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EHS-401, BIOSAFETY LEVEL 3 MANUAL

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1.0 Introduction

1.1 Purpose

The purpose of this program is to provide a set of minimum requirements for individuals working in biosafety level 3 labs (includes animal facilities and laboratories). This manual is written as a supplement to the Emory University Biosafety Manual and builds upon the concepts and requirements set forth in that manual.

1.2 Scope

The requirements of the Biosafety Level 3 (BSL-3) Manual are applicable to all Emory University personnel and graduate students working in Emory BSL-3 or animal BSL-3 (ABSL-3) facilities (henceforth referred to as facilities) on the Emory University Campus. All others must make special arrangements with the facility manager for entry.

All of the forms referenced in this manual are meant to serve as examples. Personnel are not required to use them but they include the minimum requirements in terms of documentation. Facilities may develop their own form equivalents, but documentation must be properly maintained, these documents will be referred to as facility-specific documents.

1.3 Responsibilities

Biosafety Officer (BSO)/Environmental Health and Safety Office (EHSO)

- Reviews any deviations from the recommendations in this manual.
- Conducts weekly monitoring (if designated as responsible person in facility). This function can also be performed by the Facility Manager.
- Works with facility manager, principal investigators (PIs), the Division of Animal Resources (DAR), and facilities (as applicable) to coordinate facility preventative maintenance.
- Works with the facility manager to conduct annual facility validation.
- Oversees large space decontamination procedures when needed.
- Maintains training records, annual inspections, access logs and equipment maintenance for all facilities at Emory University.

Facility Manager

- Oversees day-to-day operations of facility which include: monitors laboratory practices, identifies problems and reports adverse events and deviations from policies.
- Manages access to the facility (training, visitors, mentoring, etc.).
- Conducts weekly monitoring (if designated as responsible person in facility).
- Conducts annual self-inspection.
- Works with EHSO, PIs, DAR and Facilities (as applicable) to coordinate facility preventative maintenance.
- Works with EHSO to conduct annual facility validation.
- Maintains training records, annual inspections, access logs and equipment maintenance for the facility.
- Immediately responds to emergency facility issues.

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EHS-401, BIOSAFETY LEVEL 3 MANUAL***Principal Investigators (PI)***

- Ensures that they and their lab personnel working in facilities meet occupational health and training requirements.
- Ensures that they and their lab personnel adhere to all work practices, emergency procedures, and administrative procedures listed in this manual and facility specific standard operating procedures (SOPs).
- Ensures that all biological agents and procedures have been reviewed and approved by the Biosafety Officer prior to initiating work in the facility.

Facility Lab and Animal Care Personnel

- Successfully completes occupational health and training requirements.
- Adheres to all work practices, emergency procedures and administrative procedures listed in this manual and facility specific SOPs.

1.4 Training Requirements

Training is reviewed/conducted annually.

EHSO General Training:

- University PIs and lab personnel working in an Emory laboratory are required to complete the applicable EHSO training as described in the Emory University Biosafety Manual.

Facility Specific Training:

- In order to gain full, un-escorted access to a facility, lab personnel complete training as described below:
- PI ensures lab personnel demonstrate proficiency at biosafety level 2 (BSL-2) and verbal competence to communicate during an emergency.
- Facility Manager ensures that ancillary personnel such as Facilities, animal care, veterinary medicine, BMU, and others, have completed the BSL-3 / ABSL-3 Facility Visitor Checklist
- Facility Manager ensures that all personnel accessing the facility has completed the appropriate training and has shown proficiency in the procedures to be conducted before granting access.
- The training documentation is filed and maintained by the Facility Manager.

1.5 Recordkeeping Requirements

Training records are retained by the Facility Manager and EHSO.

1.6 Program Evaluation

The written Biosafety Level 3 Manual is reviewed annually and revised as necessary.

2.0 Facility Access Requirements

In order to conduct laboratory work in facilities, the following requirements should be in place. These requirements may be subject to periodic review. Access to facilities is a privilege and may be revoked if University and facility policies and procedures are not upheld. Individuals under the age of 18 are prohibited from entering facilities.

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2.1 Biosafety Protocol Approval

Applicable approvals are obtained before work is conducted in facilities. Applicable Emory committees may include Institutional Biosafety Committee (IBC), Research Health and Safety Committee (RHSC), Institutional Animal Care and Use Committee (IACUC), and Institutional Review Board (IRB). Protocol approvals will include confirmation of EHSO training, facility training and occupational health requirements.

2.2 Facility Manager Approval

PIs work with the facility manager to complete the facility-specific training and finalize the BSL-3 / ABSL-3 Facility Initial Training Checklist. Approval may be based on space availability and protocol requirements. Current approved biosafety protocols are necessary before access is granted.

2.3 Occupational Health Requirements

Facility access may be conditional on occupational health requirements such as respiratory clearance and vaccinations. Annual occupational health evaluations may be required. Additional evaluations and vaccinations may be required in the event that hazards change in the facility. Occupational Health requirements are outlined in the biosafety approval.

3.0 Entry/Exit Procedures

All personnel entering the facility is recorded either by electronic key card systems.

3.1 General Entry Procedures

Prior to entry to the laboratory, observe posted laboratory signage for entry requirements and laboratory hazards. Check the airflow monitors at the entry door to ensure that air moves from the corridor into the laboratory. If the flow is incorrect, contact the facility manager or other responsible person immediately and do not enter. Enter the laboratory by adhering to facility specific SOPs.

3.2 General Exit Procedures

Adhere to facility specific SOPs to remove personal protective equipment (PPE) appropriately and wash hands after exiting the facility. Observe facility specific SOPs when removing items from the facility.

3.3 Access to Facilities

Refer to the following table for access restrictions to facility:

Individual	Access Level	Documentation Required
Approved Level 3 User or Other site specific personnel who have completed required documentation	Full unescorted access	All sections of: <ul style="list-style-type: none"> BSL-3/ABSL-3 Facility Annual Renewal Training Checklist; or BSL-3/ABSL-3 Facility Initial Training Checklist
Provisional Level 3 Candidate	No access unless with designated mentor	Section I of BSL-3/ABSL-3 Facility Initial Training Checklist

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Individual	Access Level	Documentation Required
EHSO	No access unless with designated escort	BSL-3/ABSL-3 Facility Visitor Checklist
Maintenance Staff	No access unless with designated escort	BSL-3/ABSL-3 Facility Visitor Checklist
Approved Scientific Visitors	No access unless with designated escort	BSL-3/ABSL-3 Facility Visitor Checklist
Contractors/Vendors	No access unless with designated escort	BSL-3/ABSL-3 Facility Visitor Checklist

4.0 Work Practices

In addition to the work practices listed in the Emory University Biosafety Manual, adhere to the following procedures when working in facilities.

4.1 Two-Person Rule

Facilities strongly encourage that no one person works in the facility alone. This is to ensure that at least two people are present in case of emergency. Exceptions may occur in limited circumstances. In those instances warranting an exception, each facility must have developed a site specific plan that has been reviewed and approved in advance by the facility and EHSO.

4.2 Autoclave Use

Autoclaves are validated, using a biological indicator per site specific SOP. In many cases, it may be necessary to validate each load. Autoclave validation is documented.

4.3 Personal Electronic Devices

Personnel are prohibited from bringing personal electronic devices, such as cell phones, iPods, and MP3 players, into the facility.

4.4 Safe Sharps

The use of sharps in facilities is strongly discouraged. When a sharp is absolutely necessary personnel are encouraged to use sharp-safe systems. Whenever possible, sharp objects should be replaced with blunt objects or other available technology. All disposable sharps are one time use only. Refer to the Sharps Guidelines for more information on safe sharp work practices. Any changes to this practice are reviewed by the IBC or the Biosafety Officer.

4.5 Glassware

The use of glassware in facilities is minimized. Whenever possible, glassware is avoided and substituted with plastic ware in facilities. Broken glassware should be picked up with a mechanical device (ex: tongs or a dustpan and brush). Never handle broken glass directly with hands.

4.6 Minimization of Aerosol Production and Release

- Manipulate biohazardous material inside a biosafety cabinet (BSC) to reduce the risk of aerosol release. The following guidelines minimize the production of aerosols:

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- Pipetting: Do not force liquid out of the pipette tip. Allow liquid from the pipette to flow slowly down the side of tubes or flasks. Use cotton-plugged pipettes.
- Mixing: Operate mixing equipment inside a BSC. Do not mix by sucking and blowing with a pipette.
- Transfer Loops: Use an enclosed micro-incinerator for sterilization inside a BSC. Use disposable loops when possible.
- Syringes: Fill syringes carefully so that bubbles are not produced. Use luer lock syringes.
- Vacuum Equipment: Protect vacuum equipment with a high efficiency particulate air (HEPA) filter and place disinfectant in the overflow flask.
- Tube Selection: It is strongly encouraged, when working with liquids, to use screw-cap tubes rather than flip-cap tubes.

4.7 Procedures for Centrifugation

- Centrifugation is performed using lidded centrifuge safety buckets or in sealed ultracentrifuge rotors. As micro centrifuges do not have removable safety buckets, it is recommended these are operated inside a BSC. When centrifuging in facilities:
- Load samples into the safety bucket or rotor inside the BSC.
- Seal the safety bucket or rotor and wipe down with disinfectant.
- Change outer gloves.
- Transport the sealed safety bucket or rotor from the BSC to the centrifuge.
- After the run is complete allow 2-5 minutes for aerosols to settle in case of a spill inside.
- Transport the sealed safety bucket or rotor to the BSC before opening.
- Decontaminate the rotor or safety bucket inside the BSC before returning it to the centrifuge.

4.8 Housekeeping

- Decontamination of Work Surfaces/Equipment
- Decontaminate work surfaces and equipment when procedures are complete, after a spill and after a potential contamination. Work surfaces and equipment are decontaminated at minimum at the end of each work day. Use a chemical disinfectant appropriate for the agent used and allow an appropriate contact time.
- Decontamination of Large Spaces
- Large space decontamination (i.e., room or facility decontamination) is performed by a specialist with appropriate training and PPE and in conjunction with EHSO. If large space decontamination is needed in a facility, contact the EHSO.
- Floor Cleaning
- With the exception of animal facilities, the facility manager coordinates floor cleaning.

5.0 Personal Protective Equipment

- Adhere to facility specific SOPs.

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- Reusable laboratory protective clothing is autoclaved out of the facility prior to laundering. Laboratory clothing is laundered by an Emory approved vendor. Washing laboratory protective clothing at home is strictly prohibited. Non-reusable PPE is disposed of as biohazardous waste.

6.0 Removal of Items from the Facility

6.1 Waste

Waste Type	Disposal Method
Biological	<p>Biohazard containers, lined with biological waste trash bags, are present throughout the facility for the disposal of biological waste (other than sharps). Sharps containers are available at the point of generation. Collection containers remain closed when not in use and are disposed of when 3/4 full.</p> <ul style="list-style-type: none"> • <u>Solid Waste Treatment / Removal</u>: Autoclave the bag of waste and remove it from the facility. Place the autoclaved waste in the site specific container for vendor pickup. • <u>Liquid Waste Treatment / Removal</u>: Liquid waste may be decontaminated two different ways. It may be autoclaved following site specific validated procedures or treated with an approved disinfectant for the appropriate contact time. After decontamination, liquid waste may be discarded by pouring it down the sink.
Chemical	<p>The outside of chemical waste containers are sprayed with a disinfectant appropriate to the agents used in the lab and allowed appropriate contact time before being wiped down and removed from the lab. Chemical wastes are disposed of through EHSO. Refer to the Waste Management page on the EHSO website for more information.</p>
Radioactive	<p>Contact EHSO for specific disposal procedures.</p>
Mixed	<p>Mixed waste contains at least two of the following components: biohazardous waste, chemical waste, radioactive waste. Consult with EHSO for specific disposal instructions for mixed waste accumulated in facilities.</p>

6.2 Equipment and Other Non-Biological Material

- Decontaminate all equipment and non-biological material before removing it from the facility. In most cases, equipment and non-biological material are autoclaved out of the facility. Whenever possible, researchers should select equipment and material that can withstand being autoclaved out of the facility. In the event that the equipment or material cannot be autoclaved, follow decontamination procedures that are appropriate for the facility, agent, and equipment.
- Personnel are advised to electronically scan or fax documents/notes inside the facility as lab notebooks/paper may be damaged when autoclaved. Laboratory documents are not removed from the laboratory unless they have been autoclaved.

6.3 Research Biological Material

- Research biological material needing to be removed from the facility should be explained in the Biosafety Protocol and approved by the IBC or RHSC. Research biological material may be removed from the facility after adhering to the following procedure inside the BSC:
- If transporting lidded containers, ensure that they are tightly sealed. If

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- transporting plates, seal the edges (ex: parafilm).
- Wipe the outside of each tube or plate with an appropriate disinfectant.
- Place the tubes or plates in a leak-proof secondary container.
- Close the secondary container.
- Wipe the outside of the secondary container with an appropriate disinfectant and remove from the BSC.
- Prior to exiting the facility, spray the outside of the secondary container with an appropriate disinfectant.
- In the exit area (i.e. anti-room, pass through area) place the secondary container into a tertiary container bearing the biohazard symbol and close it. A sealed biohazard bag is an example of an appropriate tertiary container.
- Exit the facility following facility specific SOPs.

7.0 Emergency Response Procedures

- Reporting Adverse Events and/or Injuries/Exposures
- Adverse events and/or injuries/exposures are reported immediately per facility specific procedures.
- “Just in Time” Guide to Campus Emergencies
- “Just in Time: A Guide to Campus Emergencies” is posted near laboratory exits in facilities. It provides general guidance for a variety of campus emergencies. An electronic version is available on the Critical Event Preparedness and Response website.
- Facility Specific Emergency Plans
- In addition to the instructions provided in the “Just in Time” guide, each facility develops and maintains facility specific emergency plans. At a minimum, these plans include the following:
 - Emergency contact and phone numbers.
 - A communication system.
 - Plans for the following emergencies.
 - Medical emergencies.
 - Fire emergencies.
 - Natural disasters.
 - Utility failures.
 - Human generated disasters (e.g., explosions, threats).
 - Emergency plan drills.

8.0 Administrative Procedures

8.1 Facility Specific SOPs

- Facilities develop their own SOPs for processes specific to their facility design, agents used, and programs. These include but are not limited to: facility emergency plans, entry, exit, and designating who is responsible for allocating space inside the facility.
- Facility specific SOPs are reviewed and revised as needed by the facility, and are made available to all facility personnel.

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- The facility specific SOPs are also made available for EHSO to review.

8.2 Facility Maintenance Program

- In order to maintain a safe and functional facility, each facility undergoes various types of inspection/maintenance procedures throughout the year. The table below lists and describes each procedure in the order that they occur.

Type	Occurrence	Description
Monitoring	Weekly	A designated, trained and responsible person (e.g., facility manager or EHSO personnel) conducts and documents site specific weekly monitoring inspections. See BSL-3/ABSL-3 Weekly Monitoring Form for minimum items that are included in the weekly inspection.
Self-Inspection	Annually	Each year, the facility manager conducts a self-inspection of the facility using the BSL-3 Facility Self-Inspection Form or the ABSL-3 Facility Self-Inspection Form. After completion of self-inspection, the facility manager submits a Corrective Action Plan Form (CAP) to EHSO (following instructions on the form).
EHSO Inspection	Annually	After submission of CAP by facility manager to EHSO, EHSO conducts an inspection of the facility using the BSL-3 Facility Self-Inspection Form or the ABSL-3 Facility Self-Inspection Form.
Facility Preventative Maintenance	Recommended as needed	The Self-Inspection and EHSO Inspection are designed to highlight any issues (work practices, facility maintenance, engineering controls, etc.) that need to be resolved. Ideally, resolution of these issues along with preventative maintenance is conducted during the scheduled facility shutdown. See Facility Maintenance Items section below for specific details. The facility preventative maintenance is coordinated with the facility manager, EHSO, PIs, facilities personnel, and DAR (if applicable). Animal facilities offer more challenges than non-animal facilities. When possible, laboratory work is suspended for a period of time and the facility is decontaminated (using an appropriate method) in order for preventative maintenance to occur.
Facility Validation	Recommended after Facility Preventative Maintenance	After the Facility Preventative Maintenance is completed, a facility validation is performed by EHSO and the facility manager to ensure that the lab is ready to be re-commissioned.
Facility Verification	Annual or after major HVAC work	Testing of HVAC system to verify directional airflow, failures in the system to test for reversal of airflow and HVAC alarms.

8.3 Facility Maintenance Items

- The following items are essential for preventative facility maintenance and are coordinated by the facility manager, PI, EHSO and facilities personnel.
- Prior to purchasing and installing equipment inside level three facilities, ensure that the equipment specific maintenance or certification vendor will agree to enter the facility to provide service.
- Equipment Validation/Testing/Certification:
- Biological Safety Cabinets (BSC): BSCs are certified annually. Facility managers are responsible for coordinating BSC certification with approved a vendor approved by Emory University.

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- Chemical Fume Hoods (CFH): CFHs are certified annually. Facility managers are responsible for coordinating CFH certification with EHSO.
- Autoclaves: Facility managers are responsible for coordinating autoclave inspection and maintenance per manufacturer's recommendations.
- Other Equipment: Other equipment (such as centrifuges, freezers, etc) may require maintenance or certification and should be coordinated by the facility manager.
- Facility HEPA Filter Changes (if applicable).
- Air Pressure Differential Validation.
- Electronic Control Calibrating.

9.0 References

- Emory University Environmental Health and Safety Office Website
- Biosafety in Microbiological and Biomedical Laboratories, 5th Edition
- Emory University Biosafety Manual
- Guidelines for the Safe Use of Sharps
- BSL-3 / ABSL-3 Facility Initial Training Checklist
- BSL-3 / ABSL-3 Facility Annual Renewal Training Checklist
- BSL-3 / ABSL-3 Facility Entry / Exit Log
- BSL-3 / ABSL-3 Facility Visitor Checklist
- BSL-3 / ABSL-3 Weekly Monitoring Form
- BSL-3 Facility Self-Inspection Form
- ABSL-3 Facility Self-Inspection Form
- Corrective Action Plan Form
- Critical Event Preparedness and Response website

10.0 List of Associated Documents

- ABSL-3 Facility Self-Inspection Form
- BSL-3 Facility Self-Inspection Form
- BSL-3 / ABSL-3 Facility Initial Training Checklist
- BSL-3 / ABSL-3 Facility Annual Renewal Training Checklist
- BSL-3 / ABSL-3 Facility Entry / Exit Log
- BSL-3 / ABSL-3 Facility Visitor Checklist
- BSL-3 / ABSL-3 Weekly Monitoring Form