the group leader may request review of the hazard level classification by the appropriate lead specialist. Concurrence of the SRC is required for all such reclassifications.

Safety Review Committee (SRC): The membership and role of the SRC is described in the [Safety Review Committee Charter](#).

SRC Facilitator: A member of the SRC who is appointed to assist and guide the group leader/activity supervisor through the readiness review process.

Test Plan: A test plan prescribes the testing to be conducted during developmental review including defining hazard mitigation and includes a timeline and anticipated date when the tests will be completed.

Withdrawn: An activity the group leader/department manager has removed from consideration.

5.0 PREREQUISITE ACTIONS AND REQUIREMENTS

Annually, the SRC will prepare a list of current activities for division, institute, program director or department managers who are responsible for communicating the information to the group leaders. Group leaders shall review this list to ensure that all activities have been authorized and that no significant modifications or changes have occurred in the hazard levels of those activities since they were last reviewed. In addition, group leaders will be notified who is currently assigned to be their SRC facilitator.

Group leaders are responsible for notifying the appropriate safety coordinators, division, institute, program director or department managers, and the ESH&A office of the proposed development of a new activity or proposed changes to an existing activity at the earliest possible point in the planning process. New or modified activities will undergo a two-phase review process.

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- Developmental approval authorizes the acquisition, fabrication, and testing related to the activity.
- Operational approval authorizes operation within the defined safety envelope.

For the periodic review of existing activities (see section 6.3), ESH&A will send written notification to the group leader indicating the need to submit the documentation for review. These notices will be sent out at least **3 months prior** to the period year anniversary of the last completed review of the activity. Failure to respond to this notice or submit the readiness review documentation in a timely manner will result in a stop work order for that activity.

6.0 PERFORMANCE

6.1. Identification of Activities

An activity is one or several action(s) or process(es) with or without associated equipment, coordinated to perform a task.

Group leaders are responsible for the appropriate delineation of activities. Generally, it is recommended an activity be defined to cover classes of actions, processes and/or equipment when these actions have essentially the same potential hazards. An activity should be defined to include the potentially most hazardous conditions that could be encountered. This could eliminate the need for additional review when a change occurs in the character of the physical hazards, the chemicals used, and/or the waste generated.

Action(s), process(es), and/or equipment which have unique hazards (e.g. radiation, high toxicity, etc.) are best defined as separate activities. This will allow for the application of a graded approach to hazard management.

Ames Laboratory activities are classified as 1) laboratory/industrial type, or 2) office type. Examples of laboratory/industrial type activities include: experimental research, applied research, production, maintenance, fabrication, construction, hazardous waste handling, and warehouse shipping and receiving activities. Examples of office type activities include: theoretical research, computational activities, design, and administrative activities.

Ames Laboratory funded activities that undergo a modification will be subject to a developmental readiness review if the modification significantly alters the hazards associated with the activity or if the risk associated with a particular hazard is increased. Activities in which the hazards have changed may be identified by reviewing the [Readiness Review Hazard Identification Checklist](#). An example where the risk associated with a hazard has increased is the scale-up of an activity where larger quantities or a different class of hazardous chemical are to be used.

6.1.1. Off-site Activities

Ames Laboratory funded activities (including, but not limited to, activities funded by Royalty Funds, LDRD, etc.), that are conducted entirely, or in part, in locations other than Ames Laboratory space or Ames Laboratory rented space may be subject to readiness review. Royalty discretionary reviews of off-site activities will typically examine the experimental design or equipment and provide guidance for the safe operation of the activities. Particular areas of concern are, but are not limited to:

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personnel protection equipment (PPE), baseline monitoring, equipment testing and certification, procedural reviews and reviews of host site procedures if available and prudent. In some cases, a site visit may be necessary when risk of exposure to dangerous conditions may be present or when requested by the group leader. The cost of travel, associated with off-site visits will be the responsibility of the group leader. Ames Laboratory review of off-site activities does not replace the requirement to comply with review and safety requirements of institutions where the off-site activity may occur.

Activities conducted in ISU space (not Ames Laboratory rented space) are considered to be off-site. Readiness review of these activities will be conducted jointly by ISU Environmental Health and Safety staff and the Ames Laboratory Review Team. Coordination of joint reviews will be the responsibility of the lead specialist.

6.1.2. *Non-Ames Laboratory Funded Activities*

Non-Ames Laboratory funded activities that are conducted entirely, or in part, in Ames Laboratory space or Ames Laboratory rented spaces are subject to readiness review. It is the responsibility of the group leader to identify these activities and submit the appropriate readiness review documentation.

6.2. **Activity Hazard Levels**

All activities are categorized into one of three safety hazard levels. These levels are differentiated based on the magnitude (seriousness of potential harm) and scope (area of effect) of the hazard, as well as the risk (realistic potential for the hazard to have an impact of a particular scope and magnitude) involved. The three levels are defined as:

Hazard Level I:

Activities with hazards similar to those encountered and/or accepted by the general public in an office environment. These hazards involve limited risk to (1) the health or safety of workers or the public, (2) the environment, or (3) the facilities or mission of the Laboratory. These hazards have minimal scope and magnitude. No readiness review is required.

Hazard Level II:

Activities with hazards similar to those encountered in a typical industrial/laboratory environment. These activities are delineated into three sub categories: II-Low, II-Moderate, and II-Elevated. These activities involve hazards whose scope may involve (1) significant risk to the health and safety of workers involved in the activity or those working within the surrounding area in which the activity is being performed, (2) short-term localized environmental impacts, or (3) minimal and localized damage to facilities or negative impacts on the performance of program or Laboratory functions.

Hazard level II-Low: Activities in an industrial or laboratory setting that exhibit hazards encountered and/or accepted by the general public. Hazards may include ergonomic issues, egress requirements, lifting or bending. These activities are subject to review initially and then only when the activity is significantly modified or hazards increase.

Hazard level II-Moderate: Activities which exhibit typical industrial/laboratory hazards. Hazards may include x-ray generating devices, chemical use, and

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cryogenic systems. These activities are subject to review on a five-year cycle.

Hazard Level II-Elevated: Activities which require heightened scrutiny over typical industrial/laboratory environments. Activities involve controlled hazards that could pose a significant risk to the health or safety of users and co-workers or immediate surrounding area. Hazards may include exceptional pressures, chemical incompatibility, toxic gases or materials. These activities are subject to review on a three-year cycle. In all cases, contact the Lead Specialist or SRC Facilitator for assistance.

Hazard Level III:

Activities with hazards that involve a scope that impacts more than a single work site or laboratory area. These activities involve hazards whose scope may involve (1) significant risk to the health or safety of the public or on-site personnel who are not involved in the activity, (2) significant risk of widespread or lasting environmental effects, or (3) significant risk of damaging facilities or impeding the mission of the Laboratory.

6.3. Activity Hazard Level Categorization and Review

The following sections shall be utilized to direct the safety hazard level categorization and readiness review of office type activities and laboratory/industrial type activities. Forms required for readiness review may be obtained from the [Ames Laboratory Forms and Documents webpage](#).

All office type activities are categorized as Hazard Level I provided the activities meet the criteria described above. The categorization of office type activities as Hazard Level I does not imply that there are no safety concerns regarding these activities. Group leaders are referred to ESH&A for additional guidance on the management of hazards associated with their office type activities. They may also consult with their SRC facilitator to determine if readiness review is appropriate.

6.3.1. Procedure Steps

- 1) **Group Leader:** AL-240 Readiness Review Training is required. For planned new or significantly modified activities, consult with an SRC facilitator or ESH&A specialist to determine if a review is needed. For new activities, the group leader must provide an activity description on the [Readiness Review Approval Form](#) with sufficient detail to adequately describe the scope of work to be performed.

For periodic reviews, receives notification from the ESH&A office that review is pending. Notifies ESH&A by memo if the activity is dormant or discontinued. Responsibility for decommissioning, including status and ownership of the equipment, chemicals and materials associated with the activity is that of the group leader.

- 2) **Group Leader:** Completes a [Readiness Review Hazard Identification Checklist](#) for each activity and reviews the checklist with the appropriate safety coordinator or safety representative and obtains respective signatures.
 - For each laboratory/industrial type activity, prepares a hazard management statement for each item checked on the [Readiness Review Hazard Identification Checklist](#). The statement shall define

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the extent of the hazard and the controls (administrative or engineered) utilized to minimize the risks associated with the hazard. The detail of the hazard management statement shall be commensurate to the scope, magnitude, and risk associated with the hazard.

- For a previously reviewed activity, the hazard management statements only need to address significant changes in hazard management that have been initiated since a previous review. ESH&A maintains files containing documentation of previous reviews. This information is available to aid in the preparation of documentation for a readiness review.
- 3) **Group Leader:** Completes the “activity identification information” section of the [Readiness Review Form](#).
- The level of detail of the description of the activity should be determined by the complexity of the activity and the level of associated hazards.
 - Previously reviewed activities may reference the existing documentation for a description of the activity.
- 4) **Group Leader:** Obtains management approval of the activity on the [Readiness Review Activity Approval Form](#).
- Group leader
 - Division, institute, program director or department manager
- 5) **Group Leader:** Provides the following to the ESH&A Office
- Original of the [Readiness Review Activity Approval Form](#)
 - Original of the [Readiness Review Hazard Identification Checklist](#)
 - Copy of the Hazard Management Statements
 - Copy of the Safety Analysis Document (for Hazard Level III)
 - A list of authorized users
 - Standard operating procedures (SOPs) and additional documentation, as requested
 - Original of the [Readiness Review Training Identification Form](#) with training print outs for each authorized user attached
 - Documentation (e.g. training sign-offs) verifying completion of group/activity-specific training
 - Original of the [Personal Protective Equipment Needs Certification](#)
 - Lifting Hazard Identification Form (Form 10200.154)
- 6) **ESH&A Office:** Checks completeness of Readiness Review documentation

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- For activities not previously reviewed, assigns an activity number (YYYYY.XXX) which consists of the first five digits of the management code of the group leader (YYYYY) and a three digit series number
 - For each activity, determines the appropriate SRC facilitator and ESH&A lead specialist
 - Routes a copy of the activity documentation, for review, to Facilities & Engineering Services and Occupational Medicine. These groups will review the documentation to determine whether the activity involves hazards that are relevant to their areas. If so, they will notify the lead specialist who may include them in the review team
 - Confirms that a chemical inventory is available for the spaces where the activity takes place
- 7) **ESH&A Lead Specialist:** Reviews the information provided by the group leader and comments provided by Facilities & Engineering Services and Occupational Medicine. If an activity has been classified by the group leader as dormant or discontinued, consults with the group leader about the status and ownership of the equipment, chemicals and materials associated with the activity and determines if decommissioning is required. The Lead Specialist follows up to ensure required decommissioning has taken place.
- 8) **ESH&A Lead Specialist:** Determines the hazard level for the activity at initial review, at periodic review, and for modified activities.
- Activities designated Hazard Level I need not continue this review process
 - For Level I and Level II activities, SRC concurrence with the hazard level designation is indicated by the signature and date of the SRC facilitator on the [Readiness Review Approval Form](#).
 - NOTE: If the Group Leader/Department Manager disagree with the Hazard Level designation, it will be decided by the Division Director, Institute Director, Program Director or Chief Operations Officer. Further disputes will be decided by Chief Research Officer (CRO) or Deputy Director (operations side).
 - For modified activities, determines if only the new hazards require review or if full review of the activity is needed
 - Based on discussions with the group leader, the Lead Specialist decides if a test plan is necessary. If a test plan is indicated, it must be submitted by the group leader and approved by the ESH&A lead specialist prior to any testing. The test plan will prescribe the testing to be conducted during the developmental phase as well as the anticipated date when the activity will become operational. The detail of the test plan shall be commensurate to the scope, magnitude, and risk associated with the hazard.
 - If an agreement on hazard level is not reached between the Group Leader and Lead Specialist, the Division Director will be consulted. If

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concurrence is still not reached, the Lead Specialist will seek a final decision from the Chief Research Office (CRO).

- Activities designated as Hazard Level III will require the preparation of a safety analysis document, if none was prepared during a previous review. A designation of Hazard Level III will be reviewed by the SRC to determine the propriety of this assignment, and to make the entire committee aware of the activity. If the SRC determines that the activity was incorrectly designated as Hazard Level III, this designation may be changed to Level II with the concurrence of the lead specialist. An activity designated as Hazard Level III shall require a more formalized and comprehensive review, as described in steps 10-15.
- 9) **ESH&A Lead Specialist:** For new or significantly modified activities, conducts developmental review.
- Determines who should attend and schedules the review meeting (e.g., ESH&A Lead Specialist, activity supervisor, group leader, safety coordinator, SRC facilitator, additional specialists from ESH&A , Facilities and Engineering Services, Occupational Medicine, or off-site subject matter experts).
 - Clearly states in writing to the group leader or designated activity supervisor any and all actions required before developmental approval can be granted.
 - New or significantly modified activities designated as Hazard Level II Moderate or Level II Elevated proceed to step 16. Previously reviewed Hazard Level II and III activities proceed to step 21.
- 10) **Group Leader:** Prepares a detailed safety analysis document as described in Appendix A. Provides copies to the ESH&A Lead Specialist and the SRC.
- 11) **SRC:** Reviews safety analysis document with input from the Director, the Lead Specialist, and other specialists as called for by the scope and magnitude of the hazard. The SRC returns the safety analysis document to the group leader for corrections or amendments. This may be an iterative process.
- 12) **SRC:** Approves the safety analysis document.
- 13) **SRC:** Obtains approval of the safety analysis document from the Ames Laboratory Director.
- 14) **ESH&A Manager:** Notifies the Director of ISU's Environmental Health & Safety and DOE Field Office Operations Manager of Level III activity and forwards copies of the safety analysis document. Other interested parties (determined by the Ames Laboratory Director) may be informed of the activity at this point.
- 15) **ESH&A Manager:** After a 30 day comment period by the above parties, the ESH&A manager will notify the group leader and ESH&A Lead Specialist in writing they may proceed with the readiness review procedure.

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- 16) **Group Leader:** Completes actions required by the ESH&A Lead Specialist and requests developmental approval.
- 17) **ESH&A Lead Specialist:** Documents developmental approval on the [Readiness Review Approval Form](#), before acquisition, fabrication, and testing begin.
- 18) **ESH&A Lead Specialist:** Clearly states in writing to the activity supervisor all actions and documentation required for operational approval.
- 19) **Group Leader:** Completes actions and documentation as required by the ESH&A specialist before operational approval.
- 20) **Group Leader:** Provides the ESH&A lead specialist with copies of all additional documentation and requests operational approval. Standard operating procedures (SOPs) should be developed for tasks including but not limited to complexity, tasks that are performed infrequently, and/or material/equipment that is of high hazard. See Appendix B.
- 21) **ESH&A Lead Specialist:** Reviews the information provided by the group leader.
- 22) **ESH&A Lead Specialist:** Conducts review
 - Determines whether a review meeting is required and who should attend (e.g., ESH&A Lead Specialist; activity supervisor; group leader; safety coordinator; SRC facilitator; and additional specialists from ESH&A, Facilities and Engineering Services, Occupational Medicine, and off-site if necessary) and provides copies of all activity information to the specialists.
 - If a review is necessary, a site visit will be performed at both the developmental approval and the operational approval meeting.
 - A work observation shall be performed at either the developmental or operational approval (or both) to witness how the activity is performed. If it is infeasible (i.e., length of process) then a mockup of the work shall be performed.
 - Clearly states in writing to the group leader, with a copy to the SRC facilitator, any and all actions required before approval can be granted.
 - If the review indicates no significant changes in the hazards associated with the activity and if the hazard management that is in place addresses all current requirements, the Lead Specialist will complete the readiness review form and recommend approval for the continued operation of the activity.
 - If the review indicates changes in the activity or in the hazard management procedures, and if the Lead Specialist and review team determine that these changes do not require convening a second review meeting, the lead specialist may recommend approval contingent upon receipt of written documentation of the changes from

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the activity supervisor. This documentation will be provided within a time period determined by the Lead Specialist. Upon receipt of this documentation, the Lead Specialist will complete the readiness review form and recommend approval for the continued operation of the activity.

- If the review indicates the need for changes in equipment or procedures for hazard management and these changes are determined by the review team to require additional review upon completion, the Lead Specialist may withhold a recommendation of approval of the activity until changes are made and a second meeting is held to review those changes. If the Lead Specialist determines the situation poses no immediate hazard to personnel, the public, the environment, equipment, or the mission of the Laboratory, the activity may continue prior to completion of changes. Following the first meeting, the Lead Specialist will notify the activity supervisor in writing as to the corrections required to obtain approval. The activity supervisor will respond with a projected date for completion of these corrections and any written test plans required for these changes. Upon completion of these corrections, the activity supervisor will send the Lead Specialist a written request for another activity review meeting.
 - If the review indicates significant immediate risk of injury to personnel or the public, harm to the environment, or damage to facilities or equipment due to improper implementation of hazard management, significant changes in the condition of equipment, significant changes in legally binding requirements since a prior review, or any other reason, the Lead Specialist will request that the group leader issue a stop work order for the activity. Should the situation warrant it, ESH&A will issue a stop work order for the activity. An activity that has resulted in an ESH&A stop work order requires a full developmental readiness review of the activity prior to resumption of work.
 - ESH&A lead will submit **only** a “clean” readiness review to the SRC Chair for operational approval. There must not be hand written changes on hazard management statements or items lined out with initials.
 - At conclusion of operational review meeting, site visit by members of review team will be initiated with Group Leader or Activity Supervisor performing or simulating activity.
- 23) **ESH&A Lead Specialist:** Fills out the operational recommendation on the [Readiness Review Approval Form](#). The Lead Specialist forwards Readiness Review Approval Form to the SRC. The Lead Specialist documents attendees at both the developmental approval meeting and the operational approval meeting.
- 24) **SRC Chairperson:** Recommends operational approval to the division, institute, program director or department manager on the [Readiness Review Approval Form](#) before operation. The SRC Chair sends a copy of the Readiness Review Activity Approval Form to the group leader. The SRC Chair will not recommend approval of Readiness Review activities that are not clearly documented and formalized.

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25) **Division, Institute, Program Director or Department Manager:** Documents operational approval on the [Readiness Review Approval Form](#) before operation.

7.0 POST PERFORMANCE ACTIVITY

The following documentation shall be filed with ESH&A upon completion of the Readiness Review:

- Original of the [Readiness Review Hazard Identification Checklist](#)
- Original of the [Readiness Review Activity Approval Form](#)
- Copy of the Hazard Management Statements
- Copy of the Safety Analysis Document (for Hazard Level III)
- A list of authorized users
- Original of the [Readiness Review Training Identification Form](#) with Ames Laboratory training print outs for each authorized user attached
- Documentation (e.g. training sign-offs) verifying completion of group/activity-specific training
- Original of the [Readiness Review Personal Protective Equipment Needs Certification](#)
- Readiness Review Lifting Hazard Identification Form

In addition, the following documentation shall be retained by the group leader and shall be included in or referenced by group procedures:

- Original of the Hazard Management Statements
- Original of the Safety Analysis Document (if required)
- Copy of the [Readiness Review Hazard Identification Checklist](#)
- Copy of the [Readiness Review Activity Approval Form](#)
- Standard Operating Procedures (SOPs): SOP must be signed by **users**, dated, and indicate author of SOP. The following two links are available to assist in the development of SOPs:
 - <http://www.ehs.iastate.edu/laboratory/SOPs/development>
 - <http://www.ehs.iastate.edu/laboratory/SOPs/library>
- Activity associated procedures and additional documentation (if required)

8.0 ADDITIONAL INFORMATION

Appendix A Guidelines for the Preparation of Safety Analysis Document for Hazard Level III Activities

Appendix B Sample SOP is attached to aid Group leaders ([Form 10200.001](#))

Appendix C Readiness Review Notifications Guide

Appendix A

Guidelines for the Preparation of Safety Analysis Document for Hazard Level III Activities

Introduction

Activities identified as Hazard Level III require a greater degree of formality in documenting the hazards of the activity and a higher level of rigor during the review of the activity. The purpose of the safety analysis document is to systematically identify the hazards of Hazard Level III activities, to describe and analyze the adequacy of the measures taken to eliminate, control, or mitigate identified hazards, and to analyze and evaluate the impact of potential accidents.

Safety Analysis

The group leader, with the assistance and input from the ESH&A lead specialist and review team members, will prepare a safety analysis document that addresses the following topics in appropriate detail:

- **Introduction and General Description:** This section should provide a brief description of the activity and discuss the requirements of the activity with respect to the objective and goals of the work.
- **Summary:** This section briefly summarizes the hazards, control measures and impact of potential accidents that exists during the operation of the activity.
- **Site Description:** This section will describe the building and laboratory requirements that are prescribed for the particular hazards involved. The section will also discuss the characteristics of the proposed laboratory space and compare those characteristics with the building requirements.
- **Activity Description:** This section provides the following information
 1. General activity description
 2. Design criteria for systems, components and structures
 3. Normal and emergency operating procedures (in accordance with writing formal procedures)
 4. Operational limitations
 5. Passive safety equipment requirements
 6. Physical design features, engineering safety systems and administrative controls provided or to be provided to control, mitigate or eliminate the risks associated with the identified hazards
 7. Monitoring systems
 8. Working alone procedures
 9. Training requirements
 10. Log-keeping
- **Accident Analysis:** Probability of occurrence and predicted consequences of hazards resulting from potential accidents, including those resulting from natural phenomena.
- **Emergency Planning Requirements:** Determination of the impact of potential accidents on the Ames Laboratory Emergency Plan.

Upon completion, the group leader will submit the safety analysis document to the Safety Review Committee for review.



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Appendix B Guidelines for the Preparation of Standard Operating Procedures

I. STANDARD OPERATING PROCEDURE

Use this form to document the Health & Safety information associated with the procedure.

Procedure Title: Handling of Cryogenics Materials

Dept: _____ Bldg/Rm: _____ Supervisor: _____

Circumstances of Use: Cryogenic Materials will be defined here as any material used for cooling baths that has a melting point, boiling point or sustained temperature below -20°C. This includes dry ice (solid CO₂), dry ice-isopropanol mixture, frozen slush baths prepared from liquid nitrogen and organic liquids (methanol, ethanol, hexane, toluene, etc.) and liquid nitrogen.

Warning

1. Severe skin burns can result from even brief contact with these cryogenic liquids and solids or surfaces cooled by these materials.
2. Liquid nitrogen and dry ice can create an asphyxiation hazard by displacing oxygen from the room. Work only in a well-ventilated area.

Hazard Control Measures: (Lab coat, eye and hand protection, and closed toe/heel shoes must be selected as required by Section D of the ISU Laboratory Safety Manual.)

| | | | |
|--|--|---|--|
| <input type="checkbox"/> Latex gloves | <input checked="" type="checkbox"/> Insulated gloves | <input checked="" type="checkbox"/> Face Shield | <input type="checkbox"/> Respirator |
| <input checked="" type="checkbox"/> Nitrile gloves | <input checked="" type="checkbox"/> Safety glasses | <input checked="" type="checkbox"/> Lab Coat | <input type="checkbox"/> Fume hood |
| <input type="checkbox"/> Neoprene gloves | <input type="checkbox"/> Vented goggles | <input type="checkbox"/> Apron | <input type="checkbox"/> Biosafety cabinet |
| <input type="checkbox"/> Vinyl gloves | <input type="checkbox"/> Splash goggles | <input type="checkbox"/> Dust mask | <input type="checkbox"/> Glove box |
| <input checked="" type="checkbox"/> Closed Toe/Closed Heel Shoes | | | |

Handling Procedure:

When cryogenic liquids are transferred to containers located above waist-height of the operator the liquid must first be poured from the storage Dewar into a small, easily-handled, insulated container (such as a glass Dewar flask) and then poured into the final container. The operator must wear a face shield in addition to safety glasses when pouring cryogenic liquids above waist-level. All containers with evacuated wall space (Dewar flasks) and evacuated round-bottom flasks that have volume of greater than 500 ml. must be wrapped with tape or surrounded by protective net to contain flying glass in case the container should break while being cooled with cryogenic liquid. Only round bottom flasks should be used for freezing and thawing of organic liquids. Evacuated flasks containing liquids frozen at cryogenic temperatures must be contained in another vessel (a beaker or open dish capable of holding the entire contents of the flask at all times).

Preparation of Dry Ice Slurry:

The best low temperature baths are made with as a high a percentage as possible of the coolant (dry ice here, or ice in general). Approximately the amount of dry ice that will be needed should be crushed and placed in the container (usually a Dewar or equivalent). To this you should add the acetone or isopropanol **slowly**. This is most conveniently done with a squeeze bottle. Add only enough to cover the dry ice. If you need a looser slurry, this can be accomplished by addition of more solvent.

A very loose slurry can be made in the following way:

A suitable container, usually a Dewar flask, is filled about one-fourth to one-third full of the solvent. Acetone and isopropanol are both often used but isopropanol is less volatile, less toxic, and less flammable. A little crushed dry ice is added to the solvent and vigorous bubbling will result. As the dry ice sublimates and the solvent cools, the bubbling will become less violent. A little more dry ice can be added at this point. It should be remembered that the temperature of this bath will not be as low as with the previous recipe.

Dry ice can be added to either bath as needed to maintain the low temperature.

When finished using the slurry, allow the dry ice to sublime completely, pour the solvent into a bottle indicating the solvent is for cold baths only. Loosely cap the container for at least 24 hours, so any dissolved carbon dioxide can escape, after which the cap can be tightened.

Transportation:

Special precautions must be taken to prevent a spill while transporting cryogenics in addition to minimizing exposures from liquids and vapors. The high liquid to vapor expansion ratio could rapidly displace all oxygen in a room and result in asphyxiation. Implement the following procedures to minimize exposures:

1. Transportation within the laboratory or lab building
 - a) Wear all required PPE.
 - b) Use no fewer than two personnel to transport cryogenic liquids and use handcarts equipped with brakes for large Dewars and cylinders.
 - c) Never transport an open container of cryogenic liquid, no matter how small.
 - d) Plan the route of transport. The **BEST PRACTICE IS TO AVOID USING AN ELEVATOR**. In event of an elevator failure or spill, the space may quickly undergo oxygen displacement. If elevator use is not avoidable, send a co-worker to the receiving floor. Then load the Dewar and place a warning sign on the Dewar warning anyone who may want to use the elevator between the sending and receiving floors to wait until the transport process is complete. Remain on the sending floor while you send the Dewar to the receiving floor unmanned. After your co-worker unloads the Dewar, join him/her for the rest of the transport.
 - e) Always use care when handling equipment. Damage to Dewars could result in the loss of vacuum and increased evaporation.
 - f) When at all possible, do not hand-carry cryogenic liquids. For larger Dewars use a stable wheeled base designed for the Dewar transport. Check to ensure stability before commencing transport.

- g) When carrying a Dewar, make sure it is the only item you are carrying. Hold the Dewar as far away from the face as possible. Be on the lookout for other people who may run into you or bump you.
- h) Large mobile Dewars used for transport should be equipped with a braking mechanism. Do not use feet to brake. Steel toed boots are recommended.
- i) Take care to avoid crushing hands or fingers between the vessel or cart and walls or door frames.
- j) If there is any risk of tipping, a cart should be used. Wheeled trolleys may not be used if the vessel must pass over elevator thresholds or other slots/crevasses wider than 25% of the wheel width.

2. Transport between buildings

- a) Follow the guidelines above.
- b) In addition, avoid grates, large cracks in sidewalks/pavements, or other hazards that could cause tripping.
- c) For transport of large nitrogen Dewars outside -- over pavement, sidewalks, wheelchair curb-cuts a 4-wheel tipcart should be used. The casters welded to the tank, and/or the casters on the trollies in common use, are not meant for transport over pavement and concrete.
- d) While in route exercise great care stay completely clear of sewer grates, large cracks, and/or uneven portions of the pavement, and any other hazards which could catch a cart wheel and cause tipping.

3. Vehicular transport

- a) **NEVER** take liquid nitrogen or other cryogenic fluids in a car or a van where the driver's compartment is not segregated and sealed from the load. The load compartment of the van must be ventilated. Where a specimen needs to be transported frozen, consider whether dry ice would be suitable since it reduces the risks.
- b) Before transporting cryogenics, ensure that the following have been addressed:
 - A risk assessment has been conducted.
 - The container of the cryogenic material is labeled with the name of its contents and a danger hazard warning sign.
 - The driver has been fully informed as to what is being carried and its associated hazards.
 - The appropriate personal protective equipment has been provided.
 - An information sheet is carried within the vehicle to provide emergency response services with specific data about the material in the event of an accident.
 - The quantity to be transported is consistent with DOT regulations.

NOTE: Transportation of cryogenic substances is covered by the US Department of Transportation (DOT), 49 CFR 173. These regulations cover specific volumes/mass of dangerous goods that may be transported, duties of responsibility, correct packaging and labeling of goods, vehicle usage and driver training. Exceptions for cryogenic liquids can be found in 49 CFR 173.320 as follows:

(a) Atmospheric gases and helium, cryogenic liquids, in Dewar flasks, insulated cylinders, insulated portable tanks, insulated cargo tanks, and insulated tank cars, designed and constructed so that the pressure in such packagings will not exceed 25.3 psig under ambient temperature conditions during transportation are not subject to the requirements of this subchapter when transported by motor vehicle or railcar except as specified in paragraphs (a)(1), (a)(2), and (a)(3) of this section.

(1) Sections 171.15 and 171.16 of this subchapter pertaining to the reporting of incidents, not including a release that is the result of venting through a pressure control valve, or the neck of the Dewar flask.

(2) Subparts A, B, C, and D of part 172, (Secs. 174.24 for rail and 177.817 for highway) and in addition, part 172 in its entirety for oxygen.

(3) Subparts A and B of part 173, and Secs. 174.1 and 177.800, 177.804, and 177.823 of this subchapter.

Storage:

A cryogenic liquid storage unit left open to the atmosphere, or catastrophic failure of a storage unit, could create an oxygen deficient atmosphere. Follow these procedures to reduce the likelihood of this occurrence:

1. Glass Dewars must have an exterior coating/cover to minimize projectiles in the event of an explosion. Newer Dewars may have a plastic mesh over the exterior for this purpose. Older Dewars must be thoroughly taped or replaced.
2. Only store Dewars in well-ventilated rooms with a minimum of six air changes per hour.
3. If the ventilation rate is unknown, contact ESH&A and Facilities & Engineering Services (F&ES) to evaluate the storage area.
4. ESH&A and/or F&ES may recommend the installation of oxygen detection systems and alarms for cryogenic liquid storage areas depending on location, ventilation, and quantity of material stored.
5. Do not store cryogenic liquids with corrosive or flammable chemicals.
6. Storage units should be placed so that vents and openings are oriented away from personnel and lab equipment.
7. Bulk cryogenic liquid dispensing areas within buildings must be well ventilated. ESH&A recommends continuous oxygen monitoring equipment in all these areas. All new installations should be designed with oxygen monitoring system and alarm.
8. Storage of cryogenic liquid Dewars in hallways, unventilated closets, and stairwells is prohibited.
9. No more than one backup Dewar is allowed per piece of equipment using cryogenic liquids in research labs. Additional Dewars must be stored in areas designed for such storage. Contact ESH&A to evaluate potential storage locations.

Emergency Procedures and First Aid:

Liquid Nitrogen (LN₂) is the most commonly used cryogenic liquid. Oxygen depletion resulting from nitrogen gas may occur rapidly with no warning properties. A person entering an oxygen deficient environment may become disoriented and unable to respond properly. Nitrogen gas is odorless, colorless, tasteless, and inert. The failure of a large Dewar could spill 180 L of LN₂ which in gas form will completely

displace all oxygen in a 21x21x10 ft room. A much smaller spill in the same room could still create safety hazard. Simply reducing the oxygen content in a room below 19.5 % is considered an oxygen deficient environment. Implement the following procedures to minimize the risk of asphyxiation:

1. If ventilation in the room is less than six air changes per hour, contact EH&S for advice about installing oxygen level detection alarm.
2. If a spill occurs, immediately exit the area. With adequate ventilation, it may be appropriate to return to the area after 30 minutes. For large spills, contact EH&S immediately as the area may need to be monitored for oxygen levels area and determine when it is safe to re-enter.
3. If experiencing symptoms such as lightheadedness, dizziness, or confusion, immediately seek fresh air and receive medical attention.
4. If researcher becomes unconscious in a cryogenic liquid storage area they should only be retrieved by emergency personnel (Immediately call **911**). Over 50% of deaths associated with asphyxiation in confined spaces occur to would-be rescuers.
5. Immediately remove any clothing that has been contaminated. In the event of clothing contamination with oxygen, hydrogen, or carbon monoxide, it is important to remove clothing, evacuate personnel from the facility, and keep away from ignition sources.
6. Flush or soak the area with warm water (no greater than 105°F).
7. Do not apply dry heat or rub damaged flesh or eyes.
8. **All accidents and injuries occurring at work or in the course of employment must be reported to the employee's supervisor as soon as possible (even if no medical attention is required).**

Spill/Release Containment, Decontamination, and Clean Up Procedures:

Small Spill:

- Allow liquid to evaporate, ensuring adequate ventilation.
- Following return to room temperature, inspect area where spillage has occurred.
- If there is any damage to the floors, benches or walls, report it to F&ES.
- If any equipment has been damaged following the spillage, inform your Supervisor.

Large Spill:

- Shut off all sources of ignition.
- Evacuate area of all personnel.
- Inform ESH&A (4-2153) and your supervisor.
- DO NOT return to the area until it has been declared safe by ESH&A.

Waste Disposal Procedures:

Care needs to be taken when disposing of cryogenic liquids.

DO NOT pour cryogenic liquids down the sink - they will crack waste pipes causing potentially dangerous leaks.

DO NOT store cryogenic substances or allow them to vaporize in enclosed areas, including: fridges, cold



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rooms, sealed rooms and basements.

DO ensure that the area in which the cryogenic liquid is left to vaporize is well ventilated.

Using Substances Requiring Special Procedures? No Yes

(If Yes; identify authorized personnel, designate a use area and specify specialized safety precautions here. Refer to Section B in the ISU Laboratory Safety Manual for details.)

Use of cryogenic substances requires site specific training and the approval from the professor in charge.

Written By: _____ **Date:** _____

Approved By: _____ **Date:** _____

(PI or Lab Supervisor)



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II. HAZARD ASSESSMENT

Use the hierarchy of controls to document the hazards and the corresponding control measure(s) involved in each step of the procedure.

- Consider *elimination or substitution* of hazards, if possible.
- *Engineering Control(s)*: items used to isolate the hazard from the user (i.e. fume hood, biosafety cabinet).
- *Administrative Control(s)*: policies/programs to limit the exposure to the hazard (i.e. authorizations, designated areas, time restrictions, training).
- *Required PPE*: indicate PPE including specific material requirements if applicable (i.e. flame resistant lab coat, type of respirator or cartridge).

| Hazard | Engineering Control(s) | Administrative Control(s) | Required PPE |
|---------------------------------------|------------------------|---------------------------|--------------|
| Oxygen Deficiency | | | |
| Cold burns, Frostbite and Hypothermia | | | |
| Oxygen enrichment | | | |
| Pressurization and Explosion | | | |
| Damage to Equipment | | | |
| Flammable gas - Hydrogen | | | |

III. TRAINING RECORD

Use the following table to record the training associated with this Standard operating procedure.

| Print Name | Signature | Date |
|------------|-----------|------|
| | | |
| | | |
| | | |
| | | |
| | | |

Note: Attach to or file with written materials and methods

Appendix C

READINESS REVIEW NOTIFICATIONS GUIDE

The table below details ESH&A SME responsibilities regarding three and five year Readiness Reviews. It also includes Group Leader responsibilities required to keep an activity operational.

| Timeline | | | | |
|-------------------------------------|------------------------------------|---|---|--|
| Initial Notice – From ESH&A Lead | Second Notice – From ESH&A Lead | Third Notice – ESH&A Lead (W/O cooperation) | Fourth Notice – ESH&A Lead (W/O cooperation) | Final Notice – From Director or Manager |
| 3 Month – Initial Notification | ~2 Month – Follow Up | ~ 1 Month – Warning (no less than) | 2 Weeks - | Due Date – Revocation of “Operational Approval” – Place Activity into Dormant or Discontinued Status |
| To: Group Leader | To: Group Leader | To: Group Leader | To: Group Leader | To: Group Leader |
| CC: Activity Supervisor | CC: Activity Supervisor | CC: Activity Supervisor | CC: Activity Supervisor | CC: Activity Supervisor |
| | Copy: ESH&A Manager | Copy: Division, Institute, Program, Director(s) or Department Manager | Copy: Division, Institute, Program, Director(s) or Department Manager | Copy: CRO or COO |
| | | Copy: ESH&A Manager | Copy: ESH&A Manager and CRO or COO | Copy: ESH&A Manager, SME, and SRC Chair |
| | | | Copy: SRC Chair | Copy: Deputy Director |

Group Leaders can delegate a task(s) to Activity Supervisors but cannot absolve themselves of responsibilities.

NOTE: Extenuating circumstances (i.e., sabbatical, illness, maternity leave, etc.) can be presented to SRC Chair for extensions on a case by case basis.