

Boston Public Health Commission  
Biological Laboratory Safety Permit Application

**SECTION 15: BSL-4 TRAINING PLAN**

Boston University  
National Emerging Infectious Diseases Laboratories

June 2014

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## BU NATIONAL EMERGING INFECTIOUS DISEASES LABORATORIES

## SECTION 15: BSL-4 Training Plan

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**1.0 PURPOSE AND APPLICABILITY**

Boston University (BU) recognizes the importance of a well-trained research and support staff that conducts research work in a safe and secure manner. Consistent with the culture of safety at BU, the BSL-4 Laboratory Safety Training Plan at the National Emerging Infectious Diseases Laboratories (NEIDL) at Boston University utilizes a team approach to ensure the highest standards of safety, security, medical surveillance, facilities operations, and response. The purpose of the BSL-4 Training Plan is to promote the conduct of safe practices; to keep laboratories and equipment in safe operating order; to maintain compliance with institutional policies and local, state, and federal regulations and guidelines; and to reinforce at all levels that laboratory safety protects research, personnel, and the environment from the potential hazards associated with biomedical research.

This NEIDL BSL-4 Training Plan presents a strategy for developing a comprehensive program of training for the scientists and technicians who are authorized to conduct research in the NEIDL, the operations and maintenance employees of BU who manage the NEIDL's containment and engineering systems, and other groups of BU employees, vendors, and service personnel who work within the research environment or in support of the NEIDL. In addition, the Plan includes training for members of the community who may visit or have a role in regulating or responding to the NEIDL.

The Plan includes specific training for staff who *will* work within the maximum containment laboratory as well as those who *will not* enter maximum containment areas. All employees receive an orientation to the NEIDL. Additional training is provided to those individuals who are required to enter a maximum containment space during operations or to repair the facility (when properly decontaminated). Training for new staff will be customized based on their existing level of experience and specific job responsibilities. The training outlined in this Training Plan will focus on the minimum requirements for working within the NEIDL maximum containment laboratory. The Plan requires that participants demonstrate that they have met the learning objectives particular to their assigned duties, as outlined in each phase of training. For

trainees who will eventually work within a BSL-4 laboratory, training will include didactic and simulated exercises conducted in the NEIDL Training Simulator, and participants will be required to pass a hands-on proficiency examination, proctored by the Associate Director for Maximum Containment Training, before being permitted to enter the maximum containment laboratory.

## **2.0 ROLES AND RESPONSIBILITIES**

### **2.1 Environmental Health & Safety**

Environmental Health & Safety (EHS) provides technical and training support and implements policies and procedures created by the Institutional Biosafety Committee (IBC), Laboratory Safety Committees (LSC), Radiation Safety Committee, and other committees. EHS will work closely with the IBC, the Biological Safety Officer, and subject-matter experts to create, implement, and maintain BSL-4 trainings. EHS will document that all trainee candidates have the prerequisite training and have successfully completed and passed all components of the training program, and will maintain and administer the required annual refresher trainings.

### **2.2 Institutional Biosafety Committee**

The IBC is responsible for the oversight of the Biosafety Program at BU and BMC. The IBC ensures that all policies and procedures regarding trainings are in accordance with both best practices and the regulatory frameworks governing the use of biological materials. Additionally, the IBC will provide final review and approval of required training programs.

### **2.3 NEIDL Training Advisory Committee**

The NEIDL Training Advisory Committee (NTAC) comprises 8–10 persons, including those with the following responsibilities:

- **Training (Chair)**—Typically this would be the Associate Director for Research Safety, NEIDL.
- **Safety (EHS)**—Typically this would be the Associate Director for Research Safety, NEIDL, or a designated EHS representative.
- **Facilities Management (FM)**—Typically this would be the Director of NEIDL Facilities or a designated FM representative.
- **Emergency Response Planning (ERP)**—Typically this would be the Director of Emergency Response Planning or a designated ERP representative.
- **Animal Core (AC)**—Typically this would be the Core Director, or a NEIDL Animal Core representative.
- **Science Core**—Typically this would be someone who has attained mentor or supervisor level.

If NEIDL leadership is not represented in one of the Science Core representatives, a representative of NEIDL leadership (typically the Director or an Associate Director) would be added as a member.

The Training Advisory Committee is responsible for accomplishing the following:

- Establish the necessary qualifications and experience for individuals working in BSL-4 containment areas.
- Receive and evaluate applications for BSL-4/ABSL-4 training.
- Recommend training content, review training materials, and advise on improvements and revisions.
- Review and advise on the process of BSL-4/ABSL-4 training from initial enrollment through completion of mentorship.
- Review and advise on the NEIDL BSL-4/ABSL-4 mentorship process.
- Review and advise on the criteria for becoming a mentor.

#### **2.4 Safety: Training Oversight**

The Associate Director for Research Safety, NEIDL, is the individual with responsibility for training oversight. This position provides oversight for the development, implementation, and maintenance of the training program. The Associate Director for Research Safety, NEIDL, will work with the Training Director (currently the Associate Director of Maximum Containment Training), the compliance committees, the Biosafety Officer, and subject-matter experts to ensure that all trainings meet regulatory requirements and policies, and cover the appropriate materials and topics. The Associate Director for Research Safety, NEIDL, will oversee the operational execution and delivery of the training programs (this includes participation in the delivery of EHS portions of the training) and will identify and develop the necessary materials to address lessons learned.

#### **2.5 Training Director**

The Training Director must be uniquely equipped to assess the proficiency of BSL-4 trainees and able to provide guidance for the safe performance of laboratory procedures within the BSL-4 environment. The role of Training Director is to provide the direction and structure for new training initiatives and to ensure consistency of proficiency assessments.

#### **2.6 Mentors**

Mentorship is required, and mentors play a crucial role in developing *core-specific* (or, in the case of non-core laboratories, laboratory-specific) training and implementing those plans within the BSL-4 environment after trainees have successfully completed simulator training. Mentors provide direct instruction and oversight of procedures within the containment laboratory. There is a strict selection process, implemented by the NTAC, for individuals who wish to serve as mentors. The selection criteria are: they must be individuals who are capable of demonstrating safe and effective BSL-4 practices, knowledgeable and proficient in the required laboratory techniques and procedures for the particular core, and trained in the skills and duties of being a mentor, including development of the proper communication skills.

#### **2.7 Supervisors (Principal Investigators, Core Directors, Animal Core Supervisors)**

The supervisors will ensure that personnel destined to work in the BSL-4 facility have sufficient experience and have already demonstrated a high degree of proficiency at lower levels of containment. The supervisor is responsible for ensuring that before working with organisms in BSL-4

containment spaces, all personnel enroll in and complete the training program outlined by EHS and implemented by the Associate Director for Research Safety, NEIDL, and the Associate Director of Maximum Containment Training. Supervisors will ensure that all personnel who have completed the required EHS trainings be mentored and trained on specific laboratory procedures under the laboratory mentorship program, and demonstrate proficiency in following laboratory practices and techniques as well as operations specific to the laboratory facility.

## **2.8 Trainees**

Trainees have the prime responsibility for adopting and contributing to the culture of safety. It is imperative that trainees pay careful attention to all safety training instruction, attend to areas of concern, and strive to attain and maintain the highest level of proficiency and safety in all aspects of their intended work. It is required that all trainees commit the necessary time to progress through the training sequentially and without any significant gaps between phases.

## **2.9 Responsible Official**

The Responsible Official (RO) is appointed by the Associate Vice President for Research Compliance (AVP-RC) and is the authorized individual with responsibility, authority, and control to ensure compliance with institutional policies as well as Department of Health and Human Services (DHHS) and U.S. Department of Agriculture (USDA) Rules and Regulations pertaining to the possession, use, and transfer of Select Agents and Toxins, as well as regulatory training requirements for NEIDL staff. The Director of Research Safety is designated to serve as the DHHS/USDA RO. The AVP-RC is the RO for the Boston Public Health Commission (BPHC) Biological Laboratory Regulation training requirement.

## **2.10 Emergency Response Planning Division**

The Emergency Response Planning division of EHS has the responsibility to provide recommendations related to emergency management planning, drills, exercises, response coordination, and corrective improvements. ERP will participate in the development and implementation of emergency response plans, drills, exercises, risk reduction initiatives, and risk prevention measures. ERP serves as the liaison to local, state, and federal emergency management agencies. ERP will assist the Associate Director for Research Safety, NEIDL, and Associate Director of Maximum Containment Training in the development and implementation of NEIDL trainings relevant to incident response and emergency response preparedness.

## **2.11 Facilities Management, NEIDL**

The Director of Facilities, NEIDL, oversees the Facilities Core responsible for the operation and maintenance of the BSL-4 laboratories, including preventative and corrective maintenance, and monitoring and evaluation of laboratory systems. The Director of Facilities, NEIDL, is responsible for ensuring that all operations and maintenance employees are trained and competent to conduct work in the containment facility, including training in the safe use of all equipment necessary to conduct their work. The Director is responsible for maintaining and updating associated recordkeeping.

## **2.12 Animal Core, NEIDL**

The Director of Animal Core, NEIDL, has overall responsibility for the care of animals used in experiments conducted within BSL-4 containment areas. The Director ensures that animal care staff members are trained and competent to conduct work in the containment facility, including training in the safe use of all equipment necessary to conduct their work. The Director is responsible for maintaining and updating associated recordkeeping.

## **3.0 OVERVIEW OF NEIDL-SPECIFIC TRAINING**

The content of NEIDL-specific training is tailored to participants' responsibilities.

- Every NEIDL employee will receive an orientation that includes an overview of the BSL-4 laboratory environment.
- Staff who do not enter the laboratory during normal operations but support the laboratory during operations or when the laboratory has been decontaminated for service and maintenance will receive additional training specific to their duties.
- Oversight (external and internal), committee members (i.e., IBC and the Institutional Animal Care and Use Committee [IACUC]), and service professionals will be provided training to understand the logistics and restrictions of work conducted in BSL-4 conditions.
- This Training Plan emphasizes BSL-4 workers, those individuals working within the maximum containment laboratory. Training stages and participants are summarized in Figure 1. Specific training agendas and learning tasks are further outlined in the following section.

**Figure 1: NEIDL-specific training stages**



#### **4.0 ORIENTATION TO THE NEIDL**

##### **4.1 General Orientation**

There are two orientation trainings provided. First, all NEIDL staff, visitors, and vendors are provided a general orientation lecture that describes the NEIDL and its research program objectives, the building’s history and time line, the basic building layout and organization (which build on the basic concepts of biological safety, biocontainment, and biosecurity), and reviews safeguards that protect the public’s health from potential research hazards. Also covered are aspects of physical security, site access, and emergency response in the building, including evacuation procedures.

##### **4.2 Floor-Specific Orientation (for entry)**

Second, all staff and guests who are required to enter the BSL-4 containment space or a non-containment space associated with the BSL-4 space are provided a floor-specific orientation. This consists of a walk-through conducted by EHS personnel and serves to inform the participants in detail of the facility layout, the equipment located in those spaces, required procedures (e.g., egress procedures from the space, in the case of an emergency), and all hazards associated with those areas.

#### **5.0 TRAINING PLAN FOR BSL-4 WORKERS**

##### **5.1 Application Review and Nomination for BSL-4 Training**

Staff and guests who plan to work within BSL-4 laboratories will be required to be nominated by their Core Directors or principal investigators. An application (to be completed by the nominee) surveys the nominee’s experience and proficiency within the laboratory. The application also includes a review of the individual’s various clearances to enter maximum containment (i.e., Select Agent Registration application, health clearance from the Research Occupational Health Program). In addition, applicants’ BU and NEIDL training requirements will be reviewed (i.e., first aid CPR and AED [automated external defibrillator] training, EHS general laboratory safety training, ethics, etc.). When complete, the application is reviewed by the training staff, and an individual training plan (ITP)



is developed. The application and the ITP are presented to the NTAC for approval to proceed with training.

## **5.2 Overview**

### **5.2.1 Phased Approach**

A three-phase training process will be utilized for all personnel who enter the BSL-4 laboratory. Staff who will work within the maximum containment laboratory during normal operations will receive comprehensive reviews of the principles of biosafety, standard operating procedures (SOPs) for conducting research in the NEIDL, methods for assessing risks, biosecurity and incident response plans, sharps and hazard awareness training, and research protocols for handling specific Select Agents. The training will include didactic instruction and hands-on training in the NEIDL Training Simulator.

For scientific staff, the courses and hands-on training will enable scientists, guest scientists, and technicians to acquire and demonstrate proficiency in conducting microbiological practices, using containment equipment, carrying out research protocols for handling agents in the BSL-4 suites, and following incident response procedures. Training will be delivered by didactic, hands-on instruction, core- and laboratory-specific simulator training, scenario-based problem solving, incident drills, emergency response drills, and mentorship. Completion of the training will be a prerequisite for conducting research in the NEIDL. The training will be conducted in three stages: Stage I, positive pressure suit suitability assessment; Stage II, scenario-based training (Stages I and II are baseline trainings of EHS fundamentals); followed by core- and laboratory-specific training.

In the baseline Stage I, the staff will be provided didactic and simulated practicum training on the use of a positive pressure encapsulating suit and how to work within a BSL-4 laboratory. In baseline Stage II, the staff will build on the Stage I training through simulated exercises, including incident and emergency procedures, while gaining additional didactic training on the regulations and policies related to BSL-4 laboratory operations. The first two training stages are performed in the BSL-4 simulator laboratory space. Core- or laboratory-specific training occurs either in the simulator space or through mentored activities within the BSL-4 laboratory. Once proficiency is assured with the functions of operations within containment, the trainee will be assigned a trained mentor from within their core to begin an apprenticeship within containment. In this, the third phase, the trainee will receive specific training related to his or her anticipated duties in the maximum containment environment. All personnel will be required to demonstrate proficiency to the mentor (or supervisor) at the completion of this training.

On an annual basis, additional ongoing training consists of Emergency Response Training and Lab Safety Refresher Training. Annual training will focus on changes and lessons learned during the year. In addition, a select group of staff will be offered training to be mentors within the BSL-4 laboratory. Refresher training is provided to any staff member who has not been into the BSL-4 space within the past 90 days, as well as any individual identified as requiring remedial training.

### 5.2.2 Sample Training Sessions

There are several training sessions that are typically completed before or during BSL-4 training. These include the following:

1. **Biological Select Agent and Toxin (BSAT) – Tier 1 Select Agent Review.** Lecture covering the specifics of Tier 1 Select Agent requirements (~2 hours).
2. **Select Agent Inventory Training.** Training to include hands-on use of the electronic inventory system (~2 hours).
3. **BSAT Agent–Specific Training.** Focus on the specific biological agent including clinical signs and symptoms (~1 hour per agent).
4. **Communications within BSL-4: Vocera.** Training on proper communication using the Vocera communication system (~2 hours).
5. **Autoclave Usage Training.** Training provides the user the lecture and hands-on experience to utilize the autoclaves within the laboratory and how to achieve and verify proper decontamination with biological indicators (~2 hours and supervised usage until proficient).
6. **Research Ethics Training.** Boston University provides research staff with training in research ethics through lectures and on-line training
7. **Suitability and Reliability Policy** For compliance with tier 1 CDC select agent requirements, Boston University has developed a Personnel Suitability and Reliability policy for NEIDL. All staff in the BSL-4 training program are required to read the policy and agree to abide by the policy.

### 5.3 Stage I: EHS Suit Suitability Assessment (1 week, 40 hours, approximately)

Stage I baseline training encompasses the training related to the positive pressure encapsulating suit and entering and exiting the BSL-4 laboratory. All training in this stage is performed in didactic lectures or in the simulator space at the NEIDL. The lectures are focused on 1) Orientation to the Encapsulating Suit and 2) Biosafety Review. In addition, the trainee is provided a walking tour and overview of the critical systems that are associated with the BSL-4 operation.

Much of the hands-on training occurs in the NEIDL Training Simulator, which is a mock BSL-4 laboratory with an operating encapsulating suit shower system and doors. The simulator space offers an environment for learning where the training can be paused or stopped, and experiences provided to the trainee that would be prohibitive in an active BSL-4 laboratory. The focus is to provide knowledge and practical experience with both the encapsulating suit and laboratory features associated with a BSL-4 laboratory (decontaminating suit shower, APR doors, etc.).

Over an approximately five-day period, trainees are shown how to properly prepare and test an encapsulating suit for entry into the laboratory. The proper donning and doffing of the suit is highlighted as well as the normal entry and exit procedures for the chemical decontamination shower. Mobility while wearing the encapsulating suit, and early sharps hazard awareness are key points in the training. A review of the normal operation facility checklist is provided, and the details contained within the record that pertain to safe entry are reviewed and tested. Following demonstration of procedures by the instructor, several opportunities are provided for practice entries into the simulator.

Trainee understanding and proficiency is tested by a practicum consisting of a simulated entry with tasks that focus on mobility, sharps awareness, work flow, and pace of tasks within the simulator. The Associate Director for Maximum Containment Training performs and documents the completion of this stage of training.

#### **5.4 Stage II: EHS Scenario-Based Training in the Simulator (1 week, 40 hours, approximately)**

Successful completion of Stage I baseline training must precede progression to Stage II baseline training, in which the elements of Stage I (encapsulating suit usage and entry and exit procedures) are continued and reinforced. During Stage II, there is a progressive addition of tasks and knowledge that are essential to safe and efficient work within containment. The focus of Stage II training is to progressively introduce the various incidents and emergencies that one must be prepared to deal with while working in a BSL-4 environment. Four lectures are planned for this stage of training: 1) Orientation of SOPs and SOP review process, 2) Introduction to Emergency Response Drills, 3) Biosecurity and Tier 1 Requirements, and 4) Comprehensive Review of BSL-4 Safety.

Stage II training is accomplished through use of scenarios involving specific learning tasks within the NEIDL Training Simulator. Lectures and didactic training continue, with an emphasis on the regulations, policies, and practices associated with BSL-4 work. All BSL-4/ABSL-4 staffing areas are covered to provide an overview of staff roles and responsibilities and to highlight the hazards and logistics that each team member must understand while working in containment.

Personal risk management, laboratory decision making, and hazard avoidance are highlighted. Staff are provided outlined scenarios, detailed tasks, and demonstration of the tasks before they perform them. With each scenario, the trainee or trainees are allowed to complete the tasks outlined and learn from the experience in a safe, simulated environment. Review of the approach and the logic of the completion of the tasks are highlighted by the instructor following the exit from the simulator. Guidance and common issues are reviewed and discussed. Sharps awareness and other laboratory hazards and incidents are paramount in Stage II training. Methods and procedures (SOP-driven and best practices) are provided in this stage that cater to the future role and responsibilities of the trainee.

At the conclusion of Stage II, the trainee receives a comprehensive review lecture on BSL-4 safety and completes a written exam. When the instructor recommends the trainee for testing, the Associate Director of Maximum Containment Training performs and documents the completion of this stage of training with the practicum assessment.

#### **5.5 Mentoring and Core-Specific Training (typically 40–100 hours)**

Laboratory- and core-specific training is designed by the specific Core Directors and approved by EHS. The core tasks are diverse and unique. Moreover, trainee-specific duties within a core may vary considerably. There will be a custom trainee development plan co-designed by the Core Director or trainee supervisor, the mentor, and the trainee that will outline the types of tasks that the individual will need to perform. Following review by the Associate Director for Research Safety, NEIDL, and Associate Director for Maximum Containment Training, the plan will be presented to the NTAC for

approval. Once approved, the trainee will be trained to perform the core-specific tasks in accordance with NEIDL SOPs.

The trainee will follow a training pattern: 1) observe a task or tasks being performed by a proficient and trained mentor, 2) assist with performing the task(s), 3) perform the task(s) with assistance from the mentor, and 4) demonstrate performance of the task(s) with proficiency and independence. Once completed, the trainee will be able to document dates, times, and tasks performed with concurrence from the trained mentor. For experienced BSL-4 workers, this can be done within 10 entry and exits and 25 hours of experience. For new personnel, this will typically require a minimum of 25 entry and exits and  $\geq 100$  hours of training, depending on the number and complexity of tasks being learned.

While core training is primarily an apprentice method of training, lectures, tabletop discussions, and simulated work can be used to supplement the hands-on training. Once the trainee successfully completes Stage II, the mentor and supervisor will nominate the trainee to the Core Director for access independent of a mentor. The Core Director will ascertain the readiness of the trainee and, if appropriate, recommend to the NTAC that the trainee be granted approval for access without the mentor. NTAC will have final authority to determine which staff have successfully completed the mentoring program and are ready to work in the BSL-4 environment without a mentor.

## **5.6 Emergency Response Training (3 per year)**

All personnel who are required to work within the BSL-4 environment receive training on all aspects of Section 8: NEIDL Comprehensive Emergency Management Plan (CEMP). These extensive incident response procedures and protocols are fully elaborated in individual Emergency Response Plans (ERPs), which serve as the basis for tabletop exercises and full-scale, in-person drills. These exercises are run using Homeland Security Exercise and Evaluation Program procedures. At least three drills are run each year to test and improve on emergency response procedures. These drills include internal and external responders to ensure training is consistent and are as described in greater detail in the CEMP.

## **5.7 Refresher Training**

### **5.7.1 Annual Training Requirement:**

Annual training will be performed with all BSL-4 workers. The goal of this training is to provide updates on lessons learned during operation and discuss new approaches to performing work within BSL-4. A primary emphasis is on the update and review of safety, security, and all regulations pertinent to BSL-4 work. This training may be done in person or online.

### **5.7.2 Training for Those with Prior Experience:**

Trainees with significant prior experience may be provided refresher training focused on NEIDL operations and SOPs. This training will allow the trainee to meet the training requirements listed above.

### **5.7.3 Refresher Training**

***For Inactive Staff.*** Refresher training is also required for staff who have not remained active during a given period of time. For example, staff members with BSL-4 access who are unable to work within BSL-4 for a 90-day period will be required to have an orientation refresher led by an approved mentor before they can resume BSL-4 work. They must demonstrate their ability to perform their specific tasks within the BSL-4 laboratory environment.

***Remedial Refresher Training.*** Remedial refresher training may be required when staff are unable to perform their duties within acceptable performance criteria. A customized refresher training plan will be developed to resolve any deficiencies and reviewed by the Core Director, supervisor, trainee, and NTAC. Failure to complete or meet the requirements of the remedial refresher training will result in BSL-4 access being removed for these individuals.

## **5.8 Training for Mentors**

Mentors are among the most valuable assets in our BSL-4 training program. Mentors are selected because of two important qualities: 1) experience and knowledge, and 2) the ability to transfer knowledge to others. A mentor training program was developed in recognition of the importance of mentors and the fact that the necessary skills for effective mentorship are often learned and not inherent in individuals. The training consists of: 1) an online course designed to provide reflection and insight into an individual's mentoring skills, 2) case study review, and 3) a guided discussion on mentoring do's and don'ts. Mentor training also entails regular meetings (held at least quarterly, and more often if needed) of the mentors to discuss ongoing training issues and areas for improvement.

## **6.0 ORIENTATION AND TRAINING FOR OVERSIGHT PERSONNEL**

External and internal BU oversight personnel may request training to enter the BSL-4 working environment. In some cases, this will be done to provide an in-depth review of our operations and a summary of the overall training process. In other cases (i.e., BPHC and CDC), oversight personnel may request entry. For these individuals, an application will be completed, medical clearance obtained, and orientation training provided. As described in the NEIDL Personnel Suitability and Reliability Policy, all oversight personnel will be escorted by mentors or the Associate Director Research Safety, NEIDL, and Associate Director of Maximum Containment Training.

The training will review NEIDL-specific encapsulating suit usage (i.e., donning and doffing), mobility and dexterity within the encapsulating suit, use of the chemical decontamination shower, security, safety, and building automation systems. Both standard and nonstandard entry will be demonstrated within the simulator space. Essential incident and emergency response plans will be discussed. Both lectures and hands-on experiences will be part of the training. This training (and annual refresher training) will require a minimum of two hours when working with experienced personnel. An eight-hour training plan has been developed for inexperienced BSL-4 trainees. Additional training can be provided as requested by the oversight personnel.

## **7.0 TRAINING FOR OTHER PERSONNEL**

### **7.1 Institutional Biosafety Committee (IBC) Training**

The IBC is largely composed of scientists, animal care and veterinary personnel, and community members. As BSL-4 protocols require specialists' knowledge, ad hoc members will be added to the IBC for review of BSL-4 research protocols (and other related materials that require IBC review). Ad hoc members of the committee will not only have specific knowledge of the pathogens studied in the BSL-4 laboratories but also practical experience of BSL-4 practices and procedures.

Training for IBC members consists of providing a thorough overview of BSL-4 biocontainment principles and includes guided physical or virtual tours of the BSL-4 environment and associated spaces serving the BSL-4 laboratories (to the extent possible). It will emphasize the importance of biocontainment practices and procedures, as well as the purpose of primary and secondary barriers. This will be one-time training for existing IBC members and will be delivered on an as-needed basis for new IBC members.

An abbreviated version of this training will be delivered as an annual refresher. The focus of the refresher will be upon any areas of concern regarding the containment facility barriers or its practices and procedures. Another component of training is a thorough understanding of NEIDL SOP development, review, and approval. There is a strict document-control process for SOP development, multiple subject-matter expert reviews, revision, and sign-off. As the IBC has overall oversight responsibility, IBC members are trained in the processes used for NEIDL SOP development, review, and approval to facilitate that role.

### **7.2 Service Professionals**

Maintenance or repair of specialized equipment is essential for safe operations within the containment space. On occasion, training will be provided to the individuals who perform these tasks to allow for their function within the NEIDL. Customized training will be developed for all such personnel, based on the specific tasks they will perform. All spaces and/or equipment will be decontaminated before any service professional performs his or her work.

### **7.3 NEIDL Emergency Response Team**

Training for the NEIDL Emergency Response Team (ERT) and EHS on-call personnel consists of a series of in-person and online courses. All personnel (whether or not they are in the ERT/EHS on-call programs) must take the online course, "BU Managing Emergencies." This forms a foundation upon which further training is built. The ERT/EHS on-call personnel must then take a further online course entitled "Incident Response Command and Crisis Action Team Responder Training." As BU is committed to following the National Incident Management System, FEMA independent study (online training) is required for BU emergency responders. The specific courses are:

- IS100 – Introduction to Incident Command
- IS200 – ICS for Single Resources and Initial Action Incidents
- IS700 – Introduction to NIMS (National Incident Management System)

All personnel working in BSL-4 environments are considered first responders, since it is acknowledged that help may take some time to arrive (given the time taken to don the positive pressure suit), therefore all BSL-4 workers are trained in CPR/AED and first aid training (this is refreshed every two years).

#### **7.4 External Emergency Responders Training**

Training of public sector emergency responders is customized to provide information specific to their public safety roles. Trainings have included didactic lectures provided by EHS personnel, as follows:

1. “Microbiological Research Facility (NEIDL) Orientation”—This lecture provides an overview of the building and its mission; the type of work that will and will not be conducted in the NEIDL; the status of the building operations (e.g., active BSL-2 labs, and non-select agent BSL-3 labs, etc.); site plan and access; a summary of regulatory authorities with supervision and oversight of NEIDL activities; select agent requirements, including Tier 1; the NEIDL CEMP; the role of the NEIDL ERT in emergencies; hazards within the building; door placards; and any special hazards present (e.g., Cobalt60 gamma irradiator, MRI, etc.).
2. “Biosafety and Biocontainment”—This is an easy-to-understand overview of biohazardous agents and the mechanisms in place to contain them to prevent exposure to laboratory personnel, personnel outside of the laboratory, or release of agents into the environment.

These lectures are offered in conjunction with the training staff of the responding agency, who deliver a final lecture covering very specific site information, e.g., the building is equipped with shatter resistant windows, so firefighters cannot break through them in the event of a fire; the height of the building prevents the use of a ladder truck, etc.

Other trainings have included an escorted orientation tour of the building so that the closest responders, as well as the hazardous materials response unit, will be familiar with access and the location of the command center. This walk-through is typically an annual occurrence. An escorted orientation tour of the building is also provided to every responder as requested.

BU has provided such training to external responders for many years; the University’s commitments to continue doing so are included in Section 8: CEMP.

## 8.0 APPENDICES

### Appendix A: Training Curricula (Selected Examples)

#### Appendix A.1: Orientation Training

#### Appendix A.2: Stage I Training (Sample Curriculum)

#### Appendix A.3: Stage II Training (Sample Curriculum)

#### Appendix A.4: Refresher Training (Sample Curriculum)

#### Appendix A.5: Core-Specific and Laboratory-Specific Training (Example: Animal Core Training)

#### Appendix A.6: Orientation for Oversight Personnel

### Appendix B: Proficiency Evaluation Example—Form Used for Suit Training Assessment, Stage I

## APPENDIX A. Training Curricula (Selected Examples)

### Appendix A.1: Orientation Training (all personnel accessing BSL-4 floor)

*Introductory video.* A video covering the topics below is reviewed, with EHS, ERP, and Public Safety staff present to field questions.

- Introduction to the facility
- Building history and timeline
- Basic building layout and organization
- Security and site access
- Emergency response in the NEIDL

*Floor-/facility-specific orientation.* This consists of a walk-through with EHS to orient personnel to the facility, its hazards, equipment, and layout. For the BSL-4 floor, topics covered are:

- BSL-4 security
- Phones
- Hazard communication
- Safety, health & environment
- Emergency egress

### Appendix A.2: Stage I Training (Sample Curriculum)

Version 1 (2012)

#### Day 1: Introductory Lectures



8:00 AM	Welcome and Introductions in classroom
8:30 AM	Pre-Knowledge Assessment: (Principles & Intro to Positive Pressure Suit)
9:00 AM	Overview of BSL-4 Training Program (Lecture)
9:30 AM	Overview of the Principles of Biosafety (Lecture)
9:45 AM	Break
10:00 AM	Introduction to the Positive Pressure Suit (Lecture)
11:00 AM	Post-Training Assessment: (Principles & Intro to Positive Pressure Suit)
11:30 AM	Break: Grading and transition to the Simulator Room
12:00 PM	LUNCH BREAK (on your own)
1:00 PM	Facilities and Critical Systems (Lecture): Safety brief for tour
1:30 PM	Facilities Tour and Simulated BSL-4 External Systems Checklist
2:30 PM	Simulator: Suit and glove sizing
3:00 PM	Simulator: Suit glove assembly, pressure testing, Donning suit
4:00 PM	Simulator: Entry and exit: Exercise #1 Mobility & Dexterity , Chemical Shower, Doffing Suit
5:00 PM	Questions and Feedback forms
<b>Day 2: Entry 2, Exercise #2</b>	
<b>Time Requirement</b>	<b>Tasks</b>
1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Donning Suit & Simulator Entry: Exercise #2 Mobility & Dexterity, Chemical Shower Exit & Doffing Suit
30 minute	Cleanup, questions, log entry
<b>Day 2: Nonstandard Entry &amp; Exit, BAS: Alarms and Alerts Lectures</b>	
8:00 AM	BSL-4 Alarms & Alerts, Building Automation Systems (BAS)
9:00 AM	Break
9:15 AM	Entry & Exit: Standard and Nonstandard
10:00 AM	Encapsulating Suit and Glove Failure
10:45 AM	Transition to Simulator
11:00 AM	Walk-through of procedures and BAS demonstration
11:45 AM	Questions and feedback
12:00 PM	<b>End of training day</b>
<b>Day 3: Entry 3: Exercise 3</b>	
<b>Time Requirement</b>	<b>Tasks</b>
1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Donning Suit and Simulator Entry: Exercise #3 Mobility & Dexterity, Chemical Shower Exit and Doffing

30 minute	Cleanup, questions, log entry
<b>Day 4: Entry 4: Exercise 4</b>	
<b>Time Requirement</b>	<b>Tasks</b>
1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Donning Suit and Simulator Entry: Exercise #4 Mobility & Dexterity, Chemical Shower Exit and Doffing Suit
30 minute	Cleanup, questions, log entry
<b>Day 5: Entry 5: Exercise 5 (Optional: Repeat as needed)</b>	
<b>Time Requirement</b>	<b>Tasks</b>
1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Donning Suit and Simulator Entry: Exercise #5 Mobility & Dexterity, Chemical Shower Exit and Doffing Suit
30 minute	Cleanup, questions, log entry
<b>Day 5: Entry 6: Suit Suitability Assessment</b>	
<b>Time Requirement</b>	<b>Tasks</b>
	Practical Assessment: Guidelines Provided/Scoring
1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Donning Suit and Simulator Entry: Assessment #1 Mobility & Dexterity, Chemical Shower Exit and Doffing
30 minute	Cleanup, questions, log entry, Certificate Preparation

**Appendix A.3: Stage II Training (Sample Curriculum)**  
**Version 1 (2012)**

<b>Day 1: Advanced BSL-4 Systems and Procedures</b>	
8:00 AM	Welcome and Introductions in classroom
8:30 AM	Pre-Knowledge Assessment: (Advanced BSL-4 Systems and Procedures)
9:00 AM	Overview of Stage 2 Training – goals, aims, outcomes
9:30 AM	Review of Introduction Course (Lecture)
9:45 AM	Break
10:00 AM	Advanced BSI-4 Systems and Procedures (Lecture)
11:00 AM	Post-Training Assessment: (Principles & Intro to Positive Pressure Suit)
11:30 AM	Break: Grading and transition to the Simulator Room
12:00 PM	LUNCH BREAK (on your own)
1:00 PM	Simulator: Entry and exit, Exercise #1 (scenario-based)
3:00 PM	Glove or Encapsulating Suit tears and procedures to exit the laboratory (Lecture)
4:00 PM	Discussion, case study
5:00 PM	Questions and Feedback forms
<b>Day 2: Entry 2: Exercise 2</b>	
Time Requirement	Tasks
1 hour	Donning Suit and Simulator Entry: Exercise #2
30 minute	Cleanup, questions, log entry
<b>Day 3: Entry 3: Exercise 3</b>	
Time Requirement	Tasks
1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Donning Suit and Simulator Entry: Exercise #3
30 minute	Cleanup, questions, log entry
<b>Day 4: Entry 4: Exercise 4</b>	
Time Requirement	Tasks
1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Donning Suit and Simulator Entry: Exercise #4
30 minute	Cleanup, questions, log entry
<b>Day 5: Entry 5: Exercise 5 (Optional: Repeat as needed)</b>	
Time Requirement	Tasks

1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Donning Suit and Simulator Entry: Exercise #5
30 minute	Cleanup, questions, log entry
<b>Day 5: Entry 6: Suit Suitability Assessment</b>	
<b>Time Requirement</b>	<b>Tasks</b>
	Practical Assessment: Guidelines Provided/Scoring
1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Assessment #2
30 minute	Cleanup, questions, log entry, Certificate Preparation

*Note:* The various scenario-based exercises assess the performance of various standard operating procedures as well as incident responses (e.g., spills outside of a containment device) within the simulator environment.

**Appendix A.4: Refresher Training (Sample Curriculum)**  
**Version 1 (2012)**

<b>Day 1: Introductory Lectures &amp; Exercise #1</b>	
8:00 AM	Welcome and Introductions in classroom
8:30 AM	Pre-Knowledge Assessment: (Principles & Intro to Positive Pressure Suit)
9:00 AM	Overview of BSL-4 Training Program
9:30 AM	Overview of the Principles of Biosafety (Lecture)
9:45 AM	Break
10:00 AM	Introduction to the Positive Pressure Suit (Lecture)
11:00 AM	Post-Training Assessment: (Principles & Intro to Positive Pressure Suit)
11:30 AM	Break: Grading and transition to the Simulator Room and Orientation
12:00 PM	LUNCH BREAK (on your own)
1:00 PM	Facilities and Critical Systems (Lecture): Safety brief for tour
1:30 PM	Facilities Tour and Simulated BSL-4 External Systems Checklist
2:30 PM	Simulator: Suit and glove sizing
3:00 PM	Simulator: Suit glove assembly, pressure testing, donning suit
4:00 PM	Simulator: Entry and Exit; Exercise #1—Mobility & Dexterity, Chemical Shower, Doffing Suit
5:00 PM	Questions and feedback forms
<b>Day 2: Entry 2 &amp; Exercise #2</b>	
Time Requirement	Tasks
1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Donning Suit and Simulator Entry; Exercise #2 Mobility & Dexterity, Chemical Shower Exit and Doffing Suit
30 minute	Cleanup, questions, log entry
<b>Day 2: Nonstandard Entry &amp; Exit, BAS: Alarms &amp; Alerts Lectures</b>	
8:00 AM	BSL-4 Alarms & Alerts, Building Automation Systems (BAS)
9:00 AM	Break
9:15 AM	Entry & Exit: Standard and Nonstandard
10:00 AM	Encapsulating Suit and Glove Failure
10:45	Transition to Simulator
11:00	Walk-through of procedures and BAS demonstration
11:45	Questions and feedback forms
12:00	End of training day or Exercise #2
<b>Day 3: Regulations &amp; Entry 3 &amp; Exercise #3</b>	
8:00 AM	BSL-4 BMBL Regulations, SOPs, and Policy
9:45 AM	Break

10:00 AM	Regulations, continued
11:30 AM	Questions & Regulations Training Exam/Assessment
12:00	Lunch (on your own)
1:00 PM	Entry 2 or 3
<b>Time Requirement</b>	<b>Tasks</b>
1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Donning Suit and Simulator Entry: Exercise #3: Mobility & Dexterity, Chemical Shower Exit, and Doffing Suit
30 minute	Cleanup, questions, log entry
<b>Day 4: Entry 4 &amp; Exercise #4</b>	
<b>Time Requirement</b>	<b>Tasks</b>
1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Donning Suit and Simulator Entry: Exercise #4: Mobility & Dexterity, Chemical Shower Exit and Doffing Suit
30 minute	Cleanup, questions, log entry
<b>Day 5: Entry 5: Exercise #5 (Optional: Repeat as needed)</b>	
<b>Time Requirement</b>	<b>Tasks</b>
1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Donning Suit and Simulator Entry: Exercise #5: Mobility & Dexterity, Chemical Shower Exit and Doffing Suit Spill and Sharps awareness, Non-standard exit.
30 minute	Cleanup, questions, log entry
<b>Day 5: Entry 6: Suit Suitability Assessment &amp; Clearance</b>	
<b>Time Requirement</b>	<b>Tasks</b>
	Practical Assessment: Guidelines Provided/Scoring
1 hour	Preparation of encapsulating suit: Positive Pressure Suit Maintenance Tasks
1 hour	Donning Suit and Simulator Entry: Assessment #1: Mobility & Dexterity, Chemical Shower Exit and Doffing Suit Non-standard exit and emergency response review: small puncture in suit, loss of backup breathing air, Person-down
30 minute	Cleanup, questions, log entry, Certificate Preparation

## **Appendix A.5: Core-Specific and Laboratory-Specific Training (Example: Animal Core Training)**

### **Baseline Training**

Overseen by the EHS Core, baseline training takes individuals through their initial acclimatization to a BSL-4 laboratory in the simulator space. Trainees undertake a minimum of three entries in a relaxed environment with didactic biosafety sessions running alongside the entry sequences in order to build understanding. During this initial phase an early assessment is made by the trainer of trainees' underlying approach to BSL-4 working, their comfort levels, and readiness to proceed to Stage II of training. A short written test assists the trainer in making this determination.

Stage II of baseline training is a more involved set of entries, again only into the simulator space, but it is heavily scenario-based, focusing on emergency responses, principles of working safely within a BSL-4 suit, and procedures for potential breaks in containment, such as glove holes or tears, spills or breakages.

Upon successful completion of Stage II baseline training, and agreement between the Animal Core Director and EHS, an individual can proceed to core-specific training.

### **Animal Core-Specific Training**

Similar to the baseline training, Animal Core-specific training will consist of a phased approach to working in the BSL-4 laboratory.

#### **Segment 1**

Segment 1 may begin concurrently with baseline training and need not be complete for segment 2 to commence. It comprises the theoretical aspects of working within the Animal Core as well as accessing all Animal Core SOPs and other documents, and training on all information technology (hardware and software) used by the Animal Core. Two key didactic sessions will focus on the principles of research animal use in biocontainment, biosafety controls specific to animals in biocontainment, and a thorough review of regulations, the institutional protocol review process, and animal care responsibilities within maximum containment environments.

Segment 1 will be presented to members of the Animal Core as a handbook to refer to with sections on team culture, communication pathways, and the approach to training and working. The handbook will also provide a clear and easy-to-read reference document on all aspects of working within the Animal Core. Participants will be encouraged to use their handbooks through the training process and beyond, making their own notes and recording any updates in operating procedures.

#### **Segment 2**

Segment 2 consists of the initial five entries (minimum) of a new Animal Core member into the live A/BSL-4 space. These entries will involve direct supervision by a mentor with sole focus on the trainee. These five entries will involve observation only and not require the trainee to participate in any live work. A checklist of learning objectives, familiarization activities, and tasks will be undertaken during each entry sequence and will progress towards work participation under direct supervision. All aspects of day-to-day

working will be thoroughly reviewed during these entries. Five entries will be the required minimum for segment 2 but may be increased at the discretion of the trainer or trainee with no need for lengthy justification. At a minimum, the time taken to complete segment 2 should be five days. More frequently the segment spans a longer time span; however it should not exceed four weeks, as repetition in a shorter time frame is an important part of this segment that consolidates theoretical information learned in segment 1.

### **Segment 3A**

Upon successful completion of segments 1 and 2, a new member of the Animal Core will proceed to segment 3A. During this phase, a trainee will begin to carry out husbandry category SOPs within the ABSL-4 laboratory, at all times under the *direct supervision* of a mentor. A minimum of 10 entries working under the direct supervision of a mentor is required.

Upon completion of 10 directly supervised working entries, a mentor will review the trainee's competency and may end the direct mentoring requirement.

At this stage a further 20 entries (minimum) must be made by the new member with participation in working duties under the supervision and direction of other Animal Core members with approved BSL-4 laboratory access.

Segment 3A consists of a minimum of 30 entries; 10 with direct mentor supervision and 20 while always working with members possessing approved access clearance to the BSL-4 laboratory.

Upon completion of segment 3A entry requirements, the new member of the Animal Core will undergo a short interview with the Animal Core Director and be put forward for independent access to the ABSL-4 laboratory with competency to carry out all husbandry category SOPs.

### **Segment 3B**

This phase of training allows the Animal Core to develop new mentors. Selections of appropriate personnel are made by Animal Core directors in conjunction with EHS. Candidates will proceed to mentorship training with EHS.

### **Segment 4: Technical Category SOP training.**

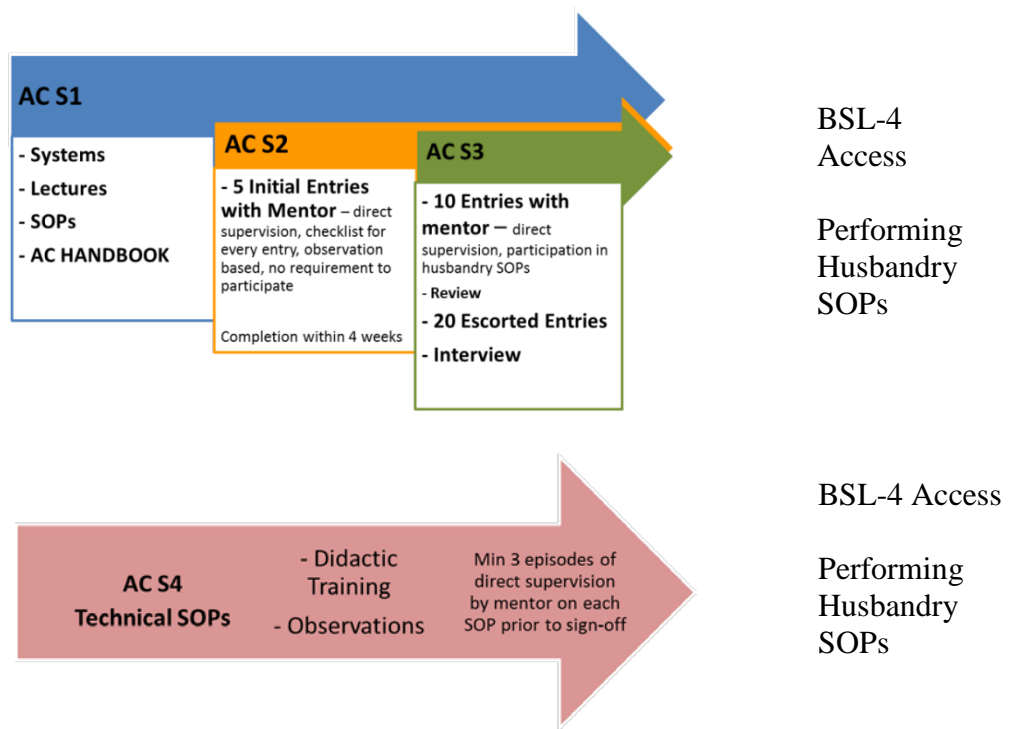
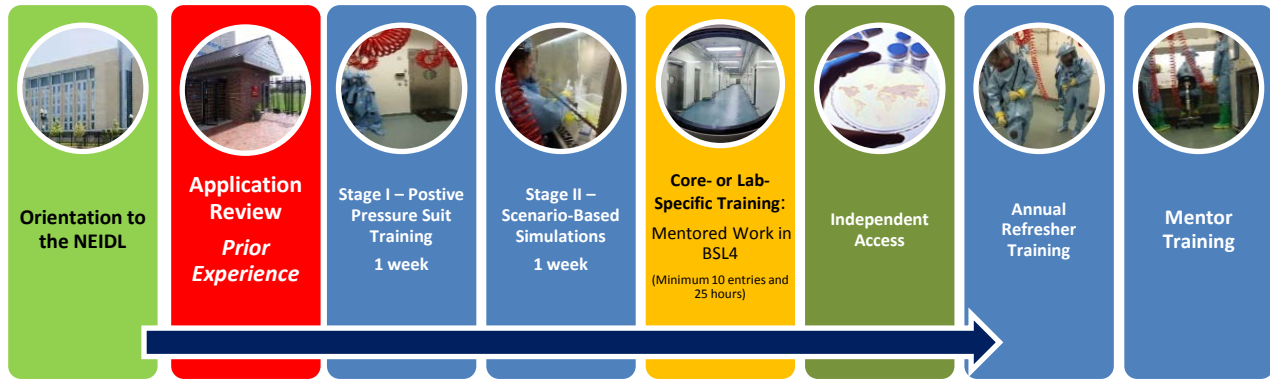
This segment of training prepares Animal Core members to carry out procedures in the technical SOP category. Technical SOPs involve procedures associated with greater risks in the ABSL-4 environment, such as use of sharps or prolonged handling of anesthetized animals. The greater risks linked with these processes require attention to mitigation strategies not commonly employed outside of the containment environment. A didactic session, including a thorough review of risks and mitigation associated with technical SOPs, is carried out as an initial introduction to segment 4 of Animal Core-specific training.

Thorough training on a technical SOP at lower containment levels will be ensured prior to proceeding to direct supervision by a mentor within the ABSL-4 laboratory.

A minimum of three episodes of direct supervision by a mentor will be required prior to sign-off on each technical SOP.



## Schematic of Animal Core Training



### Appendix A.6: Orientation for Oversight Personnel\*\*

\*\* Assumes that the participants demonstrate proficiency in the fundamentals of biosafety. Further, all visitors must acknowledge security, and safety policies during the visit. Health assessments may be required for entry.

#### X.1 Initial Training (Sample Agenda)

Version 1 (2014)

Day 1: BSL-4 Operations and Encapsulating Suit Familiarization	
8:00 AM	Welcome and Introductions in classroom

8:30 AM	Pre-Knowledge Assessment: (BSL-4 Operations and Procedures & Encapsulating Suit Familiarization)
9:00 AM	Overview of Training Program: Goals, Aims, Outcomes
9:30 AM	Encapsulating Suit Overview : ILC Dover
10:15 AM	Break
10:30 AM	BSL-4 Practices, Incidents and Emergency Procedures for Escorted Entry
11:00 AM	Orientation to the Simulator Facility
11:30 AM	Lunch
12:15 PM	Walk-through of BSL-4 floor and BSL-4 Building Systems
1:15 PM	Encapsulating Suit preparation and Simulator Entry/Exit, Modified Suit Suitability Assessment
3:45 PM	Break
4:00 PM	Cabinet Laboratory Practices & Rules/Health/Hazard Concerns for Inspectors
4:15 PM	Q&A Session
4:30 PM	Post-Knowledge Assessment: (BSL-4 Operations and Procedures & Encapsulating Suit Familiarization)
5:00 PM	Questions and Feedback forms

## Refresher Training Version 1 (2014)

Day 1: Annual Refresher (Or Greater Than 90 Days)	
8:00 AM	Welcome and Introductions in classroom
8:30 AM	Overview of Training Program: Goals, Aims, Outcomes: updates
9:00 AM	Encapsulating Suit Overview : ILC Dover: Review
9:30 AM	BSL-4 Practices, Incidents and Emergency Procedures for Escorted Entry: Review
10:15 AM	Break
10:30 AM	Escort/Mentor introductions
11:00 AM	Inspections



## APPENDIX B: Proficiency Evaluation Example

### Form Used for Suit Training Assessment – Stage I Version 1 (2012)

Baseline Training Hands-on Training Final Assessment (Stage I)	
Trainee Name:	
Date	
Core	
Supervisor Name	
Trainer Name	
+	
<b>I. Review of Previous Entries</b>	
<input type="checkbox"/> Retention of information <input type="checkbox"/> Review of any mistakes <input type="checkbox"/> Clarification of any questions	Comments
<b>II. Independent Suit Inspection</b>	
<input type="checkbox"/> Finding Size Information <input type="checkbox"/> Visual check of outer gloves <input type="checkbox"/> Visual check of suit <input type="checkbox"/> Successful glove attachment <input type="checkbox"/> Successful valve seals <input type="checkbox"/> Inflation <input type="checkbox"/> Leak detection	Comments
<b>III. Independent Donning of Suit</b>	
<input type="checkbox"/> Remove valve seals <input type="checkbox"/> Check inner gloves <input type="checkbox"/> Tape scrubs/inner gloves <input type="checkbox"/> Ability to get on & off without help <input type="checkbox"/> Overall comfort	Comments
<b>IV. Activities in lab</b>	
<input type="checkbox"/> Put on Boots <input type="checkbox"/> Reaching <input type="checkbox"/> Bending/kneeling <input type="checkbox"/> Sitting <input type="checkbox"/> Connecting/disconnecting <input type="checkbox"/> Spatial awareness <input type="checkbox"/> Typing	Comments
1	

<input type="checkbox"/> Ladder/step stool <input type="checkbox"/> Biosafety cabinet <input type="checkbox"/> Microscope <input type="checkbox"/> Communicating – phone & direct	
<b>V. Decontamination Shower</b>	
<b>Before</b> <input type="checkbox"/> Remove boots <b>During</b> <input type="checkbox"/> Actions in shower <input type="checkbox"/> Successfully complete shower <b>After</b> <input type="checkbox"/> Towel dry <input type="checkbox"/> Remove suit safely <input type="checkbox"/> Clean visor <input type="checkbox"/> Remove outer gloves <input type="checkbox"/> Careful handling of suit	Comments
<b>VI. Post-session discussion</b>	
<input type="checkbox"/> Questions <input type="checkbox"/> Action items for next session <input type="checkbox"/> Supplies to bring for next session	Comments
<b>VII. Post session assessment</b>	
<input type="checkbox"/> Strength to handle suit <input type="checkbox"/> Compliance with instructions <input type="checkbox"/> Appropriate attention to detail <input type="checkbox"/> Problem-solving abilities <input type="checkbox"/> Overall Pace <input type="checkbox"/> Ability to complete tasks independently <input type="checkbox"/> Corrected any mistakes made in Previous sessions <input type="checkbox"/> Recommend proceeding to next stage of training	Comments
Trainee Signature _____ Date _____ Trainer Signature _____ Date _____ Supervisor Signature _____ Date _____	
2	