Integrated Safety Management Plan
for the
ALS User Biology Program

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Review and Approvals

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ISM Plan for the ALS User Biology Laboratory

TABLE OF CONTENTS

1. INTRODUCTION

The Advanced Light Source (ALS) is a national user facility funded by the Office of Science's Basic Energy Sciences office. It is a 3rd generation Synchrotron with ~40 x-ray beamlines that support 2000 users each year. It is operated by the ALS Division at Berkeley Lab which also manages a range of user support functions including a variety of laboratory spaces. A subset of these is grouped together as the ALS User Biology Laboratory (referred to as the ALS Bio Lab in this document). Rooms 118 and 120 in building 15 are dedicated to this function, and are composed of ~400 square feet including three biosafety hoods. Additional facilities include freezers (-20 and -80 degree), ice machine and storage units just outside of the rooms. Together, these areas support approximately 200 individuals performing several hundred operations each year. All of this work is supported by the ALS EHS Program Office and the ALS User Biology Program Manager.

The basis for this document is Integrated Safety Management (ISM). The purpose of this document is to:

- provide an overview of the structure and responsibilities for how the biological work is carried out efficiently and safely; and
- translate the overall Berkeley Lab EHS institutional programs into specific guidance for biological work performed at ALS.

All biological work is identified, reviewed and authorized. Through this authorization process, the hazards – both process and biosafety – are identified and control measures are put in place to mitigate them. A defined review and oversight system is employed to assure that these controls are being implemented and are effective. Clear roles and responsibilities are fundamental to this ISM system and everyone with access to biology laboratory spaces is given clear guidance of their expectations in this regard. Lastly, since there is great variation in the background and experience of the users, their training and qualification is carefully evaluated and verified.

2. ORGANIZATION

This section describes the lines of authority, responsibility, and communication for health and safety functions at ALS with respect to its User Lab operations. The purpose of this section is to assure that all individuals who work in these Labs understand their roles and responsibilities as well as those of the support and oversight personnel. It also provides a tool to assure that all necessary functions are identified.

2.1 General

The Overall responsibility of implementing and overseeing the Environmental, Health & Safety Plan rests with the ALS Division Director. He is ultimate authority and responsible of all personnel, employees and visitors working in the ALS and supporting labs.

2.2 Specific Roles and Responsibilities

2.2.1 User Biology Program Manager

The User Biology Program Manager (BPM) has direct operational and oversight responsibility for the ALS Bio Lab. The specific responsibilities are to:

- Perform the work reviews for the users of the Lab. Coordinate reviews with EHS Biological Safety Office. Verify understanding of the proposed work packets, identify hazards and specify controls. Support the users in the process of either adding their details to the BUN held by the ALS Bio Lab (if biosafety level 1 work) or in the creation or update of a BUA for their group. Coordinate ALS Bio Lab work reviews with ESS reviews at the beamlines to ensure effective transition between work at the two locations.
- Provide operational support and oversight to the ALS Bio Lab users, including scheduling, training, provision of consumables, user sample storage and bio waste disposal. Provide general laboratory maintenance, including maintenance of equipment, inventory and storage of chemicals and biological material, etc.
- Contribute to the development of this ISM Plan and implement it.
- Develop and maintain the ALS-wide User Biological Use Notification (ALS BUN).
- Ensure that all personnel working on the site receive appropriate training in recognition, communication, and controls of physical hazards on the site, and comply with safety standards of this ISM plan and Berkeley Lab policies.
- Conducting periodic self-assessments, audits and inspections of the Biology Laboratory.

2.2.2 ALS Environment, Health and Safety Program Manager

The ALS Environment, Health and Safety Program Manager (EHSM) has overall responsibility for this laboratory space including the safe conduct of all operations within it. The responsibility includes:

- Provide management, support and oversight to the BPM.
- Assure proper levels of funding are available to support identified user bio functions.
- Approve this ISM Plan and assure its accuracy, completeness, and coordination with Berkeley Lab requirements.
- Assure that this ISM Plan is being executed properly and that it is effective.
- Assure coordination with EHS Division functions (Waste, Biosafety, etc.)

2.2.3 ALS Bio Lab Users (Staff and Users)

- Understand and abide by the policies and procedures in this ISM Plan and clarify those areas where understanding is incomplete.
- Maintain appropriate training necessary for access to the ALS Bio Lab.
- Make sure that all work has been reviewed and authorized by the BPM and that appropriate documentation is on file.
- Wear specified personal protective equipment (PPE) (as discussed during lab orientation procedure) whenever entering the ALS Bio Lab.
- Stop work on any unsafe conditions. Report any spills or incidents to the Emergency response group, the numbers are posted on the wall in both rooms in the laboratory.
- Properly label all materials in use or in storage.
- Coordinate with the BPM for the disposition of any chemicals and biological materials after the experiment run is over, including shipment back to the home institution, or waste disposal. Long-term storage of materials must be coordinated with both the BPM and a beamline scientist).
- Provide feedback to health and safety management to help improve the safety of the ALS Bio Lab.
- Staff should help to coordinate users' work in the ALS Bio Lab. Notify the BPM or Experiment Coordination whenever users will need access. Provide guidance to users to assure that they understand the operational and safety requirements.

3. WORK AUTHORIZATION AND TRAINING

All work performed in the ALS Bio Lab must be reviewed and authorized in a timely manner. This is the responsibility of the BPM. The basic philosophy is to plan the work carefully so that it can be performed safely, efficiently and effectively. The level of detail and formality of the work authorizations will be dependent upon the type of work to be performed, the associated hazards and the required safety controls. In general, three levels of biological work are performed at the ALS:

1. The great majority consists of relatively simple operations involving Risk Group 1 (RG1) or below. These are covered by a standing, ALS-wide umbrella Biological User Notification (ALS BUN) held by the BPM.
2. Infrequently, large quantities of RG1 materials may be used that could pose an opportunistic hazard to immuno-compromised individuals. In these cases, an experiment-specific BUN is developed, which is owned by the work lead for the scientific program.
3. The third type of biological work involves either RG2 materials e.g., recombinant DNA materials, and samples derived from humans or potential plant or animal pests or pathogens that must be registered with the USDA or equivalent. Each one of these has its own Biological Use Authorization or Registration (BUA or BUR). For these, the work lead for the scientific program is expected to take ownership of the authorization.

In the great majority of cases, the work reviews are initiated through the User Experiment Safety Sheet (ESS) process, and any experiment-specific controls that are needed, beyond the general controls specified in the EHS Biological Authorizations, are contained in the ESS.

A pre-condition of performing work in the ALS Bio Lab is that all users must have completed the appropriate training. For on-site staff, and off-site users using the ALS Bio Lab, this training will consist of standard LBNL safety courses, lab-specific safety training for particular hazards if appropriate, and on-the-job training for specific tasks. Most of the institutional training courses are offered online, but some may require attendance at a regular class. The lab-specific training will generally consist of specialized training given by the BPM to address specific safety issues in the ALS Bio Lab (i.e., the User Lab orientation). This is done in an orientation format and covers all of the institutional biosafety training elements as they apply to the ALS Bio Lab. For work covered by the ALS BUN, off-site users using the ALS Bio Lab

will receive credit for the institutional training courses by completing standard online LBNL bio-safety courses and going through the lab-specific orientation. The rationale for this is that their work scope is limited and more focused orientation is needed for their hazards and controls. This is documented by completion of training to procedure US 02-11 "ALS Biological Work Procedure". Lastly, the task-specific training, which will be given by the BPM or other authorized personnel in cases involving more complex tasks or equipment. The purpose of both the safety training and experimental reviews is to assure that all users are knowledgeable about the specific hazards that they may encounter during the course of their work and the appropriate controls to employ to mitigate those hazards. Section 3.7 contains a more detailed discussion of these trainings.

3.1 Laboratory Access

All users must receive authorization to gain un-escorted entry to the ALS Bio Lab. To do this, users must read and understand this ISM Plan, demonstrate that they have proper training, and have received lab orientation from the BPM or a designee. Upon completion of these three steps, card-key access is granted. This is documented upon completion of the ALS Division Bio Lab Access and Safety Orientation (Appendix 2 of the ALS Procedure US 02-11). This does not yet entitle individuals to do work in the ALS Bio Lab. Further authorization is required and is dependent upon the type of work and risk group category of biological material used in the lab (an exception to this is discussed below in section 3.3).

Upon significant changes in policy, the BPM may need to pull access and re-authorize everyone. Otherwise, usual communication means (e-mail and signage) are used to convey smaller changes.

3.2 ALS BUN

All User work is reviewed through the Experiment Safety Sheet (ESS) process. There are many points of entry into this process (general user, participating research time, approved program, etc.), but all users must have an accurate, current, and authorized ESS before they can perform work at the ALS beamline and the Bio Lab. If the work is newly accepted or a substantial departure from earlier work, then a new ESS must be created. Otherwise, if the work is a continuation of previously reviewed and authorized work, the existing ESS may be re-used if it has been reviewed within 12 months.

Biological work is also considered to be a 'formal' authorization according to PUB-3000 (Berkeley Lab Health and Safety Manual) and requires external EH&S Division review. Depending upon the actual risk level, it may also require EH&S Division approvals.

When biological work is scheduled through the ESS, it will be reviewed by the BPM to determine the risk level. The great majority of biological work at the ALS is RG-1 or lower, and most of the work will be categorized into the ALS BUN that the BPM holds. At this risk level, the controls specified in the ALS BUN are standardized and do not change from experiment to experiment. These are communicated to the User through the ESS, which also has this standardized language. Likewise, the ESS captures the detailed worker information in lieu of identifying all personnel included in the BUN. An on-going log is maintained that documents each ESS, the individuals on that ESS, the biological materials used, and the dates of use. This log is maintained in an electronically accessible format allowing EHS staff to view at any time.

Following standard ALS philosophy, the BPM review typically will incorporate a discussion between the BPM and the users to verify understanding, and identify and resolve any potential issues. At the discretion of the BPM, dry runs may be performed and the BPM may also restrict the operation to day shifts, require two people, or even oversee the work herself. At this time, any job specific training is performed and standard institutional training requirements are verified.

At the conclusion of this process, times and locations are agreed and approved for work. This designation is a crucial control as it allows the BPM to organize different and possibly conflicting tasks, to assure that the overall lab and personnel safety.

Once work begins, the users are expected to abide by all requirements in the ESS. The BPM will either perform periodic walk-throughs or directly oversee the work to verify this. In cases of problems, the users provide their contact information and are trained on who to contact and what to do in case of emergency. They will label all of their materials as well as have a 'placard' identifying their workspace and authorization.

At the conclusion of work, users are expected to clean up their space and to precisely identify any remaining materials for storage, return, or waste. The BPM or a designee will inspect the space within one working day to review and to ensure proper disposal of any remaining materials.

3.3 Non-Routine BUN

Some work with RG-1 may still represent an opportunistic hazard to immuno-compromised individuals. Typically, this is only in cases involving large quantities. In these cases, the work must be evaluated for its potential to create aerosols in which case a Biosafety cabinet should be used. An experiment-specific BUN will be created to analyze and implement this control. Though the work is still authorized through the ALS division as a BUN, the BPM will consult with the EHS Division to assure that proper controls are in place before work begins. Otherwise, all other work planning and control functions from the ALS BUN apply.

3.4 BUA

A small fraction of the biological work performed at the ALS involves RG2 materials. These may include recombinant DNA, samples derived from humans and plant, soil or animal pests or pathogens subject to USDA Permits. By Berkeley Lab policy, these types of activities require a Biological Use Authorization, which must be reviewed and approved by the Institutional Biosafety Committee (IBC) before work can begin. This review/approval cycle can be quite extensive so it is imperative for users to notify the BPM as early in the process as possible.

For this relatively small fraction of work, it is expected that the PI of the project will take ownership of the authorization and will directly answer all questions. The BPM will provide expert technical assistance as well as administrative support throughout this process.

All controls specified in the BUA will be referenced in the ESS and the BPM will oversee their implementation in her scheduling, operational, and follow-up support functions.

3.5 Post-Beamtime Storage

Experimental materials including chemicals and biological materials brought or shipped to the ALS generally are on-site only for a limited time (less than 2 weeks). Chemicals that are brought for less than two weeks do not need to be entered into the Berkeley Lab Chemical Management System (CMS) database. If an ALS staff person or user desires to store their biological materials for a longer period, then they may request the BPM to store the materials for them. Biological samples may be stored for an interim period, but must meet stringent requirements. The following conditions apply for storage when beamtime has finished:

- Biological samples may not be stored in the LN2 dewar or in the refrigerators.
- Biological samples may be stored in the -80 C or -20 C freezers, logged in the log book and formally owned by an ALS staff person. These samples may be stored for a maximum of one year.
- Any chemicals must be bar-coded and entered into the CMS and formally owned by an ALS staff person.
- All materials must be clearly labeled including an expiration date. Materials in storage will be disposed of after this expiration date.
- The owner must respond to requests to manage the inventory.
- The owner must notify the BPM whenever a material is moved in or out of the ALS Bio Lab storage.
- Owners must maintain appropriate training status so that they are aware of LBNL rules governing chemicals and biological materials.

The BPM will periodically run inventory reports of all hazardous materials in storage in the ALS Bio Lab (see section 4 Assurance). From time to time these will be distributed to the owners to verify that they still need the materials and can justify retaining them. These reports will also be used to:

- verify that no storage limits are being exceeded
- inspect storage to verify proper segregation
- verify that particularly hazardous materials are within ALS guidelines

At the time of the Lab orientation, the BPM will verify whether or not an individual desires to store materials. At this time a printout of his/her inventory will be made and reviewed with the BPM. The requirements above will be discussed and agreed upon as part of the blanket authorization, and the printout will be attached to the orientation form.

3.6 Training

The User Lab training program is designed to ensure that workers receive the training they need to understand the hazards and controls associated with their work. The training given for the ALS Bio Lab work will meet or exceed the Berkeley Lab training requirements. The BPM is responsible for the design and implementation of this training program and is responsible

for ensuring that employees, user and affiliates are adequately and currently trained for all tasks they need to perform in the ALS Bio Lab. Employees who have not been trained to a level required by their job function and responsibility are not permitted to use the Lab.

ALS views this training in a tiered approach:

1. General Training
2. Lab Specific Training
3. Job Specific Training

1. General

The institutional requirements to gain access to a biology lab and perform work there are:

- EHS 0405-GERT, General Employee Radiological Training
- EHS 0348- Chemical Hygiene Safety Training
- EHS 0739 - biosafety training (EHS0739) or take test

In addition, all staff who workat the ALS are required to take the following courses:

- ALS 1001, Safety at ALS
- ALS 1005, Access to ALS

For the off-site Users whose work does not require the use of ALS Bio Lab and the biological material is covered entirely by the ALS BUN, the general orientation given during review of the ESS, and documented through completion of procedure US 02-11 may be substituted for EHS 0739.

2. Lab Specific Training

An orientation to the ALS Bio Lab is provided to each individual who desires unescorted access and use of the lab. This is specifically focused on the ALS Bio Lab and its particular layout, organization, work, hazards, and controls. The basis for this training is this ISM Plan. The orientation provides necessary work practices, procedures and policies to ensure that employees and users are protected from potentially hazardous chemicals or biological materials in use in their work area. Some of the typical topics are:

- Orientation and walk around
- The location and availability of hazard control documents
  - ISM Plan
  - LBNL Biosafety Plan
  - PUB-3000
  - Emergency response guides
- Waste handling and disposal
- Sterile technique in a shared lab
- Hazards
  - biological
  - chemical
  - general lab
  - Cryogenic
- Emergency Procedures
  - Notification
  - Exits
  - Fire extinguishers
  - Safety showers/eyewashes
  - Spills
- Work review and authorization

At the conclusion of this orientation, (in addition to online LBNL bio safety classes), individuals will be granted access to the ALS Bio Lab.

3. Job-specific Training

In cases where the work may be particularly complex or hazardous, or at the discretion of the BPM, job-specific training may be given. In these cases, specific instructions or procedures will be given identifying in some detail how the particular tasks will be performed. This may include dry runs.

Typically, this training will be given by the BPM, but may also be performed by subject matter experts from the ALS, EHS, or within the research group performing the work. Documentation of this training will be done through the various authorization forms as described in procedures document US 02-12.

4. ASSURANCE

Assurance is a key function in the overall operations of the ALS Bio Lab. Various inspections and reviews are performed to verify that individual user operations, overall lab facility functions, as well as targeted risk areas are all within accepted norms. An explicit philosophy behind these is to continuously enhance the safety and effectiveness of the ALS Bio Lab.

4.1 Facility Inspections

Periodic bi-weekly inspections are performed by the BPM. This is a physical inspection of the facility including a review of all the safety equipment, PPE, spill kits, inventory of chemicals and biological materials, chemical and biological waste and lab controls. Any findings or changes are observed and noted to improve the working and safety conditions in the lab. On the basis of these findings, BPM takes appropriate measure to curb any problems and improve the work quality in the labs.

4.2 Inventory

The main function of this is to control and manage the biological inventory in the ALS Bio Lab. In general, users are discouraged from using the ALS Bio Lab for long-term storage. Any materials that are stored must be entered into the appropriate log books. This review consists of a check of the physical inventory against these logs. If any materials have been added or removed during that period, the users are contacted and the logs either updated or the materials disposed of (the preferred option).

4.3 Post-Run Inspections

The BPM or a designee performs a general visual inspection of the workbenches, biosafety hoods, aisles, storage cabinets, and waste containers Any contaminated waste or materials left for disposal should have proper labels, concentration and/or composition, generators name and contact information posted on the containers and bags. A detailed evaluation of any materials is performed before they are moved.

The BPM notes any findings and takes corrective actions and writes final reports before requisitioning the waste disposal.

4.4 Biological Waste

Weekly waste inspections are conducted by the BPM. The purpose of these inspections is to specifically inspect biological waste containers for any violations and unusual findings. All biological waste generated in the ALS Bio Lab are collected in clear biohazard bags and biohazard bag containing waste must be closed tight and placed inside the gray barrel. The waste generators are responsible for disposal of waste, with guidance from the BPM.

4.5 Experiment Reviews

At the discretion of the BPM, certain operations may be evaluated while the tasks are being performed. The purpose of these inspections is to verify that the accuracy, effectiveness, and implementation of the experimental reviews. Unless gross violations are found (which would generate Stop Work), the primary utility is to lead to continuous improvement in the overall process and these are treated as learning opportunities.