INSTITUTIONAL BIOSAFETY MANUAL

Revised: October 2016
Updated: January 2017
Updated: April 2020

Biosafety
Office of Research
UNIVERSITY OF GEORGIA

Biosafety | 706-542-5300 | http://research.uga.edu/biosafety/

INSTITUTIONAL BIOSAFETY MANUAL
TABLE OF CONTENTS

I. OFFICE OF BIOSAFETY PHONE TREE AND E-MAIL CONTACT INFORMATION

A. Phone Tree

Campus Emergencies (call Campus Police)	**(706) 542-2200**
Office of Biosafety – General	(706) 542-2697
Office of Biosafety – Select Agent and Toxin Program	(706) 542-7265
Office of Biosafety – Institutional Biosafety Committee (IBC)	(706) 542-9347
Office of Biosafety bio-alert (BAT) emergency phone	(706) 542-5300
Office of Animal Care and Use (OACU)	(706) 542-4426
UGA Occupational Health and Safety Program	(706) 542-5933
Office of Research Safety	(706) 542-9373
Human Subjects Office (HSO)	(706) 542-3199
Technology Commercialization Office (TCO) – for MTA needs	(706) 542-5929
Environmental Safety Division (ESD)	(706) 542-5801
University Health Center (UHC)	(706) 542-1162
Piedmont Athens Regional FirstCare Occupational Health Services	(706) 353-6000
Export Control – Compliance Office	(706) 542-4188

B. E-mail Contact Information

Office of Biosafety Website	http://research.uga.edu/biosafety/
General Contact and/or Questions	biosfty@uga.edu
IBC	ibc@uga.edu

Back to table of contents

II. PURPOSE

This manual outlines appropriate practices, University policies and regulatory requirements for working safely in the research laboratory with biohazardous materials at University of Georgia facilities. This manual is to be used in conjunction with a laboratory-specific biosafety manual.

It is the mission of the Office of Biosafety to provide guidance and assistance to faculty, staff and students in order to protect them from exposure to biohazardous materials in the research setting and to guard against the accidental release of such materials that may be harmful to humans, animals, plants or the environment. In doing so, the Office of Biosafety provides guidance and assistance to the University's research community on regulatory needs associated with the receipt and shipment of infectious agents, administrative support to the Institutional Biosafety Committee (IBC), managing the UGA Laboratory Blood-borne Pathogens Exposure Control Plan, advising staff who work with biohazardous materials on safe use, movement and disposal of biohazardous waste, providing assistance with obtaining regulatory permits, and the administration of the Federal Select Agent and Toxin Program (FSAP) for facilities on the University's main campus as well as the Tifton and Griffin campuses.

The purpose of this Institutional Biosafety Manual is to provide institutional policies and procedures that support this mission. Information provided in this manual is supported by a number of federal regulations and guidelines including:

- 5th Edition of Biosafety in the Microbiological and Biomedical Laboratory (BMBL; CDC/NIH, 2007)
- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines; NIH OBA, April2019)
- USDA/CDC Select Agent and Toxin Rules (42 CFR Part 73, 7 CFR Part 331 and 9 CFR Part 121)
- Arthropod Containment Guidelines (Version 3.2)
- OSHA Blood-borne Pathogens Standard (29 CFR Part 1910)
- DOT Hazardous Materials Regulations (49 CFR Part 171-180)
- USPS regulations on transporting infectious substances through the US Postal Services (39 CFR Part 20 section 135 of the International Mail Manual and Part 111 section 601.10.17 of the Domestic Mail Manual)
- ICAO Technical Instructions for the Safe Transportation of Dangerous Goods by Air
- IATA Dangerous Goods Regulations
- Importation of Etiologic Agents of Human Disease (42 CFR Part 71)
- USDA APHIS VS Importation of Etiologic Agents of Livestock, Poultry and Other Animal Diseases and Other Materials Derived from Livestock, Poultry or Other Animal (9 CFR Part 122)
- USDA APHIS PPQ Importation of Plant Pests (7 CFR 330)
- DoC Export of Etiologic Agents of Humans, Animals, Plants and Related Materials (15 CFR Parts 730–799).
- State of Georgia Biomedical Waste Regulations (OCGA 391-3-4-.15)

Back to table of contents

III. PRINCIPLES OF BIOSAFETY

The BMBL has become the code of practice for biosafety and, therefore, the primary basis and supporting document for this manual and establishes the principles of biosafety, containment and risk assessment, for the research and lab setting. For containment, the fundamental supporting elements are sound microbiological practices with safety equipment and facility safeguards incorporated. Combining these elements of containment provides for protection of lab workers, the public and the environment from potential exposures to biohazardous materials. Performing risk assessments for all work involving biohazardous materials allows the researchers, the biosafety committee and the biosafety staff to determine containment requirements appropriate for their work (i.e. appropriate microbiological practices, safety equipment and facilities) that will reduce the potential for laboratory acquired infections (LAIs).

Back to table of contents

Risk Assessment

Performance of a risk assessment is the primary responsibility of the principal investigator (PI) but is shared with the Institutional Biosafety Committee (IBC), biosafety professionals, laboratory staff and other stakeholders which may include lab animal veterinarians and caretakers, farm staff, operations staff, occupational health practitioners, etc. Three broad categories to consider in a risk assessment are agent hazards, lab procedure hazards and the capabilities of staff to control hazards. Biosafety in the laboratory, therefore, strongly depends on training, technical proficiencies, and good work habits of the laboratory staff, along with operational integrity of equipment and laboratory facilities.

Risk assessments should identify:

1. the hazardous characteristics of an agent
    - ☣ ability to infect and cause disease, infective dose, host range
    - ☣ virulence (as measured by severity of disease)
    - ☣ availability of preventative measures and effective treatments for disease
    - ☣ probable routes of transmission
    - ☣ stability in the environment
    - ☣ endemic nature of the organism
2. lab procedure hazards
    - ☣ use of needles or other sharps
    - ☣ spills or splashes
    - ☣ pipetting
    - ☣ aerosol generation - pipetting, blenders, centrifugation, sonicators, vortex mixers
3. likelihood that the agent can cause LAIs
4. consequences of an infection

Information identified in risk assessments should provide guidance for the selection of the biosafety level (BSL) for work and establish the four primary controls necessary for safe work:

- ☣ Work Place Practices
- ☣ Personal Protective Equipment (PPE)
- ☣ Administrative Controls
- ☣ Engineering Controls

PIs can utilize the IBC Protocol Review form to perform their program/project risk assessment. Pathogen safety data sheets are available in the BMBL and through Public Health Canada (see the Quick Reference Guide for link information).

Back to table of contents

IV. ROLES AND RESPONSIBILITIES

Note: In short, safety is the responsibility of everybody. Safe working practices/procedures must be adhered to at all times. Neither speed nor convenience is an excuse for deviating from safe working practices/procedures.

***Biosafety Office*.** The Office of Biosafety is responsible for the development and oversight of proper management practices for biohazardous materials in the research setting at the University of Georgia, including developing and implementing policies supporting their mission. Staff within the office provides support for health and safety, biosecurity and compliance involving biohazardous materials.

***Biosafety Officer (BSO)*.** The Biosafety Officer is appointed by the institution in compliance with the NIH Guidelines and ensures that periodic inspections are performed to ensure laboratory standards are rigorously followed. The BSO also reports to the IBC on any significant problems or violations with the NIH Guidelines or on any significant research-related accidents or illnesses, develops emergency plans for handling accidental spills and personnel contamination, and investigates laboratory accidents involving biohazardous materials. The BSO is a voting member of the IBC following the NIH Guidelines.

***Individual Lab Personnel*.** Individuals who work with biohazardous materials have a responsibility to follow the guidelines presented in this manual and to consult with their supervisors regarding the safe handling and proper disposal of specific biohazardous materials used in their work area.

***Institutional Biosafety Committee (IBC)*.** The IBC is appointed by the University president and serves as review board of all research activities involving recombinant DNA studies, as required by the NIH Guidelines. Additionally, the IBC reviews and approves research projects involving human, animal or plant pathogens, and select agents and toxins (as defined by CDC/USDA Select Agent Programs). The IBC establishes compliance policies for the NIH Guidelines (integrated within this manual). The IBC has the authority to require operational changes in the event of noncompliance with required conditions.

On behalf of the institution, the IBC notifies PIs of results of IBC protocol reviews and approvals, adopts emergency plans covering accidental spills and personnel contamination, and reports to the NIH OBA and UGA IO significant problems or violations of the NIH Guidelines or any significant-research related accidents and illnesses on projects involving rDNA research.

***Institutional Official (IO) and the University of Georgia*.** The President of the University of Georgia is ultimately responsible for health and safety issues for personnel and student. This responsibility is exercised through the normal chain of authority within the University by delegating the charge for ensuring safe work practices and adherence to established policies and guidelines to the provost, vice presidents, deans, directors, department chairs, principal investigators, supervisors and, ultimately, each employee. Regarding research activities, the IO is the Vice President for Research. Under the oversight of the IO, the institution is responsible for ensuring that research involving rDNA technologies is conducted in full conformity with provisions of the NIH Guidelines. It is also the responsibility of the institution to determine the necessity for health surveillance of personnel connected with individual rDNA projects or other research involving human

pathogens. The institution is responsible for maintaining a health surveillance programs as appropriate to the agents they work with.

***Responsible Official*.** The Responsible Official (RO) is established by senior administrators at the Athens, Griffin and Tifton campuses for registered research involving select agents or toxins, and is approved by the CDC as such. The RO has institutional authority and responsibility to act on behalf of the institution to ensure compliance with federal select agent requirements, to ensure annual inspections of each select agent lab, to report the identification and final disposition of any select agent or toxin identified during diagnostics, verification or proficiency testing, and to report the theft, loss or release of a select agent or toxin to the CDC.

***Supervisors*.** Principal Investigators (PIs), instructors and supervisors are primarily responsible for ensuring that the policies and guidelines established in this manual are strictly followed by all personnel under their jurisdiction, including collaborating researchers. To ensure biosafety, the PI, knowledgeable in appropriate laboratory techniques, safety procedures, and hazards associated with handling infectious agents is responsible for the conduct of work with any biohazardous materials used in their lab. Therefore, the lab supervisor or PI is responsible for enforcing institutional policies that restrict access to the lab and support safety for work in the lab.

Back to table of contents

V. INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

Prior to commencement of work, the UGA IBC must approve any teaching or research projects that involve the use of:

- Recombinant DNA, including transgenic animals or plants
- Risk Group 2 or higher human or zoonotic pathogens
- Animal pathogens that cause diseases reportable to the State Veterinarian
- Plant pathogens that have not been established in the State
- Any select agent or toxin
- Any diagnostic testing that involves the propagation of Risk Group 3 pathogens.

The IBC will provide full committee review (FCR) for all rDNA work that is not exempt from the NIH Guidelines, for any work involving the creation of transgenic animals or plants, for all Risk Group 3 or higher human or zoonotic pathogens, or for any select agent or toxin. The IBC will provide review of reportable animal pathogens, non-indigenous plant pathogens and Risk Group 2 human or zoonotic pathogens (that are not select agents) , that do not involve rDNA work, via designated member review (DMR). Designated member reviewers may request additional reviewers or oversight, which can include recommending a DMR protocol for full committee review.

Research projects falling under these guidelines will receive IBC review and approval prior to initiation of work.

Back to table of contents

A. Submitting an IBC Application

The PI must complete the IBC Protocol Review Form and submit it to the IBC Coordinator. Protocols can be submitted via email, fax or campus mail. The IBC Coordinator will provide an initial review to ensure all appropriate information is provided. Once the initial review is completed, if the protocol requires full committee review, the IBC Coordinator will submit the protocol to the entire IBC via email if the project requires full committee review. For protocols requiring designated member review, the IBC Coordinator will assign at least two IBC members to review the protocol. Protocol review forms can be found on the Biosafety webpage (https://research.uga.edu/biosafety/ibc/).

Back to table of contents

B. IBC Review Process

The IBC generally meets the fourth Thursday of each month to review applications for full committee review. A six-month schedule of meeting dates, times and location is available on the Biosafety webpage (https://research.uga.edu/biosafety/ibc/). A complete application must be submitted at least one month before the meeting date in order to be reviewed at the monthly meeting. If an application is returned to the PI because it is incomplete or the committee has questions, the PI has 45 days to respond. If the IBC does not receive a response within 45 days of the initial request, the application will be administratively closed and the PI must resubmit the application and signature page.

If the project requires designated member review (Risk Group 2 human or zoonotic pathogens, animal pathogens reportable to the State Veterinarian, or plant pathogens that have not been established in the State), the IBC Coordinator will create a subcommittee of no less than two IBC members and request approvals electronically. A minimum of two approvals must be met in order for a designated member review approval to be valid. If an approval is not met, the PI may resubmit additional information for a second vote or a full committee review may be required. The IBC Coordinator will coordinate this process and utilize the Chair or BSO for assistance.

Back to table of contents

C. IBC Authorization

When a project is approved by the IBC, the PI will be notified via e-mail. An authorization form, specifying any special conditions under which authorization is granted, will be forwarded to the PI by email. If approval is denied, a written notification will be sent to the PI. This notification will explain the decision and will identify possible modifications to the project that would allow approval.

Additional personnel that may receive a copy of a PI's IBC authorization include the Office of Animal Care and Use, Sponsored Projects Administration, Internal Grants, AHRC Facility Director/Manager, and co-PIs or others as designated by the PI.

In most cases, IBC authorizations are valid for five years with annual renewals and/or modifications required.
Back to table of contents

D. Annual IBC Renewal

IBC authorizations must be renewed annually. An Annual Renewal/Modification Form will be sent to the PI from the Office of Biosafety at least one month prior to the annual renewal date. The form can also be found on the Biosafety webpage (https://research.uga.edu/biosafety/ibc/).
Back to table of contents

E. Five Year IBC Renewal

Every five years a full application must be submitted to the IBC for any project (including exempt NIH protocols) in which work is ongoing. Unless the protocol has been resubmitted for approval or is currently in discussions with the IBC coordinator, all protocols reaching the expiration date will be considered terminated and will be administratively closed. If closed, according to federal regulations and University policy, all work on the project must stop. A new application must be completed and submitted to re-establish approval in this scenario. Protocol review forms can be found on the Biosafety webpage (www.research.uga.edu/biosafety/ibc/).
Back to table of contents

F. IBC Modification Procedure

If any changes are planned for an approved project before the authorization expiration date, such as changes in the research scope, personnel or facility location changes, the PI must notify the IBC utilizing the IBC Annual Renewal/Modification Form which can be found on the Biosafety webpage (www.research.uga.edu/biosafety/ibc/). IBC approval must be obtained prior to implementation of the modifications. Modification requests can be submitted by e-mail. The IBC will determine whether proposed changes are major and require a new protocol application. Approval of a modification does not alter the date by which continuing (annual) review must occur.
Back to table of contents

G. Evaluating Laboratory Safety through the IBC Protocol Submittal

The IBC Protocol Review Form includes all criteria necessary to perform a risk assessment for work with biohazardous materials and for work with rDNA. Completing the IBC Protocol Review form and performing annual reviews will help the PI, lab personnel and the IBC ensure that good laboratory safety practices are being used. More than one related research project or grant can be managed on a single IBC Protocol Form.

The IBC maintains the right to increase safety practices or containment requirements as charged by the NIH Guidelines.
Back to table of contents

VI. BIOSAFETY PRACTICES AND PROCEDURES

Safe behavior and sound work practices are the most critical parts of preventing exposure to biohazardous agents at work or their release. The best lab facility and safety equipment cannot provide protection unless personnel use good work practices and have adequate training. Biosafety levels (1-4) have been developed by the CDC and NIH to ensure that proper practices, procedures and facilities are employed for work with biohazardous materials. Containment levels for animal and plant pathogens are available and follow basic principles outlined within the BMBL. Arthropod containment levels are described in a separate manual but co-exist and compliment the standard biosafety levels outlined within the BMBL as well.

Back to table of contents

A. Laboratory Biosafety Level Criteria

The four biosafety levels protect lab users and the environment with an appropriate amount of protection based on biological risk. Biological risk is related to the infectious agent used, pathogenicity of the agent and the mode of transmission. A wide variety of requirements for both physical containment and procedural details come with increasing levels of protection.

☣ BSL-1 facilities and practices are required for work with "defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans."

☣ BSL-2 facilities and practices are required for work with "indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity."

☣ BSL-3 facilities and practices are required for work with "indigenous or exotic agents" with a potential for aerosol transmission, and which may cause serious and potentially lethal infection.

☣ BSL-4 facilities and practices are required for work with "dangerous and exotic agents that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy."

Back to table of contents

B. Basic Procedures and Practices for BSL-2 Containment

For all laboratories working with biohazardous materials, basic practices, procedures and facilities are described within this section. High containment or BSL-3 level practices, procedures, equipment and facilities are further described in addition to the fundamental principles written here. Select agent and toxin laboratories will require heightened security as defined by that program. Since there are no facilities available at the University to support BSL-4 research, no BSL-4 work is permitted on campus. BSL3-Ag facilities are available and will be described within the high containment section in this manual. Clinical

settings (veterinary or human) should follow an exposure control plan as describe by the OSHA Blood-borne Pathogens Standard and use universal precautions in all practices. For diagnostic samples from a known quarantine zone or that are considered to be suspect of containing a high consequence pathogen, BSL-3 containment will be required.
Back to table of contents

C. Laboratory Access, Signage and Labeling

Access to the lab is limited. Lab is restricted at the discretion of the lab supervisor or as defined by regulations, whichever is greater, when work with cultures or specimens are in progress. Doors are lockable, kept closed and locked when personnel are not present.

Anyone entering areas where biohazardous materials are used must be aware of the potential hazards. Therefore, a red or orange biohazard warning sign indicating presence of a human biohazard must be posted at the entrance of the lab. The lab door CAUTION sign should indicate the organisms and biosafety level, any special requirements for entry (vaccinations, PPE, etc.), and the PIs name and contact information. Utilization of the Office of Research Safety's laboratory door caution sign will suffice for use with these requirements. To obtain a lab door CAUTION sign, contact lab safety at (706) 542-5801. Appropriate signage, as designated by the Office of Biosafety, should be posted at entrances to each lab or room where biohazardous materials are used or stored and should only be placed by the Office of Biosafety.

Red or orange biohazard labels should be placed on containers and storage units used for microorganisms or biological toxins that can cause disease in humans or that hold human blood, cell lines or other potentially infectious materials as defined by the OSHA Blood-borne Pathogens (BBP) program. Contaminated equipment and biohazardous waste must be labeled in the same manner.

For appropriate biohazard stickers, contact the Office of Biosafety at (706) 542-2697 or biosfty@uga.edu.
Back to table of contents

D. Laboratory Training and Experience

Anyone planning to work with biohazardous materials must be adequately trained before beginning such work. The lab supervisor is directly responsible for providing or ensuring that personnel are appropriately trained. Lab personnel must demonstrate proficiency in standard and special microbiological practices before working with biohazardous agents. Documentation for this check off, Proficiency in Standard and Special Microbiological Practices form, is available in the Forms section of the UGA Biosafety website. Information communicated in the lab-specific training must include:

- Discussion and review of the Institutional Biosafety Manual and/or lab-specific manual as applicable and how it applies to activities conducted in specific work areas.
- An explanation of the health hazards, signs and symptoms of exposure to biohazardous materials used in specific work areas.

- A description of actions personnel can take to protect themselves from exposure, such as special work practices, use of safety equipment, vaccinations, emergency procedures, etc.
- Site specific training on analytical methods, SOPs and spill response and incident reporting should be included.
- Other applicable safety training should be incorporated such as the University's Right to Know and Blood-borne Pathogens training.

To remain compliant with the University System of Georgia records retention policy (#0472-13-027), training records must be maintained by the lab supervisor for a 30 years after separation of the employee.

Minors in BSL-1/BSL-2 Laboratories (Young Dawgs Program)

Under no circumstance should a minor be allowed in a BSL-3 or higher laboratory or any Select Agent laboratory regardless of biosafety level. The following must be strictly adhered to with regards to minors in the laboratory and the PI must have this agreement documented.

- No one under 15 years old will be permitted to work in a research laboratory.
- The PI must obtain authorization for the Minor to work in their lab from their Department Chair or a higher authority.
- The PI must obtain signed Parent/Guardian consent form, including Emergency Contact information.
- The PI's Department must submit a Volunteer form to HR which includes nature of volunteerism, expected duration, and campus contact person overseeing volunteer.
- Minors must receive a University Visitor/Volunteer ID Badge and are required to have the badge with them at all times.
- Minors must be enrolled in the University of Georgia Occupational Health Program
- A determination of the biological material that the Minor may come into contact with must be Minors will not be allowed to handle certain biohazardous materials, with exceptions. Contact the Office of Biosafety for information regarding the materials in question and any specific requirements.
- Ensure written Lab Safety Protocols for lab procedures are available, reviewed with the Minor AND sign off on by the Minor as understanding the training provided
- Provide the Minor and Supervisor with all necessary Personal Protective Equipment (PPE) and require that it be used.
- Ensure Minors are directly supervised **at all times** by a qualified supervisor. Minors must never be allowed in the lab without direct supervision.
- Hold the Supervisor and Minor accountable for all safety rules.
- Notify the Office of Biosafety of Faculty/PI, Supervisor and lab locations where Minors will be working.
- Ensure all accidents are reported.

Please contact the Office of Biosafety for other trainings available.
Back to table of contents

E. Laboratory Practices and Techniques

Laboratory acquired infections (LAI) may be infrequent or even rare, but risks are always there and they should be constantly considered to keep personnel in check. Single, known exposure incidents are not typically found in historically documented LAIs. Therefore, it is imperative that good microbiological practices and technique are used, not only for product protection but for personal protection as well.

In order for infection or disease to occur, there must be an adequate number of organisms to cause disease (known as the infectious dose) and an appropriate route of transmission to the body. Knowing how infectious organisms are transmitted and what their infectious dose is can help in evaluating risk and avoiding infection. Information like this must be gathered prior to commencement of work.

The UGA Agent-Specific Training Form can be used to provide and document training when the form is completed by the Principal Investigator. This form is available in the forms section of the UGA Biosafety website. Good starting points for safety information about human pathogens are pathogen safety data sheets provided by Public Health Canada and the agent information section of the 5th edition of the BMBL. Please contact the Office of Biosafety for UGA Agent-Specific Training Forms.

Infectious agents routinely worked with at BSL-2 are transmitted through one or more of these routes of exposure:

- Parenteral inoculation (sharps injuries and bites from animals or arthropod vectors)
- Inhalation of aerosols (microscopic particles dispersed or suspended in air; $\leq$5 μm in diameter)
- Ingestion (hand to mouth transfer or splash)
- Mucous membrane exposure (eyes, mouth, nose)

General work practices that eliminate these potential routes of exposure include the following:

- Practice good microbiological technique.
- Wear appropriate PPE – lab coats, gloves, safety glasses, etc.
- Eating, drinking, smoking, chewing tobacco and applying cosmetics or having open food or drink containers in the lab is prohibited. (Please check UGA's Chemical and RAD Safety Manuals for additional guidance on food in the laboratory as additional restrictions may apply.)

  Note: BSL-1 and some BSL-2 food storage areas may be approved on a case by case basis by Biosafety. This is very much lab dependent. General guidelines are the items will remain in storage form and the storage area must be away from any working areas of the lab and must have a physical barrier i.e. walls and door, separating it

from the lab. If such barrier is a refrigerator it must be labeled as "For Human Consumption ONLY" and must be dedicated as such.

BSL-1 labs may have a designated area for food prep and consumption but must be approved by Biosafety prior to use. General guidelines are it must have a physical barrier separating it from the lab space i.e. full walls, ceiling and door.

- Cell phones, iPods or other mobile devices must not be used while working at the bench, but can be kept and used within a designated clean space in the lab. The use of wireless headphone may be permitted on a case by case basis. Please contact the Office of Biosafety for guidance. These items will be prohibited for use in laboratory settings of BSL-2+ or higher.
- Keep potentially contaminated hands away from mouth, eyes, and non-intact skin.
- Practice good personal hygiene. Frequently wash hands - after removal of gloves and before exiting the lab. For hand washing, scrub vigorously with soap and water for 30 seconds. Physical removal of organisms from the skin is just as important as using a disinfectant.
- Disinfect work surfaces and equipment immediately after using biohazardous materials.
- Biohazardous materials must be placed in a durable, closeable leak proof container bearing the biohazard symbol and lined with double autoclaved bags during collection, handling, processing, storage or transport within a facility.

Back to table of contents

F. Personal Protective Equipment (PPE)

Basic lab-required attire as described by the Institutional Chemical and Laboratory Safety Manual must be worn in the lab (i.e. no open-toed shoes, no shorts or short skirts). PPE should be selected based on a risk assessment and chosen by considering the potential routes of exposure. Personnel must remove all PPE before leaving the room where they are handling and disposing of biohazardous materials. Never take PPE home or wear it out of the lab, this includes break rooms or to lunch rooms.

Lab Coats and Closed-Toed Shoes

At minimum, a long-sleeved lab coat worn over clothing and closed-toed shoes must be worn in any lab. The long sleeves minimize contamination of skin and street clothes and reduce shedding of microorganisms from the skin. Closed-toed shoes protect the feet from spills and injuries from dropped sharps. Appropriate disposable gloves should be worn when working with any biohazardous agent.

Lab coats must remain in the lab. This keeps any contamination in the laboratory instead of spreading it to other work areas or homes. If laundering outside of the lab facility, other than a professional laundering company, it is required that lab coats must be decontaminated prior to removal. This may be achieved by either spray disinfectant or autoclaving. Before being sent out for laundering, PPE such as lab coats must be properly containerized and labeled. Disposable lab coats are also an option.

Elastic-cuffed lab coats help prevent spills that can be caused by catching a loose cuff on lab equipment. When working with biohazardous materials inside a biosafety cabinet, elastic cuffs, double gloving, and disposable sleeves can prevent contaminated air from being blown up the lab coat sleeve onto clothing.

Gloves

Gloves prevent exposure of the skin, and any cuts or dermatitis, etc. that may be present. For the best protection, the cuffs of the gloves should overlap the lower sleeves of the lab coat.

Both latex and nitrile disposable gloves are generally recommended and will prevent exposure to microorganisms. With combined chemical use, nitrile gloves are recommended since latex provides little to no protection from chemical exposure. The Office of Biosafety can provide assistance with choosing appropriate gloves. Latex allergies should be considered when selecting gloves. Powdered gloves can create allergy issues as well and should be discussed with personnel.

Disposable gloves must not be reused. They are designed for disposal after one use or when contact with any chemical or biohazardous agent. Utility gloves, such as rubber dishwashing gloves, may be chemically disinfected for re-use if they do not show signs of wear or degradation. Gloves should be changed any time integrity has been compromised or when otherwise necessary.

Eye and Face Protection

Eye and face protection prevent splashes into the eyes, nose and mouth (mucous membrane exposure), and onto the skin.

Goggles or safety glasses must be worn to protect the eye in any lab where there is the potential to create splashes of microorganisms or other hazardous material. Face shields should be used for full face protection based on a risk assessment. Paper surgical masks provide some splash protection for the mouth and nose, but do not provide respiratory protection.

Surgical masks or dust masks may be used for splash protection as well. However, these masks are not considered to be particulate filtering respirators and will not provide respiratory protection against biohazardous material.

Respirators

Respirators in the microbiological or biomedical laboratory prevent the inhalation of aerosolized microorganisms when a risk assessment deems them necessary. The Office of Biosafety will assist in determining if a respirator is needed and which type is appropriate. HEPA filtered respirators are used for protection from particulates. Particulate filtering respirators, i.e. N95, and Powered Air Purifying Respirators (PAPRs) are typically used for

respiratory protection from biohazardous materials and are selected based on a thorough risk assessment.

Personnel who are required to use particulate respirators for personal protection must participate in annual medical monitoring (through the OHSP), fit-testing (for fitted respirators only) and respirator training. Piedmont Athens Regional FirstCare Occupational Health Services provides the medical monitoring. Through medical monitoring, pulmonary function tests (aka spirometry) will be required for personnel wearing fitted respirators. Pulmonary function is required every two years. Once an individual passes pulmonary function testing, they will be required to get fit-tested for their respirator and training on the use and maintenance of that respirator. Fit-testing must be performed annually. PAPR devices utilizing loose faced hoods are not considered "fitted" respirators, therefore, fit-testing is not required but annual training is still required. Please contact the UGA's OHSP for information regarding fit-testing and respiratory compliance at UGA.
Back to table of contents

G. Using Needles, Syringes, and Other Sharps

According to the State of Georgia Biomedical Waste regulations, sharps are any discarded article that can cause punctures or cuts. This includes, but is not limited to, needles, IV tubing and syringes with needles attached, Pasteur pipettes, and scalpel blades.

The greatest risk when using needles is accidental inoculation. Additionally, needles and syringes can create aerosols. Therefore, only use needles and syringes when no other reasonable alternative exists. Always consider the use of safety needles and syringes in these instances. The Office of Biosafety can assist in the selection of safety needles and syringes and has samples on hand for demonstration and/or testing.

Broken glass should not be handled directly. Use tools such as a brush and dustpan, tongs or forceps to collect. Plastic ware should be substituted for glassware when possible. Small amounts of contaminated broken glass can be disposed of in the sharps container. Large amounts of contaminated broken glass can be disposed of in a big sharps container, or decontaminated via appropriate liquid disinfection or through autoclaving. Non-contaminated glass (broken or intact) should be placed in a solid cardboard box, lined with a strong plastic bag (do not utilize biohazard bags since the glass should be decontaminated and free from any biological material). Once filled, seal up the cardboard box well to ensure it will not open in transport. Label all sides to indicate it CONTAINS GLASS or CONTAINS BROKEN GLASS. This box can then be placed into the regular solid waste stream and go out to the building's dumpster. It is the responsibility of individual laboratories to properly dispose of sharps generated in the lab.

For additional UGA policies on sharps please reference the Sharps, Glassware, and Pointed Plastic Waste Disposal policy.

Sharps Protocol:

- Eliminate the use of sharps whenever possible.
- Keep sharps away from fingers as much as possible.
- Do not bend, shear or recap sharps.
- Do not remove needles from syringes after use.
- If a contaminated needle must be recapped or removed from a syringe, a mechanical device, such as forceps, must be used or slide it in an appropriately sized tube.
- Use good technique to minimize the generation of air bubbles when filling a syringe.
- A pad moistened with disinfectant should be placed over the tip of the needle when expelling air.
- When using sharps and a biohazardous agent, work in a biosafety cabinet, if possible.

Sharps Disposal:

- All sharps must be collected in an appropriate puncture-proof sharps container for waste disposal.
- An appropriate sharps container must be kept close to the point of use to avoid walking around with contaminated sharps.
- Care must be taken not to overfill sharps containers. They are considered full when they are ¾ full. Never allow syringes, needles or other contents to stick out of the sharps container.

When biohazardous agents are utilized with sharps (plant, animal or human biohazards included), the sharps container must be sterilized prior to final disposition either by the end user or the contracting company used for disposal. For BSL-2 labs, PIs must ensure that sharps are decontaminated prior to final disposal. For BSL-3 labs, all sharps MUST be autoclaved prior to removal from the lab. If radioactive materials or chemical hazards are to be considered, consult with the Radiation Safety or Laboratory Safety on appropriate waste management practices. According to the State of Georgia Biomedical Waste regulations, needles or other sharps as defined are NOT permitted to go into the solid waste stream (i.e. the trash/dumpsters/landfills) under any circumstances. Sharps must be disposed of through an appropriate biomedical waste vendor. It is the PI or departmental responsibility to select and use a qualified biomedical waste vendor for sharps disposal. Check with your medical waste vendor. Further guidance can be found on our website (https://research.uga.edu/biosafety/procedures/safe-handling-of-sharps-in-the-biological-research-laboratory/).

Back to table of contents

H. Blending, Grinding, Sonicating, Lyophilizing, and Freezing

The greatest risk when using any of these devices is the creation of aerosols. When possible, blenders, grinders, sonicators, lyophilizers, etc. should be operated within a certified BSC when a biohazardous agent is present. Shields or covers must be used whenever possible to minimize aerosols and splatters.

- For work with biohazardous agents, safety blenders should be used. Safety blenders are designed to prevent leakage from the bottom of the blender jar and to withstand autoclaving. They also provide a cooling jacket to avoid biological inactivation.

- Avoid using glass blender jars. If a glass jar must be used, it must be covered with a polypropylene jar to contain the glass in case of breakage.
- A towel moistened with disinfectant must be placed over the top of the blender while operating. This practice can be adapted to grinders and sonicators as well.
- Aerosols must be allowed to settle for 10 minutes before opening the blender jar or grinder.
- Lyophilizer vacuum pump exhaust must be filtered through HEPA filters or vented into BSC.
- Polypropylene tubes should be used in place of glass ampules for storing biohazardous material in liquid nitrogen. Ampoules can explode, causing eye injuries and exposure to the biohazardous material.

Back to table of contents

I. Open Flames

The use of open flames in a laboratory is discouraged. When sterilizing inoculating loops in an open flame, aerosols, which may contain viable microorganisms, can be created. Open flames are also an obvious fire hazard. A shielded electric incinerator or hot bead sterilizer is recommended instead of an open flame. Disposable plastic loops are excellent alternatives as well.

Open flames are NOT to be used with in a biosafety cabinet. Open flames within a biosafety cabinet disrupt the laminar airflow and can damage HEPA filters in addition to being a fire hazard.

Back to table of contents

J. Pipetting

The general risks associated with pipetting a biohazardous material are the potential creation of an aerosols and/or splashes. Micropipettes can also create aerosols and/or splashes. To reduce risks associated with pipetting, the following practices are recommended:

- Mouth pipetting is strictly prohibited; mechanical pipetting aids must be used instead.
- All human biohazards should always be pipetted within a certified BSC when possible.
- Cotton-plugged, disposable pipettes should be used. Cotton-plugged micropipette tips are also available.
- Biohazardous materials must never be forcibly discharged from pipettes. “To deliver” (TD) pipettes should be used instead of pipettes requiring blowout.
- To avoid splashing, biohazardous material should be dispensed from a pipette or micropipette by allowing it to run down the receiving container wall.
- Glass pasteur pipettes must be disposed of in a puncture-resistant sharps container.

Back to table of contents

K. Working with Infected Animals

Only animals associated with current studies should be present in the laboratory. The spread of infectious agents between animal populations or between animals and humans can be prevented by adhering to basic guidelines.

- Footbaths or sticky mats must be used as required and provided for personnel and visitors both entering and exiting an animal area. The footbaths must have an appropriate disinfectant at an appropriate concentration. The risk assessment for work should describe this in detail. Footbaths must be regularly changed based on the stability of the disinfectant and the amount of traffic and use that it gets. In general, daily changes are recommended because of the complexities of maintaining an accurate concentration of disinfectant and potential load based on daily traffic from PIs, lab personnel and animal care takers.
- Animal Biosafety Level 2 (ABSL-2) room doors must remain closed and with restricted access at all times.
- Disposable gloves must be worn when handling infected animals, bedding or soiled cages and changed routinely. Never re-use disposable gloves.
- Disposable or washable outer garments (such as lab coats, gowns, coveralls) protect personal clothing from contamination when working with infected animals.
- Eating, drinking, smoking, applying cosmetics and handling contact lenses in ABSL-2 rooms or procedure rooms is strictly prohibited.
- Avoid hand contact to the nose, eyes and mouth when working with infected animals and in ABSL-2 areas.
- Hands must be washed with soap and water immediately after handling any infected animals or animal equipment, and before leaving the animal facility or laboratory.
- Extra caution must be taken with needles or other sharp equipment used with infected animals. Needles shall remain capped until ready to use, and then be promptly and properly discarded. Do not recap needles. As much as possible, reduce the use of sharps in animal areas. Look for alternatives when biohazardous substances are involved. For example, when performing a necropsy on mouse, use tape instead of pins to secure it. Safety engineered needles are in great supply and should continually be investigated for use with biohazards and animal work.
- Handle only those infected animal species for which proper handling training has been provided.
- Any animal bites or other wounds must be washed immediately with soap and water and appropriate medical attention sought. *All accidents and injuries occurring at work or in the course of employment must be reported to the individual's supervisor, even if no medical attention is required.* All UGA employees are covered by the state Worker's Compensation laws, which may provide medical and income benefits if an employee is injured on the job. If personnel suffer an injury while performing work duties, immediately report the injury to your supervisor. Supervisors will follow UGA Human Resources instructions for Worker's Compensation.
- Unauthorized persons are prohibited from entering animal rooms. Additional entrance requirements may be specified for certain research studies.

Animals in the Field

Fieldwork involving wild animals requires adapting the basic animal infection control guidelines to the particular situation in the field. Wild animals potentially transmit many diseases, including rabies, Hantavirus Pulmonary Syndrome, Leptospirosis, West Nile Virus infection, Salmonellosis, Tularemia, and plague.

- Personnel working in areas where they are likely to be exposed to wild rodents or their nesting areas should contact the Office of Biosafety to help with a risk assessment.
- Rabies vaccinations must be offered to all personnel who may be exposed to certain wild animals. Enrollment in the OHSP will provide a risk assessment to evaluate this need.
- Field work may also involve exposure to disease-transmitting insects and arthropods. Take appropriate precautions to prevent exposure to diseases, such as West Nile Virus infection, Lyme disease or other potential diseases carried by insect and arthropod vectors. Back to table of contents

L. Working with Human, Non-human primate (NHP) and other mammalian cells and tissues

General risks when working with cell cultures are low, but risk increases when handling human, other primate cells and primary cell lines from other mammals. The OSHA Blood-borne Pathogens Standard applies to all work in the laboratory with human blood, tissues, body fluids and human/non-human cell lines. The UGA Laboratory Exposure Control Plan manages these items in compliance with OSHA's BBP Standard. Since most cell and tissue cultures contain viruses, it is prudent to consider all cell lines to be potentially infectious. Most cell and tissue cultures can be safely manipulated using standard BSL-2 practices and containment. See requirements at our website The Office of Research: Biosafety.

In general, a risk assessment should be performed on the origin and source of the cells or tissues.

- Human and other primate cells should be handled as BSL-2 agents and work performed in a certified BSC with all materials autoclaved or disinfected before disposal.
- Cells or tissue cultures suspected to or known to contain a specific pathogen or an oncogenic virus or that have been immortalized using retro- or lentiviral vector, should be handled at the appropriate biosafety level for that agent.
- BSL-1 practices and containment may be used for cell lines that meet all of the following criteria. Cells must:
  - not be of human or other primate origin, and
  - have been confirmed not to contain human or other primate pathogens, including viruses, pathogenic bacteria, mycoplasma or fungi.
  - personnel working with or that may come into contact with human, non-human primate cell lines, human blood or tissues, and other potentially infectious materials (OPIMs) are required to take the Board of Regents Online Blood-borne Pathogens Training and be offered the Hepatitis B vaccination series.

Back to table of contents

M. Working with retro- or lentiviral vectors

Decisions about containment when working with any viral vectors should take into account a range of considerations including:

- the nature of the vector system and the potential for regeneration of replication competent virus from the vector components;
- the nature of the transgene insert (e.g., known oncogenes or genes with high oncogenic potential may merit special care);
- the vector titer and the total amount of vector
- the inherent biological containment of the animal host, if relevant;
- replication competent lentivirus (RCL) testing (*see Table 1*).

More detailed information can be found in the *NIH-OSP Guidance on Biosafety Considerations for Research with Lentiviral Vectors* (see Quick Reference Guide for link information).

Commercial vector systems come listed with a suggested biosafety containment level. A higher containment level may be required for work in certain cases, depending on the specific properties of the vector and/or the insert. Special care should be given to the design and use of viral vectors containing potentially hazardous genes (i.e. oncogenes, tumor suppressor genes, growth regulating products, etc.). Attention should also be paid to the envelope proteins in the packaging cell line in the system as these proteins will determine the host range of the viral vector (ecotropic vs. amphotropic). The use of viral vectors contained in cloning kits constitutes recombinant DNA experimentation and the biological safety containment level is ultimately determined by the IBC.

Normally, BSL-2 containment or enhanced BSL-2 containment is appropriate for research involving the use of retroviral and lentiviral vector systems that have multiple safety features and that segregate vector and packaging functions onto three or more plasmids. Enhanced BSL-2 containment may include attention to sharps (and use of safety needles where feasible) and the use of personal protective equipment intended to reduce the potential for mucosal exposure to the vector. These levels of containment are also expected to be appropriate even when producing large volumes of HIV-1 vectors (>10 L).

Some non-human lentivirus vectors (e.g., FIV, SIV, EIAV, etc.) are also in use. In most cases, BSL-1 containment is deemed appropriate for Risk Group 1 agents and recommended for use for certain animal viral etiologic agents not associated with disease in healthy human adults. However, replication-defective vectors in which a heterologous envelope (such as VSV-G) is used for vector packaging may require BSL-2 containment in the laboratory setting, since these vectors have the potential to transduce human cells, and thus have the potential to cause insertional mutagenesis.

All labs working with lentiviral vectors systems are required to have a post exposure plan. Please contact the Office of Biosafety for assistance.

Table 1. Biosafety Considerations and Risk Levels

No. of plasmids	Oncogenic transgene or production > 100 ml	RCV testing	Vector production	Use of viral vector in vitro	Use of viral vector in animals	Use of virus-transfected cells in animals
4 or more	Yes	Not required	BSL-2+	BSL-2+	ABSL-2+	ABSL-2+
4 or more	No	Not required	BSL-2	BSL-2	ABSL-2	ABSL-2
3	Yes	With or without RCV testing	BSL-2+	BSL-2+	ABSL-2+	ABSL-2+
3	No	May elect to test for RCV	BSL-2 (If RCV test. work may not proceed beyond this point until RCV data approved by IBC)	BSL-2 (Only after final approval by IBC following acceptance of RCV data)	ABSL-2 (Only after final approval by IBC following acceptance of RCV data)	ABSL-2 (Only after final approval by IBC following acceptance of RCV data)
3	No	No RCV test	BSL-2+	BSL-2+	ABSL-2+	ABSL-2+

Back to table of contents

N. Laboratory Equipment

Some laboratory equipment is built to provide what is termed “primary containment”, meaning that it is designed to reduce or eliminate exposure aerosols formed from biohazardous materials.

Autoclaves, centrifuges, biological safety cabinets, and fume hoods should undergo regular preventative maintenance by qualified personnel. Preventative maintenance records must be kept for each piece of equipment. The airflow must be regularly checked on the biological safety cabinets and filters changed by qualified personnel. All biosafety cabinets must be certified annually for laboratory operations.

Biosafety cabinets are the principal piece of primary containment equipment commonly found in the lab. Other types of primary containment equipment include sealed centrifuge cups and special airtight enclosures designed to contain specific laboratory equipment (such as sonicators).

Regardless of use, all lab equipment used in microbiological or biomedical research should be disinfected routinely. Thorough decontamination should be provided for any equipment after a spill, splash or potential contamination. Equipment must be decontaminated before repair, maintenance or removal from the laboratory, and a Decontamination Tag must be affixed to the equipment. Equipment that creates a hazard must be evaluated and considered when performing a risk assessment for biohazardous materials management. An example of a piece of equipment that can create a hazard is a sonicator or vortex that could generate aerosols of a biological agent.

Autoclaves

An autoclave or an appropriate means to decontaminate waste from a BSL-1 or BSL-2 must be available for all labs. An autoclave must be present in the BSL-3 laboratory and must only be operated by personnel who have been properly trained in its use. The greatest risk with an autoclave is not typically the biohazard agent present but the heat, steam and pressurization. Autoclaves use saturated steam under high pressure to achieve sterilizing temperatures. Therefore, proper use is important to ensure operator safety. Prevent injuries when using the autoclave by observing the following rules:

- A minimum sterilization time of 30 minutes at 121 degrees Celsius and 15 psi for potentially infectious waste is required. Longer times may be appropriate dependent on load and agent. Please contact the Office of Biosafety for help in determining appropriate run times.
- Tests for sterility must be conducted regularly with spore strips or other biological indicator ampoules. Please see "Autoclave Cycle Verification and Autoclave Validation" in page 45.
- Wear heat-resistant gloves, eye and face protection, closed-toe shoes and a lab coat, especially when unloading the autoclave.
- *Never put solvents, volatile or corrosive chemicals (such as phenol, chloroform, bleach, formalin, fixed tissues, etc.), or radioactive materials in the autoclave*. For questions on chemicals or radioactive materials contained in items that require autoclaving consult the Office of Research Safety for assistance. A combined hazard with biological agents may require chemical disinfection prior to hazardous waste disposal if the disinfectant does not react with the chemical or radiological constituents present.
- Double-bag all potentially infectious waste and materials to prevent the items from piercing the bag. Loosely close the bag leaving a 2-3 inches opening within the closure to allow steam to enter and to keep the bag from exploding.
- Loosen caps on all containers as they can explode when capped. Never put sealed containers in an autoclave. Large bottles with narrow necks may also explode if filled too full of liquid.
- Prevent steam burns and shattered glassware by making sure that the pressure in the autoclave chamber is zero before opening the door at the end of a cycle. Slowly open the autoclave door and allow any residual steam to escape gradually.
- Allow items to cool for at least 10 minutes before removing them from the autoclave. Be careful of glass containers that contain liquids that are potentially superheated.

Superheating is a condition that occurs quite often in autoclaves. Superheating occurs when liquids are at a temperature above their normal boiling point but do not appear to be boiling. In situations where personnel get in a hurry removing flasks or bottles from the autoclave the superheated containers can explode violently.

Centrifuges

The greatest risk with centrifugation is the creation of aerosols and leakage. Leaks can be prevented by not overfilling centrifuge tubes. The outside of the tubes should be wiped with disinfectant after they are filled and sealed. Sealed tubes, O-ring sealed rotors or O-ring sealed safety buckets must be used to provide for primary containment when BSL-3 agents are involved or if a risk assessment due to the potential generation of aerosols deems it necessary. This practice should also be utilized in BSL-2 as appropriate. To avoid spills from broken tubes, the tubes, lids, O-rings, buckets, and rotors should be inspected for damage before each use. Before use, visually inspect the load to ensure rotor is balanced. If aerosol generation is an issue, open rotors and centrifuge tubes within a Class II biosafety cabinet. General centrifuge safety recommends waiting 5 minutes after the run has finished to allow aerosols to settle in the event of an unknown breakdown in containment. If a known or potential break down in containment occurred during the centrifuge process and leave the area immediately and wait at least 30 minutes to allow for dissipation of aerosols.

Biosafety Cabinets (BSCs)

Class II BSCs are the main primary containment device used in a lab and not only provide for personal protection but provide for product and environmental protection as well. Class II BSCs use uniform vertical laminar airflow through a high efficiency particulate air filter (HEPA) to create a barrier to airborne particles. In a Class II BSC, HEPAs clean both the air entering the work area and the air exhausted to the lab. The air in most BSCs is partially recirculated over the work area through the HEPA filter before being exhausted to the environment.

Class II A2 cabinets are the typical type of BSC used throughout campus. If a laboratory has a need for another type of BSC (Class II B2 or Class III) they must first get approval from the Office of Biosafety and Physical Plant Engineering Department before purchase and installation. Both Class II B2 and Class III cabinets require direct connection to building ventilation systems and are costly for both installation and maintenance. These two types of cabinets will require a design approach with a mechanical engineer prior to installation in any space at UGA. For questions on different types of BSCs and their use, contact the Office of Biosafety. Detailed information can be found in the BMBL.

If possible, BSCs should be located far away from doors and highly trafficked areas. Care should be taken to not disrupt the airflow in a room while a BSC is being used. No doors opening, people walking by, etc.

BSCs should be used for manipulations of biohazardous materials that are likely to create aerosols in a BSL-2 lab. BSL-3 containment and above requires the use of Class II BSCs for any agent manipulation. When BSCs or other primary containment devices cannot be utilized for containment of aerosols, other engineering devices should be assessed with the research team and the Office of Biosafety. General laboratory manipulations that commonly cause aerosol generation include vortexing open tubes, pipetting, opening tubes

after centrifugation, sonication and aspirating with a syringe. Often these manipulations can be carried out within the BSC.

Any work with potentially biohazardous material regardless of biosafety level will not be permitted in a BSC that does not pass an annual certification process conducted by an NSF certified technician.

Annual Certification.
To ensure appropriate protection, BSCs must be tested and certified annually for use. Certification must be performed by a qualified contracted service company that has NSF trained and certified testers. NSF certification ensures that testing is done according to the internationally accepted standards of the National Sanitation Foundation. Each BSC should have a label on it stating the date it was last certified and PIs should be provided with documentation indicating results for all test parameters. BSC certification documents should be maintained at the lab for a minimum of three years.

Companies used for BSC certifications must follow the NSF/ANSI Standard 49 for the evaluation of Class II laminar flow biological safety cabinets. Such companies will be selected for the campus by the Office of Biosafety. The contact information for these companies will be posted on the OVPR Biosafety website. Their selection will first require that all biosafety cabinet certification technicians for UGA facilities be NSF-Accredited Class II Biosafety Cabinet Field Certifiers. Contact the Office of Biosafety for assistance.

Purchasing, Moving, Repairs
When purchasing and installing a new BSC, contact the Office of Biosafety for assistance in choosing an appropriate cabinet. The following purchasing and installation guidelines must be followed:

- BSC must be certified by NSF according to NSF Standard 49/2002 following any new installation, movement or repair. The only exception to recertification for any moved cabinet is for those Class II cabinets designed for mobility and on wheels. For questions, contact the Office of Biosafety.
- Any outlets inside the work area of the BSC should be ground fault circuit protected (GFCI) outlets.
- Installation of BSCs must allow access to both supply and exhaust filters for annual certification testing and filter changes.
- The top of the BSC must be far enough below the ceiling (at least 18 inches) to allow field testing of exhaust flow according to NSF Standard 49/2002.
- Any connections to exhaust duct work must allow access for field testing of exhaust flow according to NSF Standard 49/2002.
- If the BSC is a Class II Type A2, the preferred connection to the exhaust is a thimble connection and not a gas-tight connection unless provide through an appropriate damper located within the room's exhaust ductwork. **A**ll Class II Type A cabinets (past or present) that are exhausted outdoors must be connected by a functioning Canopy Exhaust Connection (CEC) and equipped with an exhaust airflow alarm (rooster alarm).

The use of Hard Exhaust Connections (HECs) will not be allowed. Additional details about choosing appropriate BSCs and their proper use are available in the BMBL.

- When moving or when repairs are necessary on a BSC, a risk assessment must be performed to determine if gas decontamination rather than surface decontamination is necessary. Contact the Office of Biosafety to assist with this risk assessment. FMD will not move a cabinet without biosafety approval.

Working in a BSC

- The most common failure from turning a cabinet on and off is the fan switch. With newer cabinets, pulling the sash fully down will cut off the exhaust fan and save the life of the fan switch.
- If it a cabinet is routinely turned off after use, the BSC should be allowed to run for a minimum of 10 minutes prior to loading. After completing work, the BSC should be run for 10 minutes before unloading.
- Work should be set up to move from clean to dirty (best practice). Clean pipettes or supplies should be on one side with waste containers stored on the other side.
- Disinfect the BSC after each use, at a minimum, with an appropriate disinfectant.
- As much as possible, all waste and/or disinfecting containers must be kept inside the cabinet while they are being used. Proper decontamination procedures must be in place prior to removal.
- Never use open flames or a Bunsen burner within a BSC. Open flames inside a BSC disrupt airflow, compromising protection of the worker and the material being handled and can damage the HEPA filter. Open flames are extremely dangerous around flammable materials, such as ethanol. Use electric incinerators or sterile disposable instruments to substitute for a Bunsen burner.
- Do not store incubators or storage units too close to the face of a BSC. Known instances have occurred of cross-contamination from having such equipment stored directly next to a BSC, as BSCs pull air through the face of the hood.
- Do not block the front grill with notebooks or supplies. The front grill provides for worker protection and will be compromised when blocked.
- Do not crowd the BSC or block the side or back baffles. Baffles provide for exhausting of supplied air and when blocked may compromise airflows within the cabinet.
- Be cautious if using bleach to disinfect a BSC as it is corrosive to stainless steel. If a bleach solution is used, a secondary wipe-down with 70% ethanol is needed to stop the corrosive action of the bleach. A risk assessment should be completed to determine disinfection practices within the cabinet for both effectiveness and equipment sustainability.

Use of ultraviolet (UV) lights to disinfect a BSC is NOT recommended because of its documented ineffectiveness and safety risk. UV lights lose effectiveness over time and this cannot be determined simply by run times of the BSC. Additionally, numerous factors (e.g. penetration, relative humidity, temperature and air movement) affect the activity of the germicidal effect of UV light, which require regular cleaning, maintenance and monitoring

to ensure germicidal activity. If used, please note that UV light must be turned off before beginning work. Exposure to UV light for a prolonged period will cause burns to both the skin and eyes. Newer BSCs have safeguards to prevent exposure to UV light; older models may not have safeguards.

In the event of a power outage in the lab or a failure in the cabinet when working with pathogens requiring primary containment, work must stop immediately. In the absence of a life threatening event, containers must be sealed, the sash must be closed and a sign posted on the cabinet indicating that the cabinet not be operated until the power is restored.

Back to table of contents

Flow Cytometry

Flow cytometers are automated instruments that provide measures of the quantitative properties of single cells, one cell at a time. They can measure cell size and the amounts of cell components such as total DNA, newly synthesized DNA, gene expression as the amount messenger RNA for a particular gene, amounts of specific surface receptors, amounts of intracellular proteins, or transient signaling events in living cells.

Flow cytometers take in a suspension of single, unclumped cells and run them one at a time single file past a laser beam. Most flow cytometry is analytical: after the information is obtained as it passes through the cytometer, the sample is discarded. Some flow cytometry is preparative: living cells are sorted into separate containers based on the properties of each cell.

Flow cytometers operate under pressure, generating aerosols. The experiment step most likely to generate aerosols involves the nozzle that forms a jet of microdroplets. Instrument failures such as a clogged sort nozzle or air in the fluidic system can increase the risk of aerosol formation. When flow cytometry is used to study known or potentially biohazardous materials, operators may be at risk of exposure to aerosolized materials. When possible, all biological samples should be fixed (for example, with formalin) before being run through the flow cytometer.

When performing flow cytometry on known or potentially biohazardous materials that are not fixed, the following guidelines must be followed to prevent personnel exposure:

- Flow cytometry must be conducted in a laboratory meeting BSL-2 criteria at minimum.
- The use of a Class II biosafety cabinet is highly recommended unless other provisions are available to provide for primary containment.
- Personnel must wear proper PPE, including gloves and lab coat. Eye protection must also be utilized when operating outside of the BSC.
- Only experienced, well trained personnel should perform potentially biohazardous cell sorting.
- Specimens must be kept closed at all times except when being put onto the cytometer sample introduction port.

- All biohazardous materials should be placed in leak-proof containers which are disinfected on the exterior and sealed before evacuation. Avoid the use of sharps.
- It is incumbent upon the laboratory (Principal Investigator or other research staff) requesting the analysis or cell sorting analysis to thoroughly divulge any and all potentially infectious or biologically hazardous materials in any specimen submitted.
- All samples should be logged with such information in facility logbooks.
- The catch basin should have an appropriate disinfectant added when the unit is in use.
- The flow cytometer and lab bench must be cleaned and disinfected after each use.
- Needles should not be used unless approved by lab supervisor or PI. Glassware is not recommended.

Refer to Wiley Cytometry Guidelines for additional references regarding flow cytometry biosafety (see 'Biosafety Guidelines for Sorting of Unfixed Cells').

Back to table of contents

VII. BIOSAFETY LEVEL 3 (BSL-3) REQUIREMENTS

In addition to standard routes of transmission for BSL-2 agents, BSL-3 agents present an aerosol hazard to the worker. Therefore, a heightened level of safety is required for all BSL-3 work. In addition to all the practices described within this manual following the BMBL's guidelines for BSL-2 work, BSL-3 work will require that the following practices be added:

- BSL-3 laboratories must be designed and built following UGA Office of Biosafety's high containment design criteria.
- Any requests for renovations or modifications to any UGA BSL-3 facility must first be approved by the Office of Biosafety and the UGA FMD Engineering Department. Protocols for requesting a modification request are available in the UGA BSL-3 facilities manual.
- Laboratory doors will remain closed and locked at all times. Access is restricted to persons trained and authorized to work in the BSL-3 laboratory.
- Initial commissioning of any UGA high containment laboratory must follow the UGA BSL-3 facilities manual requirements.
- Annual performance verifications are required and will follow the UGA BSL-3 facilities manual guidelines. Ensuring that annual performance verifications are completed is the responsibility of the laboratory director and will be coordinated with the Office of Biosafety and FMD BSL-3 facilities personnel.
- A risk assessment will determine necessary PPE but minimal requirements will include: disposable solid front gowns, double gloves appropriate for work (Nitrile, latex or both), and shoe covers. The need for respiratory protection and additional PPE will be determined by risk assessment.
- Entry and exit protocols will be determined by risk assessment and facility design.
- All manipulations with BSL-3 agents will be performed within a certified Class II A2 BSC or other suitable primary containment device.
- All HEPA filters used in primary containment devices within a BSL-3 laboratory or animal room will be tested and certified annually. HEPA certification records will be maintained by the lab director for a minimum of five years.

- Glassware is not permitted in BSL-3 facilities unless alternative solutions are unavailable. If glassware must be used, it should be first approved by the PI or lab director. Use of glassware in a BSL-3 lab must be documented in the IBC Protocol Review Form and approved by the IBC. If there is no alternative available, plastic coatings should be considered when selecting glassware for use in a BSL-3 lab.
- Needles or other potential sharps must be eliminated as much as possible from being used when working with BSL-3 agents. Safety engineered solutions will be used when available for any required needle or sharps. Any sharps necessary for use, must be approved by the PI or lab director. Use of such sharps must be documented in the IBC Protocol Review Form and approved by the IBC. Safety sharps with safe engineering mechanisms provided should be considered when selecting such materials for work in any lab.
- Before service or repairs are made to any equipment used within a BSL-3 laboratory, a risk assessment must be made by the PI or laboratory director in collaboration with the Office of Biosafety, to determine if surface disinfection or total room decontamination is necessary. In either case, any equipment requiring repair or service be must be cleaned and disinfected prior to service personnel handling it.
- Sinks must be available, hands free, and located close to the BSL-3 lab exit. Soap and paper towels will be provided at the sink.
- All cultures, stocks, biological waste, gloves, gowns and other contaminated articles are decontaminated via autoclaving before disposal. Onsite autoclaving is required.
- Vacuum lines are protected with liquid disinfectant traps and HEPA filters.
- A lab-specific biosafety manual will be provided to all workers in BSL-3 laboratories. This manual will be written by the PI and approved by the Office of Biosafety.

Back to table of contents

VIII. Occupational Health and Safety Program (OHSP)

The goal of an Occupational Health and Safety Program is to promote a safe and health workplace through medical support services, limit opportunities for personnel exposure, promptly detect and treat any exposures and use information gained from work related incidents that can result in injury to enhance the existing safety program. The OHSP in the research setting is a shared responsibility of personnel, safety specialists, and medical service providers. Workers must be fully informed of their work place hazards and available medical services within the OHSP. All personnel working in the University research setting with the potential for exposure to biohazards agents that can impact human health will be offered enrollment in the Office of Research OHSP; for BSL-3 enrollment in the OHSP is required. Any documents or information generated or received by UGA related to occupational health and safety are part of your employment record and your rights to confidentiality of your personal health information will be strictly maintained. The Office of Research Compliance, providing oversight for the Office of Animal Care and Use and the Office of Biosafety, administers and manages the OHSP for personnel using animals and/or working with some biohazards (those which require Institutional Biosafety Committee approval). Piedmont Regional First Care's Occupational Health Service and the UGA Office

of Research Clinical Translational Research Unit (CTRU) are contracted to provide occupational medicine support for the program.

Pregnant women, immune-compromised individuals, or personnel with health conditions that may impact them at work (such as diabetes, animal allergies, etc.) are advised to consult the Pathogen Safety Data Sheets (PSDS) for all pathogenic organisms in their work environment in order to determine if any risks exist that may impact their personnel health conditions. They should consult with their supervisor, be enrolled in the OHSP and consult with the occupational health physician concerning potential risks and how to manage those risks.

Employee supervisors will inform laboratory personnel of available medical support services and encourage an appropriate level of participation. Worker's compensation posters are located in common areas in workplaces throughout the campus. New employees will be informed of the nearest poster by the supervisor upon hire.

Medical Surveillance: Occupational health physicians are available through Piedmont Athens Regional FirstCare in Athens for medical surveillance or emergency needs. Lab personnel must be provided medical surveillance and offered appropriate immunizations as appropriate and following a thorough risk assessment for the biohazardous materials present in their laboratory.

Specific details of vaccinations, serum banking, titer checks will be based on risk assessments and agent-specific needs. When appropriate and available, personnel who work with or have the potential to be exposed to human pathogens will be offered the opportunity to receive vaccinations and will be informed of the risks associated with the vaccine. Agent-specific medical surveillance plans may be required and will include protocols for employees who are ill with signs and symptoms of the human pathogens they work with (but without any known exposure incident), as well as protocols for employees suspected of having been exposed to a live pathogen during work activities. Costs of occupational health needs will be billed to the PI or department, as applicable.

Employees working with human pathogens will receive orientation training prior to beginning work and annually thereafter as part of their occupational health program. This orientation training will include the following:

- description of the signs and symptoms commonly associated with agents of concern
- appropriate PPE and training including information on the proper fitting, donning, positioning, adjustment, and removal of PPE
- training on work related techniques designed to minimize exposure to pathogens, as well as potential routes of exposure
- training on use of incident and potential exposure reporting protocols
- training on standard contact and airborne precautions
- training on spill clean-up and emergency procedures

Information for Supervisors: One-time emergency room visits are covered under Worker's Compensation. However, utilizing Piedmont Athens Regional FirstCare for work related coverage when biohazardous agents are involved should be requested by contacting the Department of Administrative Services (DOAS) at 877-656-7475. Supervisor's will call to report the claim, ask for special provisions to utilize Piedmont Athens Regional FirstCare as the **preferred site of care** with an assigned claim number. In emergency situations, the emergency and life safety must be handled immediately. If the employee needs emergency medical care, send the employee to the nearest hospital emergency room. An ambulance for emergency transport is a covered expense under the Workers' Compensation program. If the employee needs medical care and **after** the **supervisor** has reported the injury to the DOAS number above, the employee may call 1-800-900-1582 to arrange for doctor's appointments, prescriptions, surgery, and all other needed medical care.

Work-related incidents involving UGA employees (paid by UGA to include Principal Investigators, post-doctoral students, graduate students), visitors and high-school students (part of the Young Dawgs program) should utilize Piedmont Athens Regional FirstCare, if possible. Unpaid UGA students and others should report to the University Health Center or their primary care physician.

Information about specific vaccines and exposure tests commonly given to University of Georgia personnel can be viewed from the CDC Advisory Committee on Immunization Practices web site and include but are not limited to the following:

- Hepatitis A & B
- Influenza, inactivated vaccine & live intranasal vaccine
- Rabies
- Tetanus/Diphtheria
- Tuberculosis testing

Back to table of contents

IX. Biohazardous Materials Laboratory Incidents or Accidents

A biohazardous laboratory incident or accident involves:

- Any potential or known exposure to Biosafety Level 2 (BSL-2) agents or higher
- Any potential or known system failure that could result in the release of a BSL-2 or higher organism from primary containment
- Any potential breach in biosecurity in containment facilities

Back to table of contents

A. Chain-of-notification

All University employees are responsible for reporting potential biohazardous incidents to their immediate supervisor or the Office of Biosafety. Lab supervisors and PIs are responsible for reporting biohazardous incidents to the BSO/RO or ABSO/ARO.

PIs are responsible for immediate reporting of a theft, loss or release of a select agent or toxin to the RO/ARO. Select agent and toxin labs will have lab-specific incident response plans that describe their site and agent specific protocols.

The BSO is responsible for reporting to the IBC and the Institutional Official (IO) any significant problems, violations, research-related accidents or illnesses involving work described under the NIH Guidelines for Recombinant DNA Research. In addition the RO or ARO is responsible for reporting any reported theft, loss or release of a select agent or toxin to their federal reporting agency utilizing CDC/USDA Form 3. Records related to biohazardous incidents or accidents will be maintained for a minimum of three years.

The IBC is responsible for reporting significant problems, violations or significant research-related accidents or illnesses to the Institutional Official and NIH Office of Biotechnology Activities.
Back to table of contents

B. Reporting an incident
Incident reports are initiated with an employee report to a supervisor or directly to the Office of Biosafety. Supervisors and the Office of Biosafety must be notified of all incidents in the lab. Personnel will be able to report an incident or seek medical attention without fear of reprisal. Medical evaluation, surveillance and treatment will be provided as necessary. If a medical emergency exists, personnel must first seek medical attention. Any medical incident involving potential exposure to a biohazardous substance that poses a human health threat will be reviewed by the Office of Biosafety and UGA's Occupational Health Physician. The employee's supervisor must contact the Office of Biosafety to report the biohazardous incident/accident as soon as reasonably possible. PIs of high containment and select agent laboratories will report immediately to the RO any incident resulting in the potential release of an agent outside of primary containment and as established in their written plan.
Back to table of contents

C. Investigation and Review of Incidents
Following the reporting of a biohazardous incident/accident, a risk assessment and incident review will be performed with the employee's supervisor, PI (if different), biosafety professional and any other necessary personnel (ex. medical consult). The Office of Biosafety will utilize the *Biohazardous Incident/Accident Reporting and Response form* as a record. PIs, safety professionals and medical doctors will serve as subject matter experts. Employee supervisors will provide the Office of Biosafety with protocol modifications and SOPs following an incident or accident.
Back to table of contents

D. Training Personnel
Supervisors will formally review incident reporting protocols with personnel upon hire and then annually at a minimum. If an incident involving potential exposure or release of a

biohazardous agent occurs, the supervisor will provide a follow up meeting with personnel to discuss the scenario and any program modifications or changes that apply following review of the incident. This follow up meeting will be documented.

Related to human health hazards, it is well documented that laboratory-acquired infections (LAIs) are often not associated with a single known incident. Therefore, lab personnel will be encouraged by their supervisor to seek medical evaluation for signs and symptoms that they suspect may be related to possible biohazardous agent exposure in the lab. A diagnosed LAI without a known incident is considered reportable to the Office of Biosafety.

Back to table of contents

E. Spill Response

When accidents occur that involve the release of biohazardous and/or recombinant agents, the PI should be notified as soon as possible. PIs and trained lab staff working with these agents will be responsible for mitigation. The Office of Biosafety is available for assistance and should be contacted as soon as possible (following incident reporting protocols).

If the release involves a BSL-3 agent outside of primary containment, the immediate area should be evacuated according to protocol with appropriate signage put in place and the Office of Biosafety should be contacted immediately. The names of all potentially exposed individuals should be recorded and the contaminated area should be restricted to trained individuals only.

When a spill of a pathogenic microorganism also involves radioactivity, cleanup procedures may have to be modified. The extent of the modification will depend on the level of radiation and the nature of the isotope involved. The Radiation Safety Officer (Office of Research Safety) should be called during normal working hours, or the UGA Police Department after normal working hours, in such a situation.

Spills of biohazardous materials must be first contained, decontaminated and further cleaned up by staff properly trained and equipped to work with infectious materials. Each lab using biohazardous materials must have appropriate equipment and supplies on hand for managing spills and accidents involving biohazardous materials. Permanent equipment should include a safety shower, eyewash, a hand-washing sink, and disinfection and clean-up supplies. Spill protocols should be posted in areas where agents are handled and a biohazard spill kit should be readily available. Examples of biohazard spill kit supplies:

- Nitrile or other appropriate disposable gloves
- Lab coats, disposable gowns, disposable Tyvek-like suits
- Goggles, safety glasses, or disposable face shield
- Disposable shoe covers (booties)
- Absorbent material - paper towels, absorbent pads

- Appropriate disinfectant (should be freshly prepared with available materials on hand)
- Tools to aid in collecting material - tongs, forceps, dustpan
- Biohazard bags and sharps waste containers
- Warning sign to post for restricted entry

Back to table of contents

i. Managing a Biohazardous Spill INSIDE a Biosafety Cabinet (BSC)

1. Keep the BSC running.
2. Immediately cover with absorbent material.
3. Soak absorbent material with freshly prepared disinfectant. Work from the outside of the absorbent material to the center. Allow for appropriate contact time.
4. Remove gloves and other contaminated clothing, according to standard procedures. Place in biohazard bag(s) for autoclaving.
5. Wash hands and arms thoroughly. Don a new pair of gloves and additional PPE as needed.
6. After appropriate contact time, collect disinfected materials placed on the spill area in a biohazard bag. If tubes or solid materials are involved, utilize tools such as tongs to pick up those materials. Broken glass and sharps should be placed in a sharps container rather than in a biohazard bag.
7. Wipe up spill area with disinfectant soaked paper towels.
8. Wipe down walls, work surfaces, and equipment in BSC with disinfectant.
9. If the spill material has leaked through the BSC grille
    a. wipe down all items within the cabinet and remove,
    b. ensure drain valve is closed
    c. flood tray top, drain pans, and catch basins with disinfectant
    d. allow to stand for the appropriate contact time
    e. lift out tray and remove exhaust grille work
    f. clean top and bottom surfaces with sponge/cloth soaked in decontaminating solution
    g. replace grille tray and grille work
    h. if applicable, drain decontaminating solution from cabinet base into a collection vessel containing additional decontaminating solution. A flexible tube should be attached to the drain valve and be of sufficient length to allow the open end to be submerged in the disinfectant within the collection vehicle. The drain pan should be flushed with water and drain tube removed.
    i. remove gloves and other contaminated clothing, according to standard procedures. Place in biohazard bag for autoclaving.
10. Place all contaminated materials within a biohazard bag. Autoclave all contaminated material.
11. Follow incident reporting protocols for notifying lab supervisor (PI) and the Office of Biosafety.

12. For BSL-2 labs, work may not resume until the PI or lab supervisor agrees that the clean-up is complete. For BSL-3 or select agent labs, work may not resume until PI and BSO/RO have determined the clean-up was appropriate.
13. Record spill clean-up on the Laboratory Decontamination Log sheet.

Back to table of contents

ii. Managing a Biohazardous Spill OUTSIDE of a Biological Safety Cabinet (BSC)

1. If not wearing respiratory protection, immediately leave the area.
2. In an area away from the spill, disinfect and/or remove any potentially contaminated PPE/clothes before leaving the laboratory. Wash any apparently contaminated body parts with soap and water.
3. Exit the laboratory following standard exit protocols.
4. Post signage on all lab entry doors to keep personnel from entering the spill area (signage can be found in spill kit).
5. Allow at least 20 minutes for any potential aerosols to settle.
6. Report the incident to the lab supervisor, PI and/or Office of Biosafety (OBS).
7. Once cleared by PI or OBS, re-enter the area wearing appropriate PPE, locate the spill kit, and follow appropriate spill clean-up procedures.

CLEAN-UP PROCEDURES

8. Wear gloves and lab coat. If a splash hazard is likely, also wear goggles and face protection.
9. Locate **Spill Kit**
10. Use forceps/tongs to pick up broken glass. Small pieces of glass may be discarded into a sharps container. Larger pieces should be disinfected and placed in the Broken Glass box.
11. Cover spill with paper towels to limit spread.
12. Carefully pour appropriate disinfectant onto paper towels/absorbent pads, pouring from the outside inward, in sufficient quantity to ensure effective disinfection
13. Allow for appropriate contact time. If 1:10 dilution of household bleach is used, it must be freshly prepared and allow at least 20 minutes contact time.
14. Pick up paper towels/absorbent pads with tongs or broom and dustpan, and dispose into biohazard bag.
15. Re-apply disinfectant to the spill area with appropriate disinfectant diluted to working strength. For spills at BSL-2, also wipe-down a 4-6 ft. radius around the spill area. Include any furniture or casing within the zone.
16. Place all contaminated materials, including Personal Protective Equipment (PPE), into a biohazard bag and autoclave appropriately.
17. Decontaminate any reusable items with disinfectant.
18. Wash hands with soap and water.
19. Provide detailed information to the PI and OBS for an incident report.
20. Call BIOSAFETY for advice as needed at 706.542.7265 or call the BioAlert Telephone (BAT phone) at 706.542.5300.

Back to table of contents

X. BIOSECURITY

In relation to human health, biosecurity refers the protection of microbial agents from loss, theft, diversion or intentional misuse. In recent years, there has been increasing concern regarding the potential use of certain biological materials by terrorists. In response to these concerns, the CDC has developed guidelines to address laboratory security issues in the current edition of the BMBL. Based on these concerns and established guidelines all lab personnel are responsible for:

- Controlling access to areas where hazardous materials are used and stored.
- Knowing who is in the laboratory at any given time.
- Knowing what materials are brought into the laboratory.
- Knowing what materials are removed from the laboratory.
- Acting responsibly, professionally and ethically. (UGA Ethics Policy)

When select agents or toxins are in use or other high containment organisms not defined as select agents, security risk assessments will be performed to consider appropriate security measures for their work site and agent specific needs. Lab specific protocols will further define appropriate biosecurity protocols for agent and facility specific needs. These include, but are not limited to, prevention of exposures or LAIs, limited or restricted laboratory access, inventory management, and safe packaging, labeling and containment when transferring or shipping agents, or background checks and screening of personnel working with high consequence agents.

In agricultural research, biosecurity refers to protocols and facility designs established to protect animal or plant colonies from microbial contamination. Shower out facilities, exit and PPE doffing protocols, facility enhancements, personal quarantines, locations of experimentation to potentially impacted agricultural products, and special protection and/or routine treatment of sanitary sewer drains are examples of biosecurity protocols that may be required when handling certain animal or plant pathogens. Biosecurity features and protocols should be outlined in a site-specific biosafety or biosecurity manual and based on risk assessment.

Back to table of contents

XI. TRANSPORTATION AND SHIPPING

This section of the manual only accounts for shipping needs of biologicals or biohazardous materials. Other hazardous materials or dangerous goods shipping inquiries should be directed to the Office of Research Safety. Various regulations provide for oversight of movement of biohazardous materials. The Federal Aviation Association and the US Department of Transportation monitors the shipping of Dangerous Goods. Failure to comply with federal shipping requirements for any dangerous good may result in fines of;

- Up to $250,000 and one year in jail for individuals
- Up to $500,000 per incident for an organization

Other federal agencies providing requirements and oversight for shipping of Dangerous Goods:

- International Air Transport Association (IATA)
- US Department of Transportation (DOT)
- US Public Health Service (PHS)
- Occupational Health and Safety Administration (OSHA)
- United State Postal Service (USPS)
- United States Department of Agriculture (USDA)
- US Department of Health and Human Services, Centers for Disease Control (DHHS CDC)

Biohazardous materials must always be transported following applicable regulations. Never move a biohazardous material in a vial in your pocket. Each regulator will have necessary training and protocols involved that must be followed.
Back to table of contents

A. On-Campus (Intra-entity) Transport of Biohazardous Materials

Any biohazardous materials transported between laboratories or buildings on campus must be contained as it would be within the laboratory to prevent a release to the environment. Secondary and tertiary containers should be utilized and labeled with the biohazard symbol and the identity of the material inside.

Example: Transport of a rack of test tubes containing serum samples from pigs infected with *Salmonella spp.* from an animal facility to a laboratory building:

- Tubes will be tightly capped, placed in sealed secondary container such as a plastic bag. The tops of tubes should be closed with parafilm or tape to prevent leaking. Absorbent material able to contain the total volume of biohazardous material must be placed between the primary and secondary containers
- Plastic bag will be placed into a sealed, puncture-resistant, leak-proof, unbreakable tertiary container with a biohazard label indicating *Salmonella spp*.
- Tertiary container will be placed in a secure position during transport to avoid shifting while being transported.

.

Intra-entity movement of materials classified as Category A or B, or those transported on dry ice via a vehicle on public roadways must follow DOT regulations for packaging and shipping dangerous goods, including filling out a shipper's declaration, if needed, which can be found on the Biosafety website. An intracampus transport form will also need to be filled out. Only state vehicles can be used for these intra-campus transports.
Intra-entity movement of animal and plant pathogens subject to a USDA permit can be performed only in accordance with the permit conditions. For example, a researcher has a permit to work with a plant virus in growth chambers. This virus cannot be transported to a greenhouse on campus without the USDA-APHIS approval (permit amendment). In another example, a researcher may have a USDA-APHIS permit for work with a specific animal pathogen in their lab, restricting work restricting work to *in vitro* work only. If that

researcher wants to work with that pathogen in another laboratory or *in vivo*, they must amend the existing permit or apply for a new permit to move it or work with it *in vivo*. Plant GMOs or GMO plant pests are subject to USDA-APHIS regulations (7 CFR 340.8) and labeling must be according to 7 CFR 340.7. Contact the Office of Biosafety for questions or assistance.

Transport of any Select Agent or Toxin between laboratories or buildings on campus requires CDC approval for possession, storage or transport to any location. It also requires that records be kept of the amount and locations. Select agents or toxins cannot be transported without coordination with the campus RO or ARO and registered PIs. Contact the institutional RO for questions or assistance. Back to table of contents

B. Off-Campus (Inter-entity) Transport of Biohazardous Materials

All off-campus transport of biohazardous materials must comply with federal and state shipping and permitting requirements, as described in the following sections. Off-campus sites may include across town to a collaborative research facility, out of town within the state, out of state in the United States, and out of the country. A university vehicle must be used for inter-campus transport of biohazardous materials. Please contact the Office of Biosafety for additional guidance if needed.

Back to table of contents

C. Transportation Permit Requirements

Special federal permits may be required for importing, exporting and/or transporting human pathogens, animal pathogens, animals or animal products, plant pathogens or plant pests, and plants or plant products. Permit requirements should be verified well in advance of needing the material in question. *In general, the receiver is required to be approved and hold a permit for the material before it is shipped.* The Office of Biosafety can provide assistance with any questions about shipping and/or required permits for biological materials.

Animals, Plants, Introduction of Genetically Modified Organisms

The USDA, through its Animal and Plant Health Inspection Service (APHIS), regulates transport of materials that could potentially harm U.S. agricultural products, such as livestock or crops. For this reason, APHIS permits may be required for import, export and/or transport of animal or plant pathogens, soil samples, insects, import or export of animals, animal products, plants or plant products, or introduction of genetically modified organisms into the environment. A quick reference guide to regulations including permit oversight and a web resource page are available within this manual. The Office of Biosafety staff can help determine if a permit is required and can assist with the application process. For more information go to The Office of Research: Biosafety.

Human Pathogens or Biological Toxins

The Department of Health and Human Services (DHHS), through the CDC, regulates the import and transport of biological materials that could cause illness in humans. These

regulated biological materials include pathogenic bacteria or viruses, toxins from biological sources (i.e. tetanus toxin), blood or tissues capable of containing pathogens transmissible to humans and certain animals, and insects that may harbor disease-causing organisms. The information contained on the CDC Etiologic Agent website and the Office of Biosafety can help determine if a permit is required and can assist with the application process. For more information, see CDC permit application to import biological agents or vectors of human disease.

Select Agents and Toxins

As of February 2003, the CDC and USDA regulations regarding Select Agents (42 CFR Part 73, 7 CFR Part 331 and 9 CFR Part 121) supersede any previous regulations. Entities that export, import, transport or possess select agents or toxins are required to be approved through an entity registration before possession occurs. Substantial criminal penalties apply to both individuals and organizations that do not comply with the regulatory requirements. Currently, all registered UGA campuses report to the CDC. All PIs must communicate with the RO on any issue related to select agents, such as possession, use, transport, destruction, etc. To ship or receive a select agent or toxin, contact the RO for further information. The federal government requires the RO be involved in any transportation process along with the facility reporting agency (CDC).

Following DOT regulations and IATA guidelines, biological materials, when shipped, will fall under any of the following categories:

- Unregulated biological material
- Category A infectious substance
- Category B infectious substance
- Patient specimen
- Genetically modified organism
- Material with low probability of containing infectious disease or where the concentration is at a level naturally occurring in the environment so it can not cause disease with exposure (foodstuff, environmental samples like water, dust, mold).
- Biological product, including an experimental or investigational product or component of a product, subject to federal approval, permit, review or licensing requirements such as those required by the FDA or USDA.

Back to table of contents

D. Requirements for Shipping Biohazardous Materials and Dry Ice

Biohazardous materials must be transported in accordance with Department of Transportation (DOT) requirements, 49 CFR, and the International Air Transport Association (IATA) Hazardous Materials Regulations. All dangerous goods, including biohazardous agents and dry ice, under DOT/IATA regulations, must be properly classified, packaged, documented and handled by trained personnel. A trained point of contact must be available 24 hours a day from the time the shipment leaves until it arrives at its location. Specialized dangerous goods training is required of anyone who directly affects hazardous materials transportation (including people who package, manage shipping papers, maintain

emergency response information, ship or transfer and receive a dangerous goods package). Training must include general awareness and hazard familiarization, job function-specific training, and safety and security training. Training records must be maintained for a minimum of five years and training must be provided every three years for ground transportation (DOT) and every two years for air and international transportation (IATA includes air, rail, sea, road transportation). Non-compliance can result in federal citations, fines and suspension of shipping privileges.

Shipping must be through a commercial company that allows for tracking capabilities. Maintain copies of all shipping records including tracking of materials to arrival on file with PI for a minimum of five years. Commercial Shippers include:

- DHL – will accept all shipments made according to DOT/IATA regulations
- FedEx – will accept all shipments except BSL-4 agents and Select Agents and Toxins.
- World Carrier will accept all shipments made according to DOT/IATA regulations
- UPS – will not accept Category A materials but will accept Category B shipments and exempt patient specimens
- United States Postal Service (USPS) – is highly restrictive for shipments of hazardous materials by mail. They will not accept Category A materials but will accept Category B and exempt patient specimens. Category B shipments and exempt patient specimens will require stricter packaging and labeling requirements than the standards have established. Contact USPS for requirements before shipping through them.

Back to table of contents

E. Off-Campus Transport of Biohazardous Materials by Non-Commercial Routes

University of Georgia personnel may transport biohazardous materials by non-commercial routes only in University vehicles dedicated for that transport. Personal vehicles may not be used due to insurance coverage limitations. Some materials may never be transported via non-commercial routes. For assistance call the Office of Biosafety.

Back to table of contents

F. Transportation Security Plan

Prior to shipping a package with infectious substances or dry ice, make a thorough assessment of vulnerabilities in the shipping process. Track items through a reliable carrier (which are listed within this manual). Ensure that recipients are prepared and ready for the arrival of any shipment you are sending out. Ensure that any shipments that your laboratory or facility will be obtaining are on track and someone appropriately trained is available to receive the package on arrival. Storage areas for infectious agents should be locked and inspected regularly. Inventories for materials should be kept up to date and accurate. In sensitive areas, personnel will be reviewed prior to hire through the UGA background check process and access control measure will be taken as applicable. Such access control measure to area with sensitive access will be documented.

Back to table of contents

XII. Insect and Rodent Control

The lab environment shall be maintained in such a way as to make it less conducive to pest infestation.

- Good housekeeping practices will be followed to reduce clutter and pest habitat. Strict sanitation practices will be followed to reduce pest possible nutrition sources (culture media, blood and tissue samples, etc.).
- Structural deficiencies will be repaired as discovered (door sweeps, wall damage, etc.).
- Laboratory personnel will report the sighting of any pests in or near the laboratory.
- Monitoring is the central activity of pest management and is used in place of preventive pesticide treatments.
- If pest problems arise, the University of Georgia has a contracted pest control company which visits the campus on a regular basis. The PI or designated personnel will contact FMD at 706-542-0293 to schedule a time for a representative to come to the lab to inspect the lab for pest control problems and solutions. The lab will keep a log of pest activity and procedures used to control pest problems.

Back to table of contents

XIII. Disposal and Disinfection of Biohazardous Materials

Biohazardous materials used in teaching and research laboratories at the University fall under the State of Georgia Biomedical Waste Rules (391-3-4-.15).

Back to table of contents

A. Biomedical waste means:

- pathological waste
- biological waste
- sharps
- chemotherapy waste
- contaminated, discarded equipment that was in contact with infectious agents, contaminated animal carcasses, body parts, bedding or wastes from infected animals
- cultures and stocks of infectious agents and associated biologicals from medical, pathological, research and industrial laboratories
- waste from production of biologicals
- discarded live and attenuated vaccines or
- culture dishes and devices used to transfer, inoculate and mix cultures.

Storage and containment of biomedical waste will be in a manner and location that protects materials from animals, rain and wind, does not provide a breeding place or a food source for insects and rodents, and minimizes exposure to the public.

Biomedical waste, except for sharps, must be placed in containers, lined with double autoclaved bags, which are impervious to moisture and have sufficient strength to preclude ripping, tearing, or bursting under normal conditions of use. For single bagging autoclave bags must be at least 3.0 mil thick. Sharps shall be contained for storage, transport, treatment and subsequent disposal in leak-proof, rigid, puncture-resistant containers which

are taped closed or tightly lidded to prevent loss of contents. Containers will be securely closed so as to prevent leakage or expulsion of contents during storage, handling, or transport. All containers used for contaminated biological waste must be clearly identified with the universal biohazard symbol or clearly marked with the word "Biohazard".

Biomedical waste placed in storage for handling or transport must be placed in secondary containers as well, either disposable or reusable pails, cartons, boxes, drums, dumpsters, or portable bins. These secondary containers shall be conspicuously labeled with the universal biohazard symbol and the word "Biohazard" on the sides so as to be readily visible from any lateral direction when the container is upright.

All cultures, stocks, and other potentially infectious materials should be decontaminated before disposal using an effective method. If treated in accordance with methods as described within the State of Georgia biomedical waste regulations, the waste shall no longer be considered biomedical waste and may be combined and handled as regular solid waste.

Biomedical waste consisting of recognizable human anatomical remains will not be disposed of in the landfill. Chemotherapy waste will be treated at a permitted incinerator or other facility approved by the Department of Natural Resources Director. Steam sterilization may not be used to treat chemotherapy waste. Unused chemotherapeutics should be tagged as hazardous chemical waste. Gloves, empty containers from chemotherapeutics, medical devices other products contaminated with chemotherapeutic agents will be disposed of as biomedical waste.
Back to table of contents

B. Treatment methods described within the state biomedical waste regulations:

Incineration

Incineration provides complete combustion of waste to render it nonpathogenic. Biomedical waste incinerators must be capable of maintaining an appropriate temperature in the primary chamber sufficient to destroy infectious agents and to produce a residue essentially free of odors and unstable organic matter. If chemotherapy wastes are incinerated, the incinerator must be capable of maintaining a minimum of 1800° F in the secondary combustion chamber and a minimum residence time of two seconds. Atmospheric emissions must be controlled so they do not exceed the air quality standards of the State Department of Natural Resources (DNR).

Heating with Steam Under Pressure

Autoclaves and effluent decontamination systems provide decontamination by heating with steam under pressure (typically an autoclave) so as to render the biomedical waste noninfectious. A recording thermometer must be used during each cycle to ensure the attainment of a temperature of 121°C (250°F) for 30 minutes or longer to achieve decontamination of the entire load.

Elements Required for Effective Autoclave Use

Autoclaves must be properly used to effectively sterilize their contents. Autoclave use for microbiological media preparation requires various time and temperature settings for sterilization; therefore, individual trials should be done to determine the proper loading and time settings to determine adequate sterilization.

When autoclaving biohazardous waste, take into account the volume of waste and the ability of steam to penetrate the load. Vials of biological indicators can be placed inside of a load to determine if lab specific settings are appropriate. Minimum autoclave cycle time for a light load of biohazardous waste is 30 minutes at 121°C, 15psi. The following parameters contribute to autoclave effectiveness:

- *Temperature*: unless specifically instructed by media manufacturers' directions, autoclave chamber temperature should be at least 121°C (250°F). Prions require higher autoclave temperatures but alternate disposal methods (e.g. incineration) for prions should be considered in the risk assessment. Contact the Office of Biosafety for assistance.
- *Time*: cycle time will vary according to the contents of the autoclave. If media is to be prepared, the manufacturers' instructions should be followed. An adequate autoclave time for biohazardous waste is a minimum of 30 minutes, measured after the temperature of the material being sterilized reaches 121°C and 15 psi pressure. The more waste being autoclaved, the longer it will take to reach 121°C in the center of the load. Care must be taken to ensure the autoclave is not overloaded with waste material.
- *Steam Contact*: steam saturation of the load is essential for effective decontamination. Air pockets or insufficient steam supply will prevent adequate saturation. To ensure adequate steam contact, leave autoclave bags partially open (2-3 inches) during autoclaving to allow steam to penetrate into the bag. The addition of a small amount of water inside the bag before autoclaving will help ensure heat transfer to the items being decontaminated (do not add water if it will cause biohazardous materials to splash out of the bag).
- *Containers*: use leak-proof autoclavable containers only. Always consider substitutes for glassware when selecting containers. Plastics such as polypropylene, polypropylene copolymer or fluoropolymer products are capable of being autoclaved repeatedly. Place non-borosilicate glass bottles in a tray of water to help prevent heat shock. Place plastic bags inside a secondary container in the autoclave in case liquids leak out. Autoclavable plastic or stainless steel containers are appropriate secondary containers. Make sure plastic bags and pans are autoclavable to avoid melting.
- *Autoclave cycle verification:* validation of load is required through the use of an autoclave log and an indicator of some type. Various indicators can be used with loads or separately to indicate that various test parameters have been met. With each load, chemical indicators will be used that test for the presence of heat, pressure and the presence of steam be utilized and attached to the daily use log. Chemical indicators are available through most scientific vendors and a sample autoclave log is available through the Office of Biosafety. Biological indicators (i.e. *Geobacillus stearothermophilus*) and certain chemical indicators (i.e. Sterigage) verify that the

autoclave reached adequate temperature for a long enough time to kill microorganisms. Autoclave print outs should also be maintained.

- *Autoclave validation:* biological indicators (BI) should be used annually at a minimum for performance verification. *Geobacillus stearothermophilus* spore strips or spore suspensions are the typical product of choice for BI challenges. The BI should be placed in one or more points within autoclave in a simulated load for quality assurances. For larger autoclaves, we recommend placing on BI in the center of the load and another near the drain as the weakest point in the system. Document the biological indicator results in a log book or other suitable form and maintain those records with the autoclave log in the lab. All autoclave records should be maintained for a minimum of three years. The Office of Biosafety will provide the autoclave validations. Each PI is responsible for contacting the Office of Biosafety to have their autoclave re-validated annually or after any repairs to the autoclave.

Once autoclaved waste has cooled and the run validated and logged, waste must be placed into a black garbage bag before being placed in the dumpster. It is not the responsibility of the custodial staff to transport the autoclaved waste tot the dumpster, it is the responsibility of the researcher.

Chemical Treatment

Fluid or semisolid waste not steam sterilized will be chemically treated before drain disposal as required by the local sewage treatment system. If chemical treatments and steam sterilization are not an option, alkaline hydrolysis or incineration may be the alternative method of treatment.

Items that cannot be autoclaved can generally be decontaminated using a chemical disinfectant. The choice of chemical disinfectant depends on the surface or item needing decontamination, as well as the particular organism requiring inactivation. When choosing a chemical disinfectant, refer to the agent summary sheet, if available, for information. The categories of disinfectants listed in this section and the disinfectant product label must be reviewed. Contact the Office of Biosafety for assistance in a waste solution assessment.
Back to table of contents

C. Types of Chemical Disinfectants

The following are outlines of the basic properties and examples of the most common categories of chemical disinfectants, including alcohols, chlorine compounds, liquid formaldehyde, glutaraldehyde, iodophors, peracetic acid, phenolic compounds, and quaternary ammonium compounds. Adequate contact time is very important to ensure complete disinfection. Contact time varies with the type of material being disinfected.

Alcohols

Most effective against lipophilic viruses, less effective against non-lipid viruses, and ineffective against bacterial spores. Effective concentration is 70% to 90%. Evaporates quickly, so sufficient contact time may be difficult to achieve. Concentrations above 90% are

less effective because of increased evaporation rate. Ensure fresh solutions are prepared as needed.

Chlorine compounds
Solutions of 50 – 500 ppm available chlorine are effective against vegetative bacteria and most viruses. Bacterial spores require concentrations of 2,500 ppm with extended exposure time. Prions require 20,000 ppm with extended exposure time. A 5,000-ppm available chlorine solution is preferred for general use since excess organic materials inactivate chlorine compounds. This type of solution is made by diluting household bleach 1:10 with water. For use in the laboratory, bleach solution should be prepared fresh daily or each use. Air and light inactivate diluted solutions, so solutions must be freshly made in order to maintain adequate available chlorine concentrations. These solutions should be stored in an airtight, opaque container out of the light. Strong oxidizers are very corrosive to metal surfaces, as well as to skin, eyes and respiratory tract.
Formaldehyde, liquid
Effective against vegetative bacteria, spores and viruses. Effective concentration is a 5-8% solution of formalin (formaldehyde in water; made by diluting a 37% solution). It is a suspected human carcinogen and can cause respiratory problems at very low concentrations. Inhalation limits are 2 ppm for 15 minutes, 0.75 ppm for 8 hours of exposure. It has an irritating odor and is a sensitizer, so a potential exists for developing allergic reactions.

Glutaraldehyde mixtures (for example, Cidex, Sporicidin and 3M Glutarex)
Effective against vegetative bacteria, spores and viruses (more so than formaldehyde). The effective concentration is 2%. Chemically related to formaldehyde, its vapors are irritating to the eyes, nasal passages and upper respiratory tract.

*Iodophors (*organically bound iodine compounds, for example, Wescodyne diluted 1:10 is a popular hand washing disinfectant)
Effective against vegetative bacteria and viruses, but not against bacterial spores. The effective concentration is 75-150 ppm. It is relatively nontoxic to humans, so it is often used as a general disinfectant in antiseptics and surgical soaps. It has a built-in indicator for activity. If the solution is brown or yellow, it is active. Sodium thiosulfate solution can be used to readily inactivate iodophors and remove iodophor stains.

Peracetic acid (used most commonly to sterilize gnotobiotic animal-holding chambers and equipment)
Effective against bacteria, viruses, fungi and bacterial spores. Very powerful and fast-acting. The effective concentration is 2% in water, or 0.08% solution in 10-20% ethanol. The ethanol solution has fewer adverse properties than the 2% solution in water. It is received as a 40% concentrated solution, which can explode if contaminated with heavy metals or reducing agents, or if rapidly heated. It is flammable and must be refrigerated. It is a potent respiratory irritant requires a respirator for use. It is corrosive to metal surfaces. Dilute solutions degrade rapidly, so it must be freshly prepared for use.

Phenolic compounds (for example, Vesphene II, commonly used for disinfecting contaminated walls, floors and bench tops)
Effective against vegetative bacteria, including mycobacterium tuberculosis, fungi and lipophilic viruses, not effective against spores and non-lipid viruses. Effective concentrations are 0.5-2.0%. It has an unpleasant odor and is toxic. It is an irritant to the eyes, skin, respiratory tract and gastric tract.

Quaternary Ammonium compounds (cationic detergent (surfactant) with strong surface activity, commonly referred to as "Quats"33)
Effective against fungi, Gram-positive bacteria and lipophilic viruses, but less effective against Gram-negative bacteria. It is ineffective against hydrophilic viruses or bacterial spores. Quats mixed with phenolics are very effective disinfectants, as well as cleaners. The usual effective concentration is 1:750. It is relatively nontoxic and is acceptable as a general disinfectant for general cleaning or decontaminating food equipment. It is easily inactivated by organic materials, anionic detergents (soaps), or salts of metals found in hard water.
Back to table of contents

D. Biological Toxin Inactivation
Refer to the following tables for complete inactivation of different toxins:
30 Minute Exposure Time to Sodium Hypochlorite (NaOCl) With or Without Sodium Hydroxide (NaOH)

Toxins	2.5% NaOCl +0.25 N NaOH	2.5% NaOCl	1.0% NaOCl	0.1% NaOCl
T-2 Mycotoxin	YES	NO	NO	NO
Brevetoxin	YES	YES	NO	NO
Microtoxin	YES	YES	YES	NO
Tetrodotoxin	YES	YES	YES	NO
Saxitoxin	YES	YES	YES	YES
Palytoxin	YES	YES	YES	YES
Ricin	YES	YES	YES	YES
Botulinum	YES	YES	YES	YES
Staphylococcal Enterotoxins	YES (?)	YES (?)	YES (?)	YES (?)

Autoclaving or 10 Minute Exposure to Dry Heat

		Dry Heat			
Toxins	**Autoclave**	**200°C**	**500°C**	**1000°C**	**1500°C**
T-2 Mycotoxin	NO	NO	NO	NO	YES
Brevetoxin	NO	NO	NO	NO	YES
Microtoxin	NO	NO	YES	YES	YES
Tetrodotoxin	NO	NO	YES	YES	YES

Saxitoxin	NO	NO	YES	YES	YES
Palytoxin	NO	NO	YES	YES	YES
Ricin	YES	YES	YES	YES	YES
Botulinum	YES	YES	YES	YES	YES
Staphylococcal	YES (?)	YES (?)	YES (?)	YES (?)	YES (?)

Reference*: Robert W. Wannemacher, Ph.D., Assistant Chief, Toxicology Division, US Army Medical Research Institute of Infectious Disease*

- For T-2 mycotoxin and brevetoxin, it is recommended that, for complete inactivation, all liquid samples, accidental spills, and non-burnable waste be soaked in 2.5% sodium hypochlorite with 0.25N sodium hydroxide for 4 hours. It is further recommended that cages and bedding from animals exposed to T-2 mycotoxin or brevetoxin be exposed to 2.5% sodium hypochlorite and 0.25N sodium hydroxide for 4 hours.
- Exposure for 30 minutes to 1.0% sodium hypochlorite is an effective procedure for laboratory (working solutions, equipment, animal cages, working area and spills) for inactivation of saxitoxin, tetrodotoxin, microcystin, palytoxin, ricin, botulinum toxin or staphylococcal enterotoxins (SEB).
- All burnable waste from toxins should be incinerated at temperatures in excess of 1500°F.
- Autoclaving can be used with protein toxins (Ricin, Botulinum toxin and SEB) but should not be used with any of the low molecular weight toxins.
- Tap water with normal chlorination is not a useful medium for inactivation of any of these toxins.
- Stability at high and low pH varies with the toxin used and is not a universal procedure for inactivation of toxin waste.
- If the skin is accidentally exposed to toxins, it is recommended that it be washed immediately with soap and water.
- Chemical hygiene plans with procedures to prevent contamination of personnel and equipment with these toxins should be established.

Back to table of contents

E. Prion Inactivation

Prions are resistant to conventional inactivation protocols such as irradiation, dry heat, boiling and chemical treatment. The use of conventional autoclave usage for waste management has not resulted in complete inactivation of prions. According to the 5th edition of the BMBL, the safest and most unambiguous method for ensuring that there is no risk of residual infectivity on contaminated instruments or other materials containing prions is to discard and destroy through incineration. Current recommendations for inactivation of prions on instrumentation or other materials is based on use of sodium hypochlorite, sodium hydroxide, Environ LpH and the moist heat of autoclaving with combinations of heat and chemical being most effective.

Five Options for Prion Inactivation for Reusable Instruments and Surfaces

1. Immerse in 1N NaOH, and heat in a gravity displacement autoclave at 121°C for 30 minutes. Clean and sterilize by conventional means.
2. Immerse in 1N NaOH or sodium hypochlorite (20,000ppm) for 1 hour. Transfer into water and autoclave (gravity displaced) at 121°C for 1 hour. Clean and sterilize by conventional means.
3. Immerse in 1N NaOH or sodium hypochlorite (20,000ppm) for 1 hour. Rinse instruments with water, transfer to open pan and autoclave at 121°C (gravity displacement) or 134°C (porous load) for 1 hour. Clean and sterilize by conventional means.
4. Surfaces or heat-sensitive instruments can be treated with 2N NaOH or sodium hypochlorite (20,000ppm) for 1 hour. Ensure surfaces remain wet for entire time period, then rinse well with water. Before chemical treatment, it is strongly recommended that gross contamination of surfaces be reduced because the presence of excess organic material will reduce the strength of either NaOH or sodium hypochlorite solutions.
5. Environ LpH (EPA Reg. No. 1043-118) may be used on washable, hard, non-porous surfaces (such as floors, tables, equipment, and counters), items (such as non-disposable instruments, sharps, and sharp containers), and/or laboratory waste solutions (such as formalin and other liquids). This product is currently being used under FIFRA Section 18 exemptions in a number of States. Users should consult with the Environmental Safety Division prior to use.

Working solutions of 1N NaOH equals 40grams per liter of water. Solutions should be prepared daily. A stock solution of 10N NaOH can be prepared and fresh 1:10 dilutions (1 part 10N NaOH plus 9 parts water) used daily.

20,000ppm sodium hypochlorite equals a 2% solution. Most commercial household bleach contains 5.25% sodium hypochlorite, therefore, makes a 1:2.5 dilution (1 part 5.25% bleach plus 1.5 parts water) to produce 20,000ppm solution. This ratio can be stated as two parts 5.25% bleach to three parts water. Working solutions should be prepared daily.

Such solutions described above are corrosive and require suitable PPE and secondary containment. Consult the UGA Chemical and Laboratory Safety Office for assistance. Appropriate disposal of corrosive solutions requires coordination with the UGA ESD Hazardous Materials Office.

Precautions in Using NaOH or Sodium Hypochlorite Solutions in Autoclaves:
NaOH spills or gas may damage the autoclave if proper containers are not used. The use of containers with a rim and lid designed for condensation to collect and drip back into the pan is recommended. Caution must be taken when handling hot NaOH solutions (post-autoclave) and in avoiding potential exposure to gaseous NaOH. Exercise caution during all sterilization steps and allow autoclave, instruments and solutions to cool

down before removal. Immersion of sodium hypochlorite bleach can cause severe damage to some instruments.

USDA Recommendations for Inactivation of Prions Affecting Livestock

1. Use porous load autoclaving at 134°C-138°C at 30 psi for 18 minutes holding time at temperature (does not include warm-up and cool-down). (Please note that this practice is consistent with USDA requirements for prions affecting animals, but not BMBL recommendations for prions affecting humans.)
2. Soak ground samples in 40% household bleach (5.25% sodium hypochlorite) to provide 20,000 ppm available chlorine (prepared freshly at time of use). Soak for minimum of one hour at 20°C.
3. Non-disposable instruments should be soaked in 40% household bleach for one hour, then rinsed with water and autoclaved (porous load) at 134°C for one hour.
4. Wash all surfaces with 40% household bleach, soaking for 60 minutes, then rinse with water. Note: Some surfaces are prone to corrosion from prolonged exposure to these chemicals, so rinsing is very important.

Back to table of contents

XIV. Quick Reference Guide to Federal and State Regulations by Topic

The following federal and international regulations and guidelines apply to work performed with potentially biohazardous materials.

A. Animals, Animal Pathogens or Animal Products

U.S. Department of Agriculture (USDA) regulations for animals and animal products include 9 CFR Parts 001-199

- Import/transport permits are issued by the Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) branch
- The Office of Biosafety can provide assistance.

USDA Agricultural Bioterrorism Protection Act of 2002; Possession, Use and Transfer of Biological Agents and Toxins, regulated under 9 CFR Part 121 and 7 CFR Part 331

- PIs must register through the UGA Responsible Official (RO) for the possession and transfer of pathogens or biological toxins defined under these rules
- The University of Georgia's reporting agency for any select agent or toxin is the CDC although the USDA VS Select Agents Program will coordinate with the CDC for comprehensive oversight
- Researchers must communicate with the federal government through their RO. Call (706) 542-7265 for assistance at UGA.
- The CDC and USDA share a website called the National Select Agent Registry (NSAR) for more information.

B. Biological Safety Cabinets (BSCs)

National standards for construction, testing and maintenance of Biological Safety Cabinets (BSCs) is the National Sanitation Foundation (NSF) Standard 49/2002 for the Evaluation of Class II Laminar Flow Biological Safety Cabinets

- Information on the NSF Biohazard Cabinetry Program, which sets the criteria for standard methods by which biosafety cabinets are to be tested in order to be certified is available on their website.
- For human, plant or animal pathogens (BSL-2), select agents and toxins, work involving rDNA BL2 or higher, and all BSL-3 laboratories, UGA requires annual testing with NSF certifiers and companies approved for work by the Office of Biosafety.
- For information and assistance, call the Office of Biosafety at (706) 542-2697

C. Human Blood, Other Potentially Infectious Human Body Fluids or Tissues, and Human Cell Lines

U.S. Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard (29 CFR 1910.1030)

- For research laboratories working with known blood-borne pathogens, an exposure control plan providing oversight on this program is included in this manual as an appendix.
- Online BBP training for all scientific staff is available on the Biosafety website.
- For assistance, contact the Office of Biosafety.

D. Human Pathogens and Biological Toxins

General guidance is provided through the 5th Edition of the BMBL. Other guidelines utilized include the NIH Guidelines for Research Involving Recombinant DNA and ACME/ASTMH Arthropod Containment Guidelines (Version 3.2).

- This manual's general contents are based on the 5th edition of the BMBL
- Quick safety references for a number of human pathogens are available within the BMBL
- Safety datasheets are for human pathogens are available through the CDC website and the Public Health Agency of Canada.

U.S. Public Health Service (USPHS) Foreign Quarantine and Etiologic Agents, Hosts, and Vectors (Part 71.54) Regulations include 42 CFR Part 71

- CDC Importation Permits for Etiologic Agents
- For assistance, contact the Office of Biosafety.

CDC provides regulatory oversight on human pathogens and biological toxins defined under Possession, Use and Transfer of Select Agents and Toxins in 42 CFR Part 73

- PIs must register through the UGA Responsible Official (RO) for the possession and transfer of pathogens or biological toxins defined under these rules
- The University of Georgia's reporting agency for any select agent or toxin is the CDC although the USDA VS Select Agents Program will coordinate with the CDC for comprehensive oversight
- Researchers must communicate with the federal government through their RO. Call (706) 542-7265 for assistance at UGA.
- The CDC and USDA share a website called the National Select Agent Registry (NSAR) for more information.

E. Plants, Plant Pests, Plant Pathogens, Noxious Weeds and Soil

USDA Regulations for the Import and Export provided under Title 9 CFR Parts 300-399

- Import/export permits issued by the APHIS Plant Protection and Quarantine (PPQ) branch.
- For export of plant materials, plant pests, plant pathogens, or soil samples, check with Biosafety for permit requirements or to determine whether a phytosanitary certificate is needed prior to shipping.
- For assistance, contact the Office of Biosafety.

USDA Introduction of Genetically Engineered Organisms (GMO) Regulations provided under 7 CFR 340.0-340.9

- Biotechnology transport, introduction and import permits issued by the APHIS Biotechnology Regulatory Services (BRS) branch
- Use this link for information on labeling and packaging of GMO material prior to shipping.
- Permits required for field testing of Genetically Modified Plants.
- For assistance, contact the Office of Biosafety.

F. Recombinant DNA, Transgenic Plants and Transgenic Animals

NIH Guidelines for Research Involving Recombinant DNA Molecules

- NIH requirements for all research involving rDNA if any federal funding is awarded for any such research at the institution.
- Provides for the guidelines for IBCs and the establishment of a Biosafety Officer.
- IBC Charter provided for in this manual.
- Biosafety Considerations for Research with Lentiviral Vectors.

G. Shipping Biohazardous Materials

U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration (DOT PHMSA), Hazardous Materials Regulations (49 CFR 100-185)

- Federal requirements for transport of any hazardous material. Biological hazards fall under Dangerous Goods section.
- Federal Aviation Association (FAA) Guidelines/Regulations
- For assistance with infectious agents, biological materials and dry ice, contact the Office of Biosafety. Other Dangerous Goods questions should be directed to the Environmental Safety Division.

International Civil Aviation Organization (ICAO) Technical Instructions on the Safe Transport of Dangerous Goods by Air

- An international organization that provides requirements for air transport of hazardous materials.
- Purchasing information available online.

International Air Transport Association Dangerous Goods Regulations

- Manual for international air transport of hazardous materials, based on the ICAO's Technical Instructions on the Safe Transport of Dangerous Goods by Air. Purchasing information available online (IATA DGR)
- For assistance in shipping dangerous goods classified as infectious agents or dry ice, contact the Office of Biosafety. All other dangerous goods inquiries should be directed to the Environmental Safety Division.

Certified packaging materials for Dangerous Goods Shipping
SAF-T-PAK www.saftpak.com
DGS Supplies, Inc http://www.dgsupplies.com/ (now https://us.shop.rigidcontainer.inmarkinc.com/)

H. Biohazardous Waste Disposal

U.S. Environmental Protection Agency (EPA) Hospital/Medical/Infectious Waste Incinerators Regulations (40 CFR Parts 60 and 62).

- Performance standards for hospital/medical/infectious waste incinerators constructed after June 20, 1996.
- Emissions requirements for hospital, medical and infectious waste incinerators.
- Federal plan requirements for hospital, medical, infectious waste incinerators constructed after June 20, 1996.

State of Georgia Department of Natural Resources (DNR) Environmental Protection Division (EPD) manages State Solid Waste Regulations, Rule 391-3-4-.15, Biomedical Waste.

- Defines disposal methods for biomedical wastes.
- Provides definition and disposal requirements for sharps.
- Contact the Office of Biosafety for assistance.

Back to table of contents

XV. DEFINITIONS

Biohazardous Material: materials of biological origin that have the potential to cause harm to humans, plants, or domestic or wild animals. Biohazardous materials can include the following: recombinant DNA; transgenic animals or plants; human, animal or plant pathogens; biological toxins (such as tetanus toxin); human blood and certain human body fluids; and human or primate cell cultures.

Biomedical Waste: as defined by the State of Georgia biomedical waste regulations (391-3-4-.15) includes the following:

Pathological wastes – all recognizable human tissues and body parts except teeth which are removed during surgery, obstetrical procedures, autopsy, and laboratory procedures.

Biological wastes – human blood and blood products, exudates, secretions, suctionings, and other body fluids which contain free liquids and cannot be or are not directly discarded into a municipal sewer system.

Cultures and stocks from infectious agents and associated biologicals including cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures.

Contaminated animal carcasses, body parts, their bedding, and other wastes from such animals which are infected with or which have been exposed to infectious agents, capable of causing disease in man.

Sharps – any discarded article that may cause punctures or cuts. Such wastes include, but are not limited to, needles, IV tubing and syringes with needles attached, and scalpel blades.

Chemotherapeutic waste – any disposable material which has come in contact with cytotoxic/antineoplastic agents (agents toxic to cells) and/or antineoplastic agents (agents that inhibit or prevent growth and spread of tumors or malignant cells) during the preparation, handling, and administration of such agents. Such wastes include, but are not limited to, masks, gloves, gowns, empty IV tubing bags and vials, and other contaminated materials. The above waste must first be classified as empty which means such quantity that it is not subject to other federal or state waste management regulations prior to being handled as biomedical waste.

Discarded medical equipment and parts, excluding expendable supplies and materials included in other biomedical wastes, which have not been decontaminated, and that were in contact with infectious agents.

Recombinant and Synthetic DNA Molecule:

(i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids; (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or (iii) molecules that result from the replication of those described in (i) or (ii) above. Back to table of contents

Date	Page #	Description of Revisions	Revised by	Reason for revisions
10/25/2016	all	Update material	Andrea Ferrero- Perez Patrick Stockton Nancy Mead	Document was due for updating information and policies for PIs and lab supervisors.
04/13/2020	all	Revision	Molly Smith Andrea Ferrero-Perez Patrick Stockton Nancy Mead	Document was due for revision.
