

**The Marine Biological Laboratory (MBL)**

BIOLOGICAL  
SAFETY  
HANDBOOK

# BIOSAFETY MANUAL

**APPROVAL:**

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Director and CEO Date

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Chief Academic and Scientific Officer Date

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MBL Biosafety Committee Chair Date

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Environmental, Health & Safety Manager Date

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## **1.0 PURPOSE, SCOPE, AND RESPONSIBILITIES**

### **1.1 Purpose**

The purpose of the MBL Biosafety Manual is to define policies and procedures that will minimize risks to personnel, facilities, and the environment resulting from the use of biological agents at the MBL. The work practices and policies specified in this manual are based on current regulatory requirements and accepted good biosafety practices. Implementation of these measures will reduce the likelihood that an incident involving a biological agent will occur, and will fulfill regulatory biosafety expectations. Laboratory microbiological work usually involves exposure not only to biological hazards, but to chemical and radiological hazards as well. Consequently, this manual should be used in conjunction with the MBL Chemical Safety Handbook and the MBL Radiation Safety Handbook, as appropriate.

### **1.2 Scope**

This manual applies to all MBL activities involving biological agents and all MBL personnel working with biological agents. Biological agents include all infectious microorganisms (bacteria, chlamydia, fungi, parasites, prions, rickettsias, viruses, etc.) that can cause disease in humans, or significant environmental or agricultural impact, and toxins derived from such organisms. Additionally, recombinant DNA; human or non-human primate tissues, fluids, cells or cell culture; transgenic plants or animals; and work with animals known to be reservoirs of zoonotic diseases are wholly or partly covered by the procedures and policies in this manual.

### **1.3 Responsibilities**

The responsibility for biosafety at the MBL is a team effort requiring the direct involvement of the MBL Institutional Biosafety Committee, Principal Investigators (PIs), laboratory workers, the MBL Biosafety Officer and Environmental Health and Safety Office (EH&S).

#### MBL Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) and the Environmental Health and Safety Office (EH&S) develop policies and provide leadership with the goal of reducing risk to the MBL community due to biological agents. The IBC is composed of at least five members that collectively represent experience and expertise in a wide range of biosafety areas applicable to MBL activities. At least two members of the IBC must be from outside the MBL community (not otherwise affiliated with the MBL). Non-committee faculty or staff with special expertise may be asked to advise the IBC, as appropriate.

Responsibilities of the IBC include:

1. Developing biosafety policies applicable to MBL activities with EH&S, including work practices, biohazardous waste, and medical surveillance of personnel if necessary.
2. Reviewing and approving new research proposals in accordance with CDC/NIH guidelines.

3. Setting required containment levels for research projects. Generally, the biosafety levels (BSLs) established by the CDC and NIH will be used as the level of containment; however, the IBC can increase or decrease the level of containment according to the specific circumstances of the project.
4. Developing design specifications and criteria for containment facilities.
5. Investigating significant violations of MBL biosafety procedures or policies, and significant accidents or illnesses involving biological agents. If appropriate, the IBC will recommend disciplinary action to the proper MBL officials.

#### MBL Biosafety Officer

The MBL Biosafety Officer (BSO) or designee is responsible for providing guidance on safe handling of biological agents and overall management of the Biosafety program. The BSO is a member of the IBC. Specific responsibilities of the BSO include:

1. Working with the biosafety committee to provide technical advice to PIs on biosafety protocols.
2. Providing emergency response to accidental spills and personnel contamination, and investigating incidents involving biological agents.
3. Making periodic inspections of laboratories to assess biosafety issues.
4. Keeping the IBC informed of pertinent biosafety issues and program status.
5. Providing general biosafety training for MBL personnel on a regular basis.

#### Principal Investigators

Principal Investigators (PIs) are responsible for the health and safety of all personnel in their laboratory. Specific responsibilities of the PI include:

1. Ensuring that specific laboratory hazards are effectively communicated to laboratory personnel, and that controls are in place to minimize risks associated with these hazards.
  - a. Developing laboratory-specific standard operating procedures (SOPs) that cover the hazards and activities (both routine activities and unusual events) relevant to the laboratory.
  - b. Ensuring that engineering controls are available, are in good working order, and are used appropriately to minimize exposure to biohazardous agents.
  - c. Ensuring that appropriate personal protective equipment is available and used by laboratory personnel.

2. Ensuring that all laboratory personnel receive general Biosafety training conducted by the Biosafety Officer, as well as specific training on the hazards, procedures, and practices relevant to the laboratory they are working in. All training must be documented and records maintained.
3. Notifying the IBC and obtaining prior IBC approval for work involving biohazardous material as specified in this manual (see Section 2).
4. Ensuring that laboratory workers are provided immunizations and medical surveillance prior to exposure to biohazardous agents as appropriate (based on current recommendations of the Centers for Disease Control and Prevention, and IBC recommendations).
5. Notifying the BSO of any spills or incidents involving biological agents that result in exposure to laboratory personnel or the public, or release to the environment. Note: PIs are responsible for calling Falmouth hospital to warn them if any MBL personnel have been biologically contaminated with a hazard such that hospital staff could be at risk while treating the injured MBL person .
6. Ensuring that biological agents are disposed of according to regulations and as outlined in this manual.
7. Ensuring that biohazardous materials to be transported are packaged and shipped in accordance with regulations.
8. Ensuring that periodic assessments of the laboratory are conducted.

#### Laboratory Workers

Laboratory workers are the most important element in developing and maintaining a safe laboratory environment. Laboratory workers are responsible for their own health and safety, as well as that of their coworkers. An incident caused by one laboratory worker can have a widespread affect on others. Specific responsibilities include:

1. Following procedures and practices established by the MBL and the laboratory.
2. Using accepted good laboratory practices to minimize exposures to biological agents, and to avoid other incidents (such as fire, explosion, etc.).
3. Attend biosafety and other laboratory safety training as required.
4. Report unsafe laboratory conditions to the PI, EH&S, or other responsible party.
5. Utilize control measures such as biological safety cabinets and personal protective equipment to prevent exposure to biological agents, and contamination of personnel and facilities.

## Facilities Department

1. Maintains autoclaves.

## E, H, and S Department

1. Certifies Biological Safety Cabinets (BSCs) to NSF 49. Note: Performed by contractor.

## **2.0 APPROVAL OF RESEARCH PROJECTS**

### **2.1 Projects Requiring Approval**

All projects involving the use of (i) potential human pathogens, (ii) recombinant DNA; (iii) human or non-human primate tissues, fluids, cells or cell culture; or (iv) transgenic plants require prior approval from the MBL Institutional Biosafety Committee (IBC). (Visiting Summer) Principal Investigators must submit a RESEARCH REGISTRATION FORM ([forms.mbl.edu](http://forms.mbl.edu)) to the MBL Administration in order to initiate the approval process.

The use of human or non-human primate tissues, fluids, cells or cell cultures shall be discussed in the research protocol and reviewed by the biosafety committee if any biological safety hazards exist.

Year- Round Principal Investigators and Visiting Principal Investigators may be required to submit one of the following two forms; depending on the biosafety hazard their research presents:

- Exempt-Non-Exempt Recombinant DNA Experiment ([www.mbl.edu/inside/what\\_services/index.html](http://www.mbl.edu/inside/what_services/index.html))
- Application for the use of potential human pathogens. Note: Form can be obtained from Biosafety Committee (This form includes all biological agents (e.g. viruses, bacteria, or protozoans) that are potential pathogens of humans and require biosafety Level 2 containment (See 2.2 below).

The above two forms may be submitted to the Assistant to the Chief Academic and Scientific Officer.

Note: The use of potential parasites only in non-humans must be approved by the IACUC.

### **2.2 Biological Agents**

*All work involving biological agents must be reviewed by the MBL Institutional Biosafety Committee (IBC) for adherence to NIH/CDC biosafety guidance published in the latest edition of *Biosafety in Microbiological and Biomedical Laboratories*, the latest edition of *NIH Guidelines for Research Involving Recombinant DNA Molecules*, applicable regulations, as well as MBL policies and current biosafety practice.*

### Biosafety Level 1 (BSL1) and Animal Biosafety Level 1 (ABSL1)

Organisms in this category are not known to cause disease in healthy human adults.

### Biosafety Level 2 (BSL2) 3 (BSL3) and Animal Biosafety Level 2 (ABSL2)

All work involving biological agents classified as BSL2 or BSL3 must be reviewed by the IBC. Containment levels, facility requirements, and work practices will generally follow NIH/CDC guidance; however, the IBC can modify these requirements as appropriate.

### Biosafety Level 3 (BSL3) or Animal Biosafety Level 3 (ABSL3) and Biosafety Level 4 (BSL4) and Animal Biosafety Level 4 (ABSL4)

Projects involving BSL3 and BSL4 organisms are currently prohibited at MBL.

Note: Research involving animal parasites (ABSL1 or ABSL2) are reviewed by the IACUC.

## **2.3 Recombinant DNA**

As a condition of funding from the National Institutes of Health (NIH), all research at MBL involving recombinant DNA must be conducted in accordance with the most current version of *NIH Guidelines for Research Involving Recombinant DNA Molecules*. PIs are required to make an initial determination of the required biological and physical containment required. The approval level required for the proposed research is dependent on the NIH category to which the work corresponds. **Prior approval by the IBC is required for all proposed experiments involving recombinant DNA, including those exempt from NIH Guidelines.** Principal Investigators must submit the appropriate form to the IBC in order to request approval.

### Experiments requiring IBC approval, RAC review, and NIH approval (NIH section III-A)

Experiments involving the deliberate transfer of a drug resistance trait to microorganisms that do not acquire the trait naturally, where such acquisition could compromise the use of the drug to control disease in humans, veterinary medicine, or agriculture are included in this category. These experiments are considered "Major Action" and require review by the Recombinant DNA Advisory Committee (RAC) at NIH, and specific approval by NIH, prior to initiation. Additional information on the Office of Biotechnology Activities (OBA) and the RAC is available at the NIH web site. Approval by the IBC is required prior to initiation of the experiments.

### Experiments requiring IBC and NIH approval (NIH section III-B)

Experiments in this category include the cloning of genes encoding toxic molecules with an LD<sub>50</sub> for vertebrates less than or equal to 100 ng/kg. This includes microbial toxins such as botulinum toxins, tetanus toxins, and diphtheria toxin. These experiments cannot be initiated without submission of relevant information on the proposed experiment to the OBA. IBC approval is required prior to initiation of the experiments.

#### Experiments requiring IBC and RAC approval, with NIH registration (NIH section III-C)

These experiments involve the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into humans (human gene transfer). Prior to initiation of laboratory work, these experiments must be approved by the IBC, the RAC, and be registered with the OBA.

#### Experiments requiring IBC approval (NIH section III-D)

This category includes whole animal or plant experiments, as well as experiments involving DNA from Risk Group 2, 3, or 4 agents. These experiments must be approved by the IBC prior to initiation.

#### Experiments using Risk Group 1 agents (NIH section III-E)

Experiments in this category are low risk and can be conducted using BSL1 containment. Examples include experiments in which all components are derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes. IBC approval is required prior to initiation of the experiments.

#### NIH exempt experiments (NIH section III-F)

Although these experiments are exempt from the NIH Guidelines by NIH policy, MBL Biosafety Policy requires the PI must describe these experiments as part of the Registration of Exempt/Non-Exempt Recombinant DNA Experiments to the IBC prior to initiation of the work (see end of Section 2.1). The following recombinant DNA (rDNA) experiments are included in the NIH Guidelines as "exempt experiments":

1. rDNA that is not in organisms or viruses.
2. rDNA consisting entirely of DNA segments from a single non-chromosomal or viral DNA source.
3. rDNA consisting entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host or when transferred to another host by well established physiological means.
4. rDNA consisting entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids when propagated only in that host.
5. rDNA consisting entirely of DNA segments from different species that exchange DNA by known physiological processes.
6. rDNA that does not present a significant risk to health or the environment.

## **2.4 Biological Project Registration Form Amendment and Termination**

Changes involving additional biological agents, significant procedural changes, or modifications that increase the risk of the project must be approved by the IBC. PIs wanting to modify a current Biosafety Research are required to submit a revision to the MBL IBC Chair. The PI is required to notify the Assistant to the Chief Academic and Scientific Officer ([ibc@mbl.edu](mailto:ibc@mbl.edu)) when a project is completed or is no longer active.

### 3.0 Biosafety Regulations and Guidelines

The following federal agencies either regulate or provide guidelines covering the use of biological agents. A summary of these regulations and guidelines is provided below. Links to applicable web sites are found on the EH&S web site ([http://www.mbl.edu/inside/what/services/serv\\_enviro.htm](http://www.mbl.edu/inside/what/services/serv_enviro.htm)). Refer to the American Biological Safety Association (ABSA) Risk Group Table for assistance with biosafety hazard level and classification.

1. Centers for Disease Controls and Prevention (CDC) and the National Institutes of Health (NIH): *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). This document contains guidelines for microbiological practices, safety equipment, and facilities that constitute the four established biosafety levels. The BMBL is generally considered the standard for biosafety and is the basis for this manual.
2. National Institutes of Health (NIH): *Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines). This document provides guidelines for constructing and handling recombinant DNA molecules (rDNA), and organisms containing rDNA. Although these guidelines are not subject to regulatory enforcement, institutions that receive any NIH funding for rDNA research are required to comply with these guidelines as a condition of funding. This document requires that each institution establish an Institutional Biosafety Committee with the authority to approve proposed rDNA research using the NIH Guidelines as a minimum standard.
3. Occupational Safety and Health Administration (OSHA): *Bloodborne Pathogens*. This regulation covers occupational exposure to human blood and other potentially infectious material, including human tissue and cells. OSHA specifies a combination of engineering controls, work practices, and training to reduce the risk of infection. Personnel potentially exposed to human blood and other potentially infectious material must be offered immunization against Hepatitis B and receive training. Personnel who work with HIV or Hepatitis B in a research laboratory must receive additional training and demonstrate proficiency in working with human pathogens.
4. Centers for Disease Control and Prevention (CDC): *Possession, Use, and Transfer of Select Agents and Toxins* and USDA Animal and Plant Health Inspection Service (APHIS): *Agricultural Bioterrorism Protection Act of 2002: Possession, Use, and Transfer of Biological Agents and Toxins*. These regulations require institutions that possess, use, or transfer certain biological agents and toxins ("Select Agents") to be registered and approved by the CDC and/or APHIS. Individual MBL laboratories that possess, use, or transfer any of these agents must be included on the MBL institutional registration. This regulation requires that laboratories comply with the BMBL (see above) and the OSHA Laboratory Standard (see the MBL Chemical Hygiene Plan). Each transfer of a Select Agent must be accompanied by a specific CDC/APHIS form (EA-101) that requires the signature of the MBL Responsible Official (IBC Chair) and serves to document the chain of custody. Several written safety- and security-related documents are required and must be developed and maintained by affected laboratories. Background checks are required for persons seeking approval for access to select agents. See Section 5 of this manual, "CDC/USDA Select Agents," for additional information.

## 4.0 BIOSAFETY PRINCIPLES

### 4.1 Containment

Laboratory biosafety practices are based on the principle of containment of biological agents to prevent exposure to laboratory workers and the outside environment. Primary containment protects the laboratory workers and the immediate laboratory environment from exposure to biological agents. Primary containment is achieved through good microbiological technique and the use of safety equipment and personal protective equipment. Secondary containment protects the environment outside the laboratory, and is provided by facility design and operational procedures.

### 4.2 Laboratory Practice and Technique

The use of good microbiological technique is the most important element of containment. Personnel working with biological agents must be aware of hazards, and must be trained to safely handle and dispose of these materials. Although we are all responsible for our own safety, the Principal Investigator has ultimate responsibility for ensuring that persons working in their laboratory are adequately trained. The MBL Biosafety Manual has been developed to provide general policies and procedures when working with biological agents at MBL. Each individual laboratory must supplement this manual with laboratory specific policies, procedures and training that will minimize the specific risks present in the laboratory.

### 4.3 Safety Equipment

Safety equipment includes biological safety equipment, safety centrifuge cups, and other engineered controls designed to minimize exposure to biological agents. Biological safety cabinets (BSCs) are the most important safety equipment for protection of personnel and the laboratory environment, and most BSCs also provide product protection. Safety equipment is most effective at minimizing exposure when workers are trained on the proper use of such equipment, and the equipment is regularly inspected and maintained.

### 4.4 Personal Protective Equipment

Personal protective equipment includes safety eyewear, lab coats, and gloves, and is used to supplement the containment provided by laboratory practices and safety equipment. Personal protective equipment is considered the least desirable containment method since its failure results in direct exposure of personnel to the biological agent.

### 4.5 Facility Design

Facility design and security features include physical separation of laboratories from public access, specially designed ventilation systems (to prevent airborne biological agents from migrating outside the laboratory), and autoclaves. These design features protect personnel working outside the immediate laboratory, as well the outside environment.

### 4.6 Biosafety Levels

The CDC/NIH has developed four biosafety levels that describe laboratory practices and techniques, safety equipment, and facility design features recommended for work with specific infectious organisms. Descriptions of the biosafety levels, as well as assigned biosafety levels for specific organisms, are contained in the CDC/NIH document, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). The recommended biosafety level for an organism represents conditions under which the agent can normally be handled safely; however,

specific circumstances may dictate that the recommended conditions be raised or lowered. As outlined in the BMBL, the four biosafety levels are summarized below on the following page:

Biosafety Level	Agents	Practices	Safety Equip.	Facilities
1	Not known to cause disease in healthy adults.	Standard Microbiological Practices	None required	Open bench top, sink required
2	Associated with human disease, <i>hazard</i> : auto-inoculation, ingestion, mucous membrane exposure	BSL-1 practice plus: <ul style="list-style-type: none"> <li>_ Limited access</li> <li>_ Biohazard warning signs</li> <li>_ Sharps precautions</li> <li>_ Biosafety manual</li> </ul>	<i>Primary barriers</i> : Class I or II BSCs or other containment used for manipulations of agents that cause splashes or aerosols of infectious materials; <i>PPE</i> : lab coats; gloves; eye/face protection as needed	BSL-1 plus: Autoclave available BSL $\geq 2$ : Ventilation negative relative to hallway & uncontrolled areas
3 (Prohibited)	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practice plus: <ul style="list-style-type: none"> <li>_ Controlled access</li> <li>_ Decontamination of all waste</li> <li>_ Decontamination of lab clothing before laundering</li> <li>_ Baseline serum</li> </ul>	<i>Primary barriers</i> : Class I or II BSCs or other physical containment devices used for all manipulations of agents; <i>PPE</i> : protective lab clothing; gloves; respiratory protection as needed	BSL-2 plus: <ul style="list-style-type: none"> <li>_ Physical separation from access corridors</li> <li>_ Self-closing, double door access</li> <li>_ Exhausted air not recirculated</li> <li>_ Negative airflow into laboratory</li> </ul>
4 (Prohibited)	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agent with unknown risk of transmission	BSL-3 practices plus: <ul style="list-style-type: none"> <li>_ Clothing change before entering</li> <li>_ Shower on exit</li> <li>_ All material decontaminated on exit from facility</li> </ul>	<i>Primary barriers</i> : All procedures conducted in Class III BSCs or Class I or Class II BSCs in <u>combination with</u> full-body, air-supplied, positive pressure personnel suit	BSL-3 plus: <ul style="list-style-type: none"> <li>_ Separate building or isolated zone</li> <li>_ Dedicated supply/exhaust, vacuum, and decon systems</li> <li>_ Other requirements outlined in BMBL</li> </ul>

## 5.0 CDC/USDA SELECT AGENTS

### 5.1 Introduction

The Centers for Disease Control and Prevention (CDC) and the United States Department of Agriculture (USDA) have identified specific biological agents and toxins that are considered to be a severe threat to public health and safety as bioterrorism agents. These materials are referred to as select agents by the CDC; and high consequence livestock pathogens and toxins, and listed plant pathogens by the USDA; and their transfer, possession, use, and disposal are strictly regulated. This Section will refer to all these agents simply as “select agents.” The current list of select agents is provided on the EH&S web site. Since the list of select agents may be revised, it is recommended that the CDC Select Agent Program web site and the USDA Agriculture Bioterrorism Protection Act web site be checked before acquiring pathogenic agents and biological toxins.

The regulations associated with select agents are very complex and strict, and there are significant monetary fines and criminal penalties associated with non-compliance. The information in this Section is a summary of the select agent regulations; it is not a complete description of the regulatory requirements associated with select agents. Investigators must review and understand the select agent regulations and their responsibilities prior to acquiring or working with, any select agent (see above links to regulatory information).

### 5.2 Responsible Official

Select agent regulations require that a Responsible Official (RO) be designated for each institution that possesses and uses select agents. Currently, MBL is **not** registered to possess select agents. The Environmental, Health, and Safety Manager is the RO for the MBL. The RO has institutional responsibility for the biosafety, security, and regulatory compliance of select agents, and as such, must be contacted prior to obtaining any select agents.

### 5.3 Authorization to Possess and Use Select Agents

Prior to obtaining any select agent, a Research Registration Form (see Section 2) covering the proposed work must be submitted to, and approved by, the MBL Institutional Biosafety Committee. In addition, PIs who want to acquire, possess, or use any biological agent or toxin listed as a select agent must be registered and approved with the appropriate agency (CDC or USDA) prior to obtaining the agent(s) or toxins(s). Both the institution (MBLI) and the individual laboratory must be approved by the appropriate agency. Investigators who want to possess and use select agents must contact the RO or the EH&S Office for assistance with the registration application process. Approval by the CDC or USDA can take several weeks to a several months (plan a minimum of three to six months), and PIs should plan research projects accordingly.

The select agent regulations contain very strict requirements regarding biosafety, training, emergency response, security and accountability, as well as other requirements. Investigators wanting to acquire select agents should review the CDC or USDA select agent regulations (whichever is appropriate) thoroughly before initiating the registration application process.

#### **5.4 Exemptions and Exclusions**

Diagnostic labs that do not maintain select agents are largely excluded from the CDC and USDA select agent regulations; however, there are notification and possession time limits and other requirements that do apply. Additionally, the CDC and USDA can grant exclusions for temporary public health emergency situations, and other special circumstances. Consequently, any laboratory that conducts diagnostic or verification testing for any select agent must identify themselves by contacting the MBL RO as soon as possible. Identification of any select agent in a specimen or isolate must be reported to the RO as soon as possible.

Several specific select agent microbial strains and toxin forms have been determined to not present a severe threat to public health and safety, and are therefore excluded from the CDC/USDA select agent regulations. The list of excluded biological agents and toxins is dynamic and the most current list is available on the CDC and USDA select agent web sites. Toxins are excluded based on threshold quantities. Laboratories maintaining exempt quantities of select agent toxins must keep an accurate inventory of toxin amounts to verify that total quantities are below the threshold.

#### **5.5 Safety Plan (see step 5.6)**

Each select agent laboratory must develop and implement a written safety plan that addresses the biological and chemical safety issues associated with the specific select agents maintained by the laboratory, before the select agents arrive. In particular, the plan must address the hazards associated with the select agents, methods to be used to prevent exposures, including use of laboratory ventilation (biological safety cabinets and lab hoods) and personal protective equipment, disinfection and decontamination methods, waste handling and disposal procedures, and the proper response to spills, personal contamination, and other incident response.

#### **5.6 Security Requirements**

Should the MBL register with the CDC to possess limits above what is considered exempt, all persons who will have access to any select agent must be approved by the Department of Justice. Approval requires that each individual successfully pass a background security check (conducted by the FBI in accordance with the USA PATRIOT Act) and submit fingerprints to the FBI. Anyone who has not been approved for access to select agents must be denied access unless they are escorted by an approved person.

Each select agent laboratory must have a written security plan that addresses the following topics:

- Physical security
- Cyber security
- Inventory of select agents
- Select agent transfers
- Training
- Reporting of unauthorized persons and missing materials
- Provisions for cleaning, maintenance, and repairs

Any theft or loss of select agents must be immediately reported to MBL EH&S (x7424), who will in turn notify the CDC or USDA as appropriate.

### **5.7 Emergency Response (if Step 5.6 applies)**

Before the select agent arrives, each laboratory that possesses or uses select agents must develop a written emergency plan that is laboratory specific, but which is coordinated with the department, building, and MBL emergency plans. The plan must address the hazards of the select agents, planning and coordination with emergency responders, building evacuation, site security and control, decontamination and emergency medical treatment, and other emergency response issues.

### **5.8 Training (if Step 5.6 applies)**

All persons approved for access to select agents must receive documented training covering biosafety of select agents and their safe handling, use, and disposal; security requirements and procedures; inventory and accounting procedures; and emergency response procedures. Training is required before beginning work with select agents and annually thereafter.

### **5.9 Transfers (if step 5.6 applies)**

Select agents can only be transferred between entities that are currently approved by the CDC or USDA to possess and use select agents. All transfers of select agents (including intrafacility transfers) require prior approval of the CDC or USDA. Both the sender and recipient must complete a common transfer form (EA-101), and the recipient submits the completed form to the CDC or USDA. The EA-101 requires the signature of the RO from both the sender and recipient facilities. When the select agent is consumed or destroyed, the recipient must submit the EA-101 to the CDC or USDA notifying them of this fact. The form is only available hard-copy through the RO.

### **5.10 Inventory and Disposal of Select Agents (if step 5.6 applies)**

An accurate record of all select agents, from receipt to destruction or disposal, must be maintained by the RO. The inventory must include specific information on individual containers and vials, as well as a record of each use, and ultimate disposal. The select agent inventory must be verified at least monthly to account for all quantities and containers of select agents. Any discrepancies between the inventory record and the actual inventory must be reported as soon as possible to the MBL RO.

### **5.11 Records (if step 5.6 applies)**

The select agent regulations require that several records be maintained, including the following: detailed inventory of each select agent and associated containers; access to select agents; access to the area where select agents are used or stored; safety, security, and emergency response plans; training records; transfer documents (EA-101 forms); and safety and security incident reports. Each individual laboratory is responsible for maintaining these records. EH&S will keep records of any training that it conducts. Laboratories must maintain records of training conducted by laboratory personnel or any other applicable training. EH&S will maintain EA-101 forms and any other CDC or USDA select agent forms; however, laboratories must also maintain copies of these forms. The recordkeeping requirements are complex, and therefore the CDC or USDA regulations should be reviewed for a complete description of the recordkeeping requirements.