Environmental Health and Safety

BIOLOGICAL SAFETY GUIDE

Version 2.1 – Revised April 2017

Biological Safety Office
Environmental Health and Safety Division
1405 Goss Lane
Augusta, GA 30901
706-721-2663
biosafety@augusta.edu

TABLE OF CONTENTS

INTRODUCTION

Purpose

This Biosafety Guide has been developed by the Division of Environmental Health and Safety (EH&S) Biosafety Office and the Institutional Biosafety Committee (IBC) at Augusta University. This Guide is part of the Augusta University Biosafety Program instituted to accomplish the following goals:

- Protect personnel from exposures to biological agents;
- Prevent environmental contamination;
- Provide an environment for high quality research while maintaining a safe work place;
- Comply with applicable federal, state and local regulations and guidelines, and;
- Create a secure laboratory environment to prevent unauthorized utilization of a biological agent.

Scope

The Biosafety Guide and Biosafety Program is applicable to all personnel who are engaged in research or instructional activities where biological materials are used or the potential for exposure to biological materials exists. This guide focuses on Biosafety Levels (BSL) 1 and 2. No work which will require BSL3 or BSL4 containment shall be conducted at Augusta University.

Accessibility

- The Biosafety Guide shall be maintained by the EH&S Biosafety Office.
- It shall be made available upon request and is readily accessible from the Biosafety webpage.

Review/Revision

- The Biosafety Guide shall be reviewed and updated annually or as needed to reflect new procedures or standards.
- All requests for changes to this manual shall be submitted to the Biosafety Office for consideration.

Usage

The Biosafety Guide primarily follows the guidance of the following regulatory/guidance sources:

- Federal Select Agent regulations for use, possession and transfer of Select Agents and Toxins.
- U.S. Department of Transportation Regulations, U.S. Public Health Service and IATA guidelines for shipping and/or transport of hazardous or etiological materials.
- U.S. Departments of State, Commerce and Treasury Regulations related to Export control laws.
- U.S. Department of Agriculture Animal and Plant Health Inspection Service Regulations related to transportation, importation or exportation of animal or animal products, genetically engineered organisms, plants or plant products and/or soil samples.
- U.S. Public Health Service importation and/or exportation requirements for Etiologic Agents, any arthropod and/or other animal host or vector of human disease, including unsterilized specimens of human and animal tissues (such as blood, body discharges, fluids, excretions or similar material) containing an infectious or etiologic agent.
- Georgia and OSHA standards for bloodborne pathogen handling, medical surveillance, training and record-keeping.
- Georgia EPD Solid Waste Management Laws for Biomedical Waste.
- The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids.
- CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories. 5th Edition.

Additional sources used will be cited throughout the Biosafety Guide. When the BMBL or other regulatory/guidance documents do not adequately address the hazards associated with a particular agent or process, University-recognized IBC or Biosafety guidance documents shall be used. The content of the Biosafety Guide will be discussed briefly during Initial Biosafety and Bloodborne Pathogen training; however, it is the responsibility of each researcher or instructor to be aware of the full content of the guide.

CHAPTER 1 – ROLES AND RESPONSIBILITIES

Implementation of an effective Biosafety Program is a cooperative effort between the Department Chairperson and/or Center/Institute Director, the Principal Investigator/Instructor/Clinical Director, laboratory personnel/students, the Biosafety Office and the Institutional Biosafety Committee (IBC). The following is a list of assigned or expected roles and responsibilities that will ensure that the Biosafety Program is successfully implemented.

Department Chairperson and/or Center/Institute Director

The Department Chairperson and/or Center/Institute Director bears overall responsibility for the implementation and maintenance of safe practices and procedures in the department. Department/Center/Institute Heads have the following responsibilities:

- To ensure that each Principal Investigator/Course Instructor has received approval from the Biosafety Office or the IBC prior to initiation of work.
- To ensure that students, staff and faculty within their department/center/institute have had instruction in safety procedures in research and teaching laboratories where biological agents present.
- To ensure that resources are made available to researchers, laboratory and/or clinic staff, instructors and/or students who require health screening and/or vaccination due to potential risk of exposure to particular biological materials.
- To assume responsibility for maintaining the appropriate Biosafety standards and documentation of shared departmental facilities or delegate that responsibility to an appropriate faculty member within the department.
- To provide leadership in laboratory, classroom or clinic safety at the management level in the department, center or institute.

Principal Investigators, Clinical Directors, Course Instructors

The Principal Investigator (PI), Clinical Director or Course Instructor bears the ultimate responsibility and authority for:

- Maintaining compliance with Federal, State and Local regulations and guidelines, Augusta University policies and procedures and industry standards related to possession, use, transfer and/or disposal of biohazardous materials in consultation with the Biosafety Office. This includes, but is not limited to, the following regulations, guidelines and standards:
- Performing a risk assessment of research projects or instructional activities. The risk assessment should include an analysis of the risks posed by the organism(s) and other factors that may affect that risk (i.e. procedures, experience, and health status). Each assessment should be completed before work is undertaken and the project should be reassessed periodically as new data is obtained.
- Registering biological materials with the Biological Safety Office. Biological materials must be registered by completing a Biosafety Protocol (BSP) or Clinical Biosafety Protocol (CBSP) application. Research or instructional activities shall not be initiated without review and approval from the Biosafety Office or the IBC. Modifications to the original application to include changes in agents, personnel, procedures, equipment or locations must be submitted as an amendment(s) to the Biosafety Office.
- Establishing laboratory and/or agent specific safety practices and procedures prior to bringing new biological agents to campus and/or before initiating any new research project (independent of funding status). This involves:
- Being knowledgeable of good laboratory practices and maintaining current knowledge of new safety practices and/or equipment which may improve safety within the laboratory.
- Demonstrating a positive safety attitude.
- Developing Standard Operating Procedures (SOPs) that are easily available to laboratory staff and students.
- Supervising and monitoring the performance of the staff to ensure that required safety practices and techniques are employed.
- Providing documented laboratory and/or agent specific training, in addition to general safety training provided by the Biosafety Office. Ensuring that laboratory staff and students complete the Biosafety Office and IBC-required training modules.

- Informing the laboratory staff and students of the risks involved with the biological agents in the laboratory, the reasons and provisions for any precautionary medical practices (e.g. physical examinations, serum collection, and vaccinations), and the procedures for dealing with accidental spills, personnel contamination, and other laboratory accidents or emergencies.
- Reporting any accident, potential exposure, suspected illness, release from containment of any biohazardous agents or any significant problems pertaining to the operation and implementation of containment practices, procedures or facilities to the Biosafety Office.

Laboratory/Clinical Staff and Students

Laboratory/Clinical staff and students are responsible for:

- Completing all requirements for approval to work in the laboratory (i.e. training, safety checklist, immunizations, etc.).
- Knowing the potential hazards associated with the agents and procedures used in the laboratory or classroom setting.
- Receiving training prior to initiating work, if inexperienced in handling animals, human materials, recombinant or synthetic nucleic acids, nanomaterials, tissue culture and/or unfamiliar laboratory techniques.
- Implementing the laboratory-specific Standard Operating Procedures (SOPs) for work with biological materials. Report to the PI or Course Director any practice indicated in the SOPs that is impossible, impractical or requires amending to allow the PI or Course Director to amend their SOPs to accurately reflect the practices within the laboratory or classroom setting.
- Familiarizing yourself with emergency procedures (i.e. in the flip chart posted on the wall in the laboratory, clinic or classroom or available in the SOPs).
- Securing all infectious agents (i.e., agents stored in a locked freezer, locked laboratory, lock box, etc.).
- Maintaining neat and clean work areas (i.e. bench tops, floors, biosafety cabinet work surfaces, etc.).
- Maintaining safety equipment in good working order (i.e. biosafety cabinet, autoclaves, vacuum traps/filters, personal protective equipment, etc.).
- Labeling all containers in which biohazardous materials are placed with the biohazard symbol.
- Disposing of biohazardous waste properly according to laboratory SOPs.
- Reporting to the PI or Course Director any medical restrictions, reportable illnesses, exposure events or potential hazards.

Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) serves to maintain institutional compliance with laws and regulations governing research and instructional activities with biohazardous materials and to establish policies, procedures and practices to ensure that research and instructional activities at Augusta University do not present unacceptable risks to the health or safety of faculty, staff, students, visitors, or the general public.

The IBC is responsible for:

- Performing a comprehensive risk assessment of the work proposed in a Biosafety Protocol and indicating the risk mitigation methods required to obtain approval. The IBC or a subcommittee of the IBC shall review applications involving:
    - Recombinant or synthetic nucleic acids (e.g. viral vectors, plasmids, transgenic mice)
    - Use of CDC/USDA regulated Select Agents/Toxins
    - Potentially infectious microbial agents
    - Human gene transfer/therapy
    - Large scale cultures > 10 liters at any one time
    - Mammalian cells, cell lines, tissues, fluids, organs or cultures requiring > Biosafety Level (BSL) 1 containment (e.g., human and non-human primate materials)
    - Use of nanomaterials in association with biohazards or animals
    - The use of toxins of biological origin (e.g. pertussis toxin, diphtheria toxin, tetrodotoxin) or poisonous, toxic or venomous plants, animals or insects
    - Use of any biological material where the initial risk assessment indicates > BSL1 containment is required

- Serving as an advisory committee to the President, Provost, Vice Presidents of Research and Administration and the Associate Vice President of the Division of Environmental Health and Safety (EHS) and/or other pertinent offices on policies, guidelines and procedures related to biological safety in the research community.
- Adopting emergency plans covering accidental spills and personnel contamination resulting from biohazardous research and instructional activities.
- Instituting appropriate sanctions for non-compliance with biological safety standards, guidelines, or regulations.
- When applications involve Select Agents, ensuring that approval is granted only to those individuals who meet the access requirements stated in Federal Regulations on the Possession, Use, and Transfer of Select Agents and Toxins.
- When experiments involve rDNA in humans, the IBC will grant no approval and ensure that no activities are conducted until NIH Recombinant DNA Assurance Committee approval has been obtained, when applicable, and compliance with Appendix M of NIH Guidelines can be ensured.

The IBC's composition, meeting procedures and review process adhere to those dictated in NIH Guidelines and are further discussed in the IBC Policy and Procedures available on the IBC website.

Biological Safety Office

Augusta University's Biological Safety Office serves as a resource for researchers, instructors, administration, compliance and maintenance departments.

The Biosafety Office is responsible for:

- Assisting researchers in maintaining compliance with federal, state, local and institutional requirements for work with biological materials.
- Evaluation and inspection of laboratory facilities for work with infectious agents, recombinant or synthetic nucleic acids and other potentially hazardous biological agents
- Advising on safety measures and equipment for new procedures that may be utilized to mitigate risks associated with potentially hazardous materials.
- Providing general biosafety training programs related to proper handling of biological materials.
- Providing assistance and/or guidance in the event of large, high hazard or public biological material spills.
- Investigation of laboratory incidents, accidents, exposures or releases from containment to ensure appropriate emergency follow-up procedures have been followed and to recommend additional safety measures to prevent future occurrences.
- Providing advice on laboratory security.
- Coordinating/consulting with other institutional safety and compliance offices to maintain compliance and safety standards.
- Serve as a point of contact and information for Facilities Maintenance, Security, IT, Public Safety, internal and external responders related to safety with biological materials and research activities within Augusta University facilities.
- Develop informational and training seminars and workshops on biohazards for the Augusta University community.

Additionally, the Biosafety Office is responsible for the administration of the IBC which involves pre-review of Biosafety Protocol applications, communication of IBC review decisions, maintenance of protocols and IBC-related records (i.e. minutes/agendas), scheduling IBC meetings and implementation of standards set by the IBC.

Biological Safety Officer

Within the Biosafety Office, the Biological Safety Officer serves as the Institutional Biological Safety Officer for recombinant or synthetic nucleic acid research according to the NIH Guidelines and as the Institutional Responsible Official (RO) for compliance with the Federal Regulations on the Possession, Use, and Transfer of Select Agents and Toxins. The Biosafety Officer also serves as the liaison between external agencies and the Institution on biosafety-related reports and issues. The Biosafety Officer manages the Biosafety Office and reports issues of non-compliance and accidents/incidents to the IBC.

CHAPTER 2 – BIOSAFETY REQUIREMENTS

The following information describes the requirements for Augusta University researchers as defined by the Institutional Biosafety Committee and the Biosafety Office. It is the responsibility of each Principal Investigator, Clinical Director and/or Instructional Course Director to obtain approval from the Biosafety Office prior to bringing biological materials to Augusta University or initiating research involving their use.

Obtaining Approval for the Use of Biological Materials

Institutional Biosafety Committee (IBC) review and approval is required prior to bringing biological materials to Augusta University or initiating research involving their use. Please refer to this document for training and occupational health requirements and for instructions for completing a biosafety protocol (BSP) application. All forms and templates are available on the Biosafety Office webpage. Note: Obtaining approval for use of biological materials for instructional purposes is covered in Chapter 11.

Biosafety Protocol Application Forms			
Type of Research	**If your work involves:**	**For your initial application:**	**For protocol changes:**
Basic Research (i.e. works with biological materials in a basic lab setting)	Recombinant or synthetic nucleic acids, human/animal cell lines or tissues, biological toxins, nanoparticles, etc.	Complete a *Biosafety Protocol (BSP) "Full" Application*	Complete a *Biosafety Protocol (BSP) Amendment Application*
Clinical Research (i.e. involves human research subjects)	Collection of biological materials from human research subjects Introduction/exposure of human research subjects to biological materials	Complete a *Clinical Biosafety Protocol (CBSP) Application* **Note:** Each human subjects research protocol requires a separate CBSP application	Complete a *Clinical Biosafety (CBSP) Protocol Application*

Notes and Instructions:

- BSPs must be approved by the Institutional Biosafety Committee (IBC) or the Biological Safety Office (Administrative Review) prior to the initiation of research.
- Approval is valid for three years, but protocols must be amended as needed in the interim.
- Whenever you amend or initiate a new Animal Use Protocol (AUP) or human subjects research protocol, obtain new grant funding or otherwise add agents, change personnel/location, or modify a procedure, you must amend your BSP.
- BSPs requiring Full IBC review must be submitted to the Biosafety Office by the 1st of the month to be placed on that month's agenda.
- Submit the electronic documents to biosafety@augusta.edu. To authenticate, the Principal Investigator (PI) must send from his/her Augusta University email account/mailing address or the preparer must copy the PI in the email.

Standard Operating Procedures (required):

Standard Operating Procedures (SOPs) are safety measures which are expected to be followed by all members of your research team. The Biosafety Office has developed general SOPs for use in BSL1 and BSL2 laboratories and for use in clinical research. If these SOPs cannot be followed as they are written, please include modified SOPs for review with this application. The SOPs are available on the Biosafety Office webpage.

Additionally, the IBC may require supplemental SOPs for specific, higher hazards agents or operations in the laboratory. If applicable, the Biosafety Office will communicate this requirement to you during the review process.

Biosafety and laboratory specific training requirements:

The Biosafety Office provides training as outlined in the table below. All training is available electronically through Workforce Learn Online and will be assigned by the Biosafety Office based on the information provided in your BSP application.

Additionally, the Principal Investigator is responsible for laboratory specific and procedure specific safety training. Once the application and review process has been completed, a copy of the approved BSP and SOPs should be made available in the laboratory for reference. The PI should provide laboratory specific safety training with all personnel, including review of these documents, and should maintain a record of that training (i.e. signature log).

Augusta University/ Augusta University Medical Center Biosafety Training Requirements	
University and Health System personnel and/or personnel who work in University or Health System facilities on research projects, if you:	**You must satisfactorily complete the following training:**
Work with biological materials in a basic/wet laboratory setting, including clinicians who have a basic/wet laboratory.	**Biosafety and Bloodborne Pathogen Training** *An initial online training session is required prior to initiation of work.* *Annual Biosafety Refresher required thereafter.*
Work with biological materials in a clinical laboratory setting. *Involves taking human blood, tissues or fluid specimens from patients who are not considered infectious with any agent ≥RG3, preparation of serum or plasma samples, aliquotting of specimens.	**Biosafety and Bloodborne Pathogen Training** *An initial online training session is required prior to initiation of work.* *Annual Biosafety Refresher required thereafter.*
Involved in research that is subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids Molecules. *Introduction of genetically modified materials into human research subjects (i.e. DNA vaccines, personalized therapies)	**NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules** *An initial online training session is required prior to initiation of work.*
Responsible for marking, labeling, packaging, shipping, transporting, or receiving Biohazards (infectious agents, biological toxins, human clinical specimens, animal diagnostic specimens, dry ice, liquid nitrogen, genetically modified organisms)	**Shipping Biological Substances and Support Materials** *Current training is required for anyone involved in the shipping process. Required biennially (i.e. once every 2 years)*

Risk Assessment and Mitigation:

The PI is asked to conduct an initial risk assessment and to propose methods to reduce that risk. This information should be provided in the **Risk Assessment and Mitigation** questions found in the forms. Procedures with increased risk of exposure to biological materials (i.e. due to splash, aerosol production, sharps handling, etc.) should be discussed in these sections along with proposed methods to reduce the risks and potential consequences of exposure (i.e. vaccinations, additional PPE, use of a biosafety cabinet or safety sharps, etc.). Safety standards and guidelines that may pertain to your research are provided in the **Information and Useful Links** section of the Biosafety Office webpage:

Laboratory Assistance Visits:

Routine Laboratory Assistance Visits (LAVs/lab inspections) are conducted twice a year by Environmental Health and Safety. In many cases no additional inspection is required as part of the protocol review process. However, if the protocol is associated with a new laboratory space, or if the proposed experiments present an increased risk

requiring additional safety measures, the Biosafety Office or the IBC may require an LAV. The inspection checklist is available on the Biosafety Office webpage.

Occupational Health Requirements:

Occupational health clearance may be required prior to release of Biosafety or Institutional Biosafety Committee (IBC) approval to handle biohazardous agents or to enter patient care areas or areas where biohazardous agents are used. Clearance is required if the proposed research involves any of the following:

- Human or non-human primate materials, including cell lines
- Direct contact with human research subjects
- Influenza Virus (wild-type or genetically modified)
- Vaccinia Virus (wild-type or genetically modified)
- Rabies Virus (wild-type or genetically modified)
- Biological Toxins

In order to obtain clearance

- Complete an **Occupational Health Clearance Form**
- Provide the form to the Employee Health and Wellness Office, the Student Health Office, or to your licensed health care provider at the time of your evaluation
- If seen outside the Employee Health and Wellness Office, return completed and signed form to
  Employee Health and Wellness Office (FG-1174)
  1515 Pope Avenue
  Augusta, GA 30901
  employeehealth@augusta.edu
  706-721-3418

Important Note: Occupational Health Clearance may also be required by the Institutional Animal Care and Use Committee (IACUC). If you will be working with research animals in additional to biohazardous agents, please contact the IACUC occupational health Coordinator (ANIMALOHP@augusta.edu) to coordinate your Occupational Health Clearance visit.

Communication/Coordination with Other Compliance Offices

Division of Sponsored Program Administration (DSPA)

As part of each application for sponsored funding, DSPA acts on behalf of the Senior Vice President of Research to ensure that each research project or contract complies with Federal, State, funding agency and institutional standards. The routing form that accompanies each application for funding serves as a way for DSPA to document that the Principal Investigator has satisfied all compliance requirements. Any use of biological material must be fully disclosed on the routing sheet(s.

Prior to establishment of an account associated with a sponsored project or contract, DSPA will contact the Biosafety Office to request verification regarding the approval status of the specific project. If approval cannot be verified, DSPA will not establish the account associated with the sponsored project.

Institutional Review Board (IRB)

The Biosafety Office or IBC reviews research involving human subjects with emphasis on the health and safety of the researchers, the clinical care staff, the community and the environment. PIs must submit an IRB application to the IRB in addition to a CBSP application to the Biosafety Office. In some instances approval from the Biosafety Office or the IBC may be obtained simultaneously with internal or external IRB approval. However, there are certain types of research (i.e. gene therapy/transfer, use of biological toxins, stem cells) where Biosafety Office or IBC approval may be required before the internal IRB will issue approval or release the study for enrollment.

Institutional Animal Care and Use Committee (IACUC)

The Biosafety Office or IBC reviews research involving animals/animal products with emphasis on the health and safety of the researchers, the animal care staff, the community and the environment. PIs must submit an Animal Use Protocol (AUP) to the IACUC Office in addition to a BSP/CBSP application to the Biosafety Office. The Biosafety Office reviews each AUP to ensure that Biosafety or IBC approval has been obtained prior to approval of the AUP. Therefore, PIs are encouraged to submit their BSP to the Biosafety Office prior to/simultaneously with submission of their AUP to avoid delays.

Renewal of Biological Registration Information

Approvals for BSPs/CBSPs are valid for three years from the date of approval. A new application must be submitted for review every three years. During the 3-year cycle, researchers are expected to amend their BSP/CBSP as needed to reflect changes in agents, personnel, locations, etc.

Amendments to BSPs/CBSPs

Amendments to BSPs/CBSPs must be submitted electronically by the PI directly or copied to the PI to ensure that he/she is aware of the submission and must be approved prior to implementing any change(s). There are two ways to amend an existing BSP/CBSP. To amend a BSP, complete a BSP Amendment form indicating only the change(s). To amend a CBSP, complete a new CBSP application indicating only the change(s). The BSP Amendment form and the CBSP application are available on the Biosafety Office and IBC websites. Amendments should be submitted for the following:

Adding or removing personnel: before a new employee, student, volunteer, or visitor may handle the biological material documented on a BSP/CBSP, they must be added to the appropriate BSP/CBSP and must complete all required biosafety training modules. The PI, Clinical Director or Course Instructor is responsible for providing new personnel agent, laboratory, or project specific training, infection/exposure control procedures pertinent to the area or project and emergency response procedures and laboratory entry requirements (i.e. providing PPE, immunizations, etc.).

Adding new or modifying existing biological agents: Biological Agents to be utilized in the laboratory *that are not covered in the previously-approved BSP/CBSP*, must be documented to allow the Biosafety Office or IBC to perform the final comprehensive risk assessment and indicate mitigation methods appropriate for the new/modified agents. In particular, any changes in non-exempt recombinant or synthetic nucleic acid materials or procedures must be documented and submitted to the IBC for review and approval to maintain compliance with *NIH Guidelines for Research with Recombinant and Synthetic Nucleic Acid Molecules*. **This includes changes in inserts, vectors or target cells/tissues/organisms.** This is a condition of NIH funding to the entire institution and applies to all research at the institution, independent of its funding source.

Adding new or modifying existing experiments/SOPs: Changes to the types of experiments or safety measures for a previously approved agent also requires an amendment. For example, if a previous BSP/CBSP included approval for handling the biological agents *in vitro*, and the PI wishes to initiate a study involving *in vivo* administration of the biological agent into animals or humans, this change must be submitted and approved by the IBC prior to initiation.

Any change which might alter the risk of a BSP/CBSP: For instance, if a previous BSP/CBSP included approval for handling blood samples obtained from non-infectious patients and the PI wishes to initiate a study involving taking blood specimens from infectious patients (*e.g.,* HIV+ patients), this change must be submitted and approved prior to initiation.

Adding or removing locations: If biological agents will be handled or stored in locations *that are not covered in the previously-approved BSP/CBSP*, the new location(s) must be documented and approved by the Biosafety Office or the IBC in order to ensure that the containment is appropriate to handle the risks presented by the agents. The Biosafety Office may perform a laboratory assistance visit to assess the new location.

Addition of or changes in safety equipment used to contain or handle biological agents: Adding or removing a biosafety cabinet or other containment device may not only impact the risk, but may also require certification prior to use, therefore, such equipment changes must also be documented on your amendment.

Adding new grant or study titles: A single BSP/CBSP Number may cover multiple projects, studies or grant titles. When submitting an initial BSP/CBSP the PI is asked to indicate the project, study or grant titles associated with the BSP/CBSP. Once approved, new projects, studies or grant titles can be added under the BSP/CBSP number administratively. In the event that a new project, study or grant involves agents, equipment, location, personnel or operations that is not covered by the existing BSP/CBSP the PI will need to amend their BSP/CBSP. The Biosafety Office may perform an audit to compare the experiments and agents described in the grants, contracts, or protocol descriptions verified by the PIs with the contents of their approved BSPs/CBSPs to ensure compliance. During these audits, the PIs will be requested to provide the grant, contract or protocol information to the Biosafety Office for review.

Other amendments: There are special circumstances where important documents associated with a study are amended (i.e. an Informed Consent Document) and will need to be submitted to the Biosafety Office for review. Additionally, copies of any adverse event reports related to gene transfer/therapy must be provided to the Biosafety Office within the time frames described in Appendix M of NIH Guidelines. Human gene transfer

protocols must be reviewed by the IBC at least annually. Therefore, any updated information related to the protocol must be provided to the Biosafety Office no later than 11 months after the IBC approval anniversary.

Laboratory Record-Keeping

A Laboratory Manual or Binder should be maintained within each laboratory for training and reference for all laboratory personnel. This manual/binder should include the following material:

- A copy of the Augusta University Biosafety Guide.
- The Laboratory BSP/CBSP, amendments and renewal documentation.
- Standard Operating Procedures (SOPs).
- Documentation of agent, project or laboratory specific training of all laboratory staff from the PI or a designee. This documentation should be signed, dated and indicate the content of the training covered.
- Copies of Occupational Health Clearance Forms or other documentation (i.e. emails, physician's note, etc.) indicating that each person authorized to work within the laboratory has been offered Employee Health screening/counseling and vaccinations by the PI as appropriate for the agents within the laboratory and as described in the laboratory SOPs and approval documents.

CHAPTER 3 – OPENING, CLOSING OR MOVING A LABORATORY

Incoming New Faculty/Opening a Lab

New Augusta University researchers must receive authorization from the IBC prior to transfer of any biological material to campus. Initial applications to transfer biological agents to Augusta University may be done via email and must, at minimum, document:

- The biological agents to be transferred to Augusta University.
- The method of transfer (which must be in compliance with IATA/DOT standards, and any required USDA or CDC permits for infectious materials must be obtained by the PI prior to shipment. See Appendix H-Shipping, for further information).
- The location(s) where these materials will be stored prior to the new faculty member's laboratory establishment.
- The Augusta University personnel responsible for the materials prior to arrival of the new faculty member (if applicable).

The Biosafety Office will review the above to ensure containment issues have been addressed and compliance with regulations, guidelines and policies are met, and will typically issue authorization only for the transfer of the material. Prior to initiation of research in Augusta University facilities, the incoming faculty member is expected to complete all of the Biosafety Requirements indicated in Chapter 2 – Obtaining Approval for the Use of Biological Materials.

Laboratory Close-outs

Any faculty member who may be vacating a laboratory needs to ensure that all biological materials have been removed from the laboratory and the laboratory has been decontaminated prior to departure.

Biological materials should be removed from the laboratory by one of the following methods:

- Decontamination/deactivation and disposal of the biological material (as per the PI's SOPs)
- Disposal in the authorized biohazard waste containers (as per the PI's SOPs)
- Transfer of the biological materials to another authorized user (or to another authorized location)

If the material is to be transferred to another Augusta University laboratory, written documentation of this transfer should be provided to the Biosafety Office using the Amendment form. If the materials are being transferred to a different PI, the receiving PI should have authorization to possess this material in the new locations prior to transfer. The receiving PI must also agree to take responsibility for the new materials.

If the material is to be transferred outside of the institution, this must be done in accordance with IATA/DOT standards by personnel with documented training (since many biological materials and dry ice are considered hazardous materials by the federal government). Any transport, import and/or export permits must also be obtained by the PI prior to transfer for shipping (See Appendix H - Shipping for more details).

After removal of the biological materials from the laboratory, all surfaces and equipment must be decontaminated using the appropriate disinfection procedures as documented in the laboratory standard operating procedures prior to departure from the laboratory. Some equipment, such as biosafety cabinets, may require additional decontamination methods, such as gaseous fumigation with paraformaldehyde or vapor hydrogen peroxide (VHP), prior to removal from the laboratory. Contact the Laboratory Equipment Services (LES) office (706-721-6124) to arrange for decontamination of biosafety cabinets prior to moving.

After removal of all biological materials and decontamination of the laboratory and equipment, the Biosafety Office must be notified to complete the "clearance" process.

Laboratory Moves

If biological materials or equipment are to be transferred from one Augusta University laboratory to another, the PI, Clinical Director and/or Instructional Course Director must:

- Submit a BSP/CBSP amendment to the Biosafety office to approve the new locations prior to moving the materials.
- Transport the biological materials in a method which complies with their laboratory standard operating procedures.
- Arrange for a full laboratory assessment with the Biosafety Office to ensure appropriate containment measures are in place in the new laboratory prior to initiation of work in the new laboratory.

- Complete the laboratory close-out procedures for the former laboratory.

If biological materials will need to be transported outside of the laboratory, they must be:

- Transported by authorized personnel (i.e., those personnel listed on the BSP who are familiar with the risks associated with the biological material, the emergency spill and exposure/release procedures).
- Contained in a sealed, leak-proof primary container inside a well-labeled, sealed, leak-proof, durable secondary container.

Laboratory moves are often accomplished with the help of non-authorized personnel (*e.g.,* professional movers or personnel from the Augusta University's Materials Management Office). PIs are reminded that these personnel are not authorized to handle biological materials because they have not been fully educated in the risks or received appropriate medical evaluation/vaccinations. Therefore, whenever possible, equipment containing biological materials should be transported separately by authorized personnel. However, if this is not feasible (due to the size/weight constraints of the equipment), the equipment containing the biological materials should be securely sealed to prevent moving personnel from exposure (*e.g.,* refrigerators and freezers should be locked and/or securely taped shut), the exterior of the equipment should be decontaminated prior to the movers handling them and during the move, the movers and equipment should be accompanied by at least one member of the authorized laboratory staff equipped with the appropriate spill clean-up materials to ensure proper emergency procedures are followed should a spill/release occur *en route*.

Secondly, biological materials are often transported in refrigerators, freezers and cryotanks during laboratory moves to maintain the integrity of the samples. In preparation for moving, any glass, breakable items or other hazardous materials (*e.g.,* chemicals or radiological materials) should be removed from refrigerators or freezers. Biological materials should be contained in sealed, durable containment within the refrigerator or freezer and secured to prevent spills within the freezer. Tubes and vials should have tightly secured lids and should be in fitted containers which would prevent movement during transport (or contained within ziplock bags). Filling any open spaces within the freezers/refrigerators with packing materials will also prevent shifting of materials during transport. The refrigerator or freezer should be sealed shut (locked or securely taped shut) and the exterior decontaminated prior to moving.

The need for gaseous decontamination of a Biosafety cabinet (BSC) must be evaluated by the Biosafety office prior to moving. Should a BSC require decontamination, arrangements must be made in advance with Laboratory Equipment Services (LES) (706-721-6124) to perform this service before the BSC can be moved.

CHAPTER 4 – RISK ASSESSMENT

The PI, Clinical Director or Course Instructor is responsible for reviewing the research or instruction activities to be conducted in their laboratory, clinic or classroom to identify potential hazards (risk assessment) and to adopt appropriate safety procedures before initiation of the experiments (risk mitigation). The PI must also monitor the work to ensure that the safety procedures are being utilized by the staff and assess whether any improvements should be made based on logistics of the experiments or additional safety concerns.

The five P's of risk assessment and risk mitigation are:

1. Pathogen – hazardous biological agent(s)
2. Procedures – proposed experimental manipulations and safe work practices
3. Personnel – appropriate training and skills
4. Protective equipment – protective clothing and safety equipment
5. Place – laboratory design

Pathogens

The World Health Organization (WHO), *NIH Guidelines for Research with Recombinant and Synthetic Nucleic Acid Molecules*, and CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) established a risk-group (RG) classification system based on the risks that the agent presents to the health of healthy human adults. These groups represent a starting point for the agent's risk assessment.

NIH Guidelines Definitions of Risk Groups	
Risk Group (RG) Classification	**Description of Risk of Agents**
RG 1	Agents that are not associated with disease in health human adults
RG 2	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available.
RG 3	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (high individual risk but low community risk).
RG 4	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available (high individual risk and high community risk).

It should be noted that these guidelines do not account for individual health considerations, such as allergies, pregnancy, breast feeding, medication effects, a compromised immune system (due to illnesses or medical treatments such as steroids or chemotherapy) or other illnesses which may make individuals more susceptible to illness. In addition, the potential for differential effects of these agents in the immature systems of minors are also not considered in these guidelines.

Recombinant/Synthetic Nucleic Acid Molecules

In the context of the *NIH Guidelines*, recombinant and synthetic nucleic acids are defined as:

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; or

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.

Typically, these molecules are composed of a vector and an insert. The vector is usually microbial in origin though it may lack several genes related to host invasion or pathogenicity. However, the vector may still be infectious or capable of causing an immune response. The insert or gene of interest may be tumorigenic, confer drug resistance to a microorganism not known to acquire the trait naturally, be derived from a RG>2 organism or Select

Agent/Toxin or be a toxin of biological origin. Additionally, over or under expression of some inserts may modulate biologically active molecules (i.e. oncogenes, , proto-oncogenes, tumor suppressors, anti-apoptotic molecules or immunomodulatory molecules).

The *NIH Guidelines* also specifies that synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart.

Select Agents and Toxins (SATs)

Select Agents and Toxins (SATs) are agents that the U.S. Department of Health and Human Services (HHS) and/or the Department of Agriculture/Animal & Plant Health Inspection Service (USDA/APHIS) considers to have the potential to pose a severe threat to human health, animal or plant health, or to animal or plant products. The SAT regulations pertain not only to the intact agents or toxins, but also several genetic elements or recombinant or synthetic nucleic acids from these agents.

There are specific risks associated with each of these agents; however, an additional risk to consider is the biosecurity of these agents. Any individual who intends to possess, use or transfer any SAT must contact the Biosafety Office immediately. These agents must be registered with the HHS or USDA prior to bringing them to campus.

Toxins of Biological Origin

Biological toxins can cause injury or be lethal at small doses and the potential for electrostatic dispersal of dry/freeze-dried, concentrated forms of toxin pose uniquely high risks. Additional security measures may be required to limit access to the stored biological toxins. Toxins may not be deactivated by typical disinfectants used against pathogens, and therefore may require special procedures.

Human Blood, Body Fluids, Cells, Tissues and Other Potentially Infectious Materials

Human blood, tissues,fluids or cell lines may harbor infectious agents (bloodborne pathogens) such as Hepatitis B, HIV, etc. Human cancer cell lines also carry the risk of tumor formation.

The risks associated with human stem cells are the same risks associated with other human materials (i.e. bloodborne pathogens). However, due to the potential for stem cells to develop further into specified lineages, some risks are unknown. Some cells may develop cancer-like characteristics resulting in formation of a tumor. Additionally, induced pluripotent stem cells often utilize recombinant viral technologies to acquire stem cell characteristics.

The IBC requires that <u>all</u> cell and organ cultures of human or primate origin, including well-established cell lines, be handled in accordance with the OSHA Bloodborne Pathogens Standard and under Biosafety Level 2 (BSL-2) containment. Because of the extra protection that the laboratory worker's functioning immune system affords him/her in case of accidental needlestick or exposure, laboratory workers should never handle autologous cells or tissues.

Consult the Bloodborne Pathogen Exposure Control Plan in Appendix A for additional information. Contact the Biosafety Office for assistance with exposure determination, training information or to ask questions.

Animal Research Risks/Zoonotic Disease Risks

Animal research involves the risk of exposure to zoonotic diseases (diseases which are communicable from animals to humans) in addition to the risk from any agents introduced into the animals (i.e. human cell lines, recombinant viruses). This can be complicated by the somewhat uncontrollable nature of animals. Some animals are natural carriers of infections which may be associated with mild symptoms in animals, and therefore difficult to diagnose; however, some of these diseases can be quite serious or lethal in humans. The potential symptoms of zoonotic diseases which may be carried by the research animals used in the laboratory should be part of the laboratory-specific training/education measures provided to all personnel working with the materials and should be communicated to any health care provider, should any exposures or symptoms present.

Contact Laboratory Animal Services or the Biosafety Office for additional information about zoonotic diseases, preventative measures and post-exposure response before beginning research involving animals.

Amount of Material Present

Large quantities or high concentrations of infectious material pose a greater risk of spread than small quantities and require additional considerations of the risk of spills, splashes, and laboratory logistics. Cultures of recombinant materials in volumes exceeding 10 liters have specific biosafety standards which should be followed, as described in Appendix K of the *NIH Guidelines*.

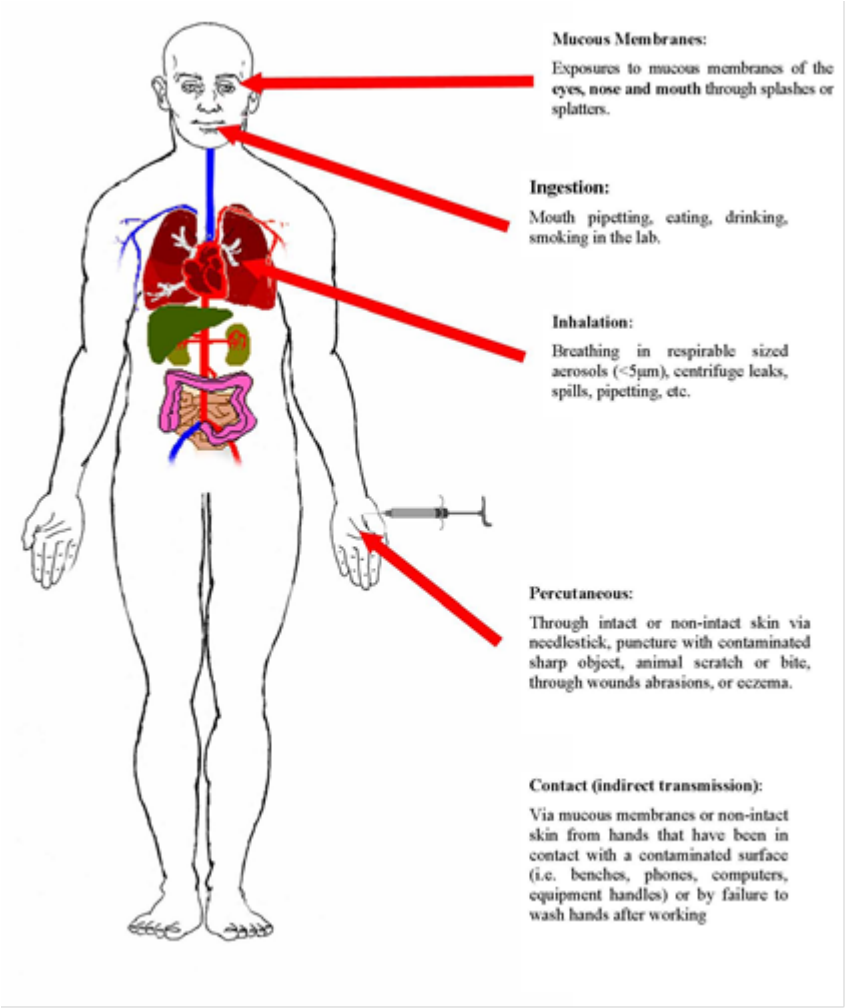
Environmental Stability

Because of their resistance to common disinfectant measures and their heat stability, biological agents such as endospore-forming species of bacteria (e.g., strains of Bacillus, Clostridium), and cyst-forming protozoan parasites pose an additional risk than agents which are more easily decontaminated.

Infectious Dose

It is difficult to determine a minimum infectious dose when discussing biohazards. The same dose of a pathogen may produce no disease symptoms in one individual but may cause serious or even fatal disease in another. There are microorganisms for which it is thought one organism entering the body is sufficient to invade and promote the disease process; Mycobacterium tuberculosis, the bacteria that causes tuberculosis or Coxiella burnetii, the causative agent of Q fever are examples. For many pathogens, 10 to 100 or more organisms must enter the body to cause infection leading to disease.

Routes of Exposure



In order for microbiological agents to cause disease, they must enter the body in sufficient numbers. Routes of entry include inhalation, ingestion, mucous membranes and/or non-intact skin (sharps injuries, animal bites or scratches). Any risk assessment process should consider the possible unique routes of entry presented during the course of the proposed experiment in addition to the consequences of potential spread outside of the laboratory should a researcher be inadvertently infected. Please note: these infectious routes of entry in the laboratory may differ from the natural routes of infection. For instance, although a parasitic infection may normally require a specific arthropod vector to transmit the infectious agents, and the risk of having the arthropod vector within the laboratory may be extremely low, the researcher must also consider that a parasitic infection may arise in the laboratory after accidental parenteral introduction of the organism (via a needlestick, for instance).

Procedures

Procedures that involve the use of sharps or that generate splashes, sprays or aerosols increase the risk of exposure to biological agents. The following laboratory operations are associated with additional risk of exposure via sharps injury or splash or aerosol release. Therefore, these activities must be documented on all Biosafety Protocols for the IBC to review. Additional risk mitigation methods may be required and are outlined in Chapter 5.

- Blowing out pipettes
- Cell sorters (FACS)
- Shaking, vortexing or stirring
- Opening lyophilized or Vacutainer tubes
- Opening snap top tubes
- Breakage of culture containers
- Flaming loops or slides
- Pulling needles out of septums
- Filling a syringe
- Placing liquids under pressure
- Splashing liquids (i.e. ELISA washes)
- Centrifugation
- Sonication
- Homogenizing, blending, grinding
- Cell disruption with French press, sheering cells through needles
- Injection of animals
- Intranasal inoculation of animals
- Cage cleaning, changing animal bedding
- Harvesting infected material from animals, eggs, and other virology procedures
- Necropsies of infected animals

Personnel

Augusta University personnel receive basic biosafety training in the initial biosafety and bloodborne pathogen and annual refresher training modules. However, specialized training in laboratory-specific operations and safety measures is the responsibility of the PI. If a laboratory is utilizing technology which no one, including the PI, has previous experience in (e.g. recombinant viral vector systems or use of new equipment, such as a French Press), additional training should be sought by the PI before embarking on these experiments.

CHAPTER 5 – **RISK MANAGEMENT AND BIOSAFETY LEVELS**

Management of the risks associated with research involving biological materials is accomplished via a combination of Practices (i.e. sharps disposal) and Places (i.e. laboratory design and safety equipment). The CDC, WHO and NIH have established standards for four biosafety levels (BSLs 1-4) for work with all biohazardous materials, outlined in the publication *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). These standards are reflected (although not always identical) to the four biosafety levels (BLs) described for work with recombinant DNA materials in Appendix G of the *NIH Guidelines for Research with Recombinant DNA Molecules* ("*NIH Guidelines*"). Both publications provide general descriptions of the combination of microbiological practices, laboratory facilities, and safety equipment needed to contain biological agents which may be infectious to humans, or impact the environment. The standards above also specify four biosafety levels for research with animals, Animal Biosafety Levels (ABSLs 1-4). The American Committee of Medical Entomology of the American Society of Tropical Medicine and Hygiene has also developed arthropod containment levels (ACLs 1-4) for research with arthropods.

The table below outlines the containment levels currently employed at Augusta University. Work with biological agents that require BSL3 or BSL4 containment are not permitted.

Biosafety Levels			
Biosafety Level	**BSL-1**	**BSL-2**	**BSL2+**
Pathogen type	Agents that present minimal hazard to personnel and/or the environment	Agents associated with human disease and that pose moderate risk to personnel and/or the environment	Agents/operations associated with increased risk of exposure or higher consequence from exposure
Containment	Work outside of containment (i.e. on the open bench) is permitted	Work with hazardous agents must take place in containment (i.e. in biosafety cabinet)	Additional personal protective equipment or other safety practices may be required.
Sample agent /operations	Field caught fish, non-pathogenic strains of *E. Coli*	Human blood, adenovirus, FACS of RG1 agents	FACS of RG2 agents

General Laboratory Safety Procedures:

These procedures are for use in all research laboratories where biological materials are handled.

Before beginning work with biological materials:

- All research personnel must be added to the appropriate biosafety protocol (BSP) and must complete Initial Biosafety and Bloodborne Pathogen Training; refresher training must be completed annually.
- All research personnel must obtain clearance from Employee Health and Wellness before working with potentially infectious materials (including unfixed human specimens or cell lines) or with biological toxins.
- Research personnel must receive laboratory specific training and be made aware of the hazards and appropriate safety precautions before working with biological materials; this training will include review of the BSP and any SOPs.

General safety procedures:

- Laboratory doors must be kept closed; laboratory doors should not be propped open.
- Laboratories should be locked when unattended.
- All persons entering the laboratory must be advised of potential hazards.
- Access to the laboratory must be limited to staff, or other persons with permission of the Principal Investigator, when work with biological materials is being conducted.
- Laboratory staff will treat biological materials using Universal Precautions, AS IF potential infectious.
- The laboratory must have a sink for hand washing and adequate supplies must be available (i.e. soap and paper towels).
- The laboratory must have an eyewash and safety shower.
- The eyewash must be flushed at least monthly by research personnel.

- The area around the safety shower and eyewash must be kept clear of obstructions.
- Laboratory doors must be locked when unattended.
- Laboratory furniture and furnishing must be non-porous to allow for disinfection – carpeting, cloth chairs are not permitted.
- Spaces between benches, cabinets, and equipment must be kept accessible for cleaning.
- Absorbent material such as cardboard boxes (other than biohazard boxes) must not be placed on the floor
- Laboratory staff will not eat, drink, smoke, handle contact lenses, chew gum, or apply cosmetics in laboratory.
- Food or drink for human consumption or utensils or cups must be stored outside laboratory work area in refrigerators designated for that purpose only.
- Contaminated gloves must be removed immediately and placed in the biohazard waste container for disposal.
- Under NO CIRCUMSTANCES will gloves be reused.
- Laboratory staff must wash hands after handling biological materials, after removing gloves, and before leaving the laboratory.
- Protective clothing must be removed and left in laboratory before going to non-laboratory areas (cafeteria, library, administrative areas).
- Protective clothing must be either disposed of in laboratory or laundered by institution. (NEVER taken home!)
- Only mechanical pipetting devices must be used in the laboratory (no mouth pipetting).
- All procedures must be performed in a manner that minimizes creation of splashes or aerosols.

Biosafety cabinets (BSCs):

- A Biosafety Cabinet must be used for all procedures with potential for creating infectious aerosols or splashes, or whenever handling high concentrations of potentially infectious materials.
- Refer to the BSP or agent/procedure specific SOPs to determine when use of a BSC is required.
- BSCs must have a current (annual) certification.
- BSCs must not be used until it is recertified after repair or relocation.

Centrifugation:

- Centrifuges used for potentially infectious agents (human specimens or cell lines, viral vectors, bacterial cultures) must have sealed rotor heads or centrifuge safety caps
- Safety caps must be opened only in a BSC.
- If a vial breaks during centrifugation, do not open the centrifuge; call the Biological Safety Office for assistance.

Decontamination and waste handling:

- Surfaces
    - Laboratory equipment and surfaces must be decontaminated on a routine basis, after work with infectious materials is finished, and especially after overt spills or splashes of viable material.
    - Equipment must be decontaminated before removal from the laboratory (for repair maintenance or other purposes).
    - A freshly diluted 10% bleach solution (v/v) will be applied to all surfaces and allowed to air dry for 30 minutes; this may be followed by a water or 70% ethanol rinse (note: stainless surfaces will corrode if not rinsed)
- Liquids
    - All infectious liquids must be decontaminated or disinfected prior to being poured into drain.
    - Vacuum lines should be protected from contamination by liquid waste via HEPA filter or two flask system.
    - Vacuum flasks should be emptied and cleaned at least once per week.
    - Add concentrated bleach to a final concentration of 10% bleach – treat for 30 minutes, pour into drain.
- Solids
    - All non-liquid contaminated cultures, stocks, plastics and other biologically contaminated waste (i.e. bench pads, gloves, paper towels) must be placed in biohazard containers.
    - Solid waste that is not contaminated with biological material (packaging, paper, paper towels from handwashing) should be placed in a non-hazardous waste container (regular trash can).

    - Do not overfill biohazard boxes – Environmental Services will remove when they are 2/3 full.
- Sharps
    - Reusable sharps should be stored in hard walled containers when not in use.
    - Place disposable sharps in an approved sharps container immediately after use.
    - Do not overfill sharps – Environmental Services will remove when they are 2/3 full.

Biological materials storage procedures:

- Refrigerators and freezers where biological materials are stored will only be accessible to authorized personnel.
- Locations where biological materials are stored will be marked with biohazard stickers.

Animal waste:

- Soiled cages/bedding and animal carcasses/tissues must be returned to the appropriate animal facility of origin for disposal (cages/bedding or carcasses/tissues should not be placed in laboratory waste containers).
- Animal carcasses may be stored temporarily in a plastic bag in a laboratory freezer; temporary storage must be emptied regularly.

Transport of specimens:

- This SOP is only applicable for transport of samples from one location to another without leaving the campus. Shipping or transport of biological materials to or from an off-campus location (or between campuses, i.e. from Summerville to the Health Sciences Campus) requires specific training – contact the Biological Safety Office for more information.
- Samples must be placed in a leak proof, puncture proof outer container for transport (i.e. a Rubbermaid type container)
- Outer container must be labeled with contact information and a biohazard sticker.
- Decontaminate outer container before removing from the laboratory.
- If a biological spill occurs during transport, contact the Biological Safety Office for assistance.

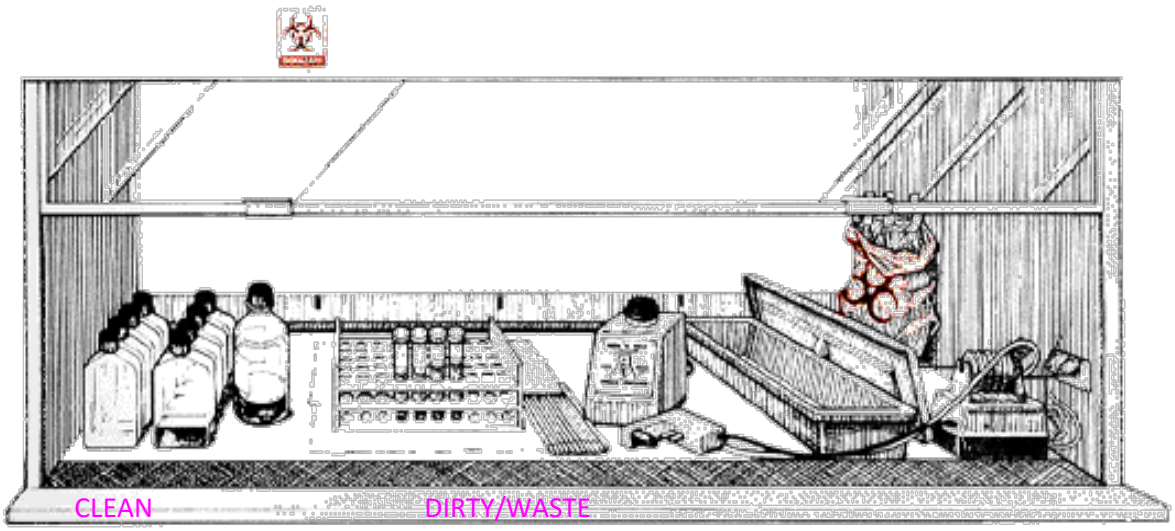
Biological spills/accidents/exposures:

- Spills and laboratory accidents that result in exposure to biological materials must be immediately reported to the Principal Investigator and the Biological Safety Office.
- All spills, injuries or exposures involving recombinant or synthetic nucleic acids must be immediately reported to the Principal Investigator and the Biological Safety Office.
- Please consult Augusta University's Emergency Response flipchart, Chapter 7 of this Guide and the Biological Safety Office webpage for guidance documents that are specific to spill clean-up, accidents and injuries: http://www.augusta.edu/services/ehs/biosafe/.

Tissue, Cell and Microbiological Culture Practices

Adhering to appropriate tissue culture techniques protects the worker and the environment but also aids in maintaining sterility of the agents being manipulated. The following measures are general guidelines for improved safety while performing cell culture techniques within a biosafety cabinet (BSC, also commonly called a "tissue culture hood").

- Maintain a clean lab coat reserved solely for cell culture work.
- Avoid causing unnecessary air disturbances in and around the BSC; avoid moving ones hands in and out of the biosafety cabinet or sweeping side-to-side motions; avoid talking during culture manipulations as aerosols may be drawn into the work area; BSCs should be placed in low traffic areas and away from doors.
- Place all reagents and supplies inside the Biosafety cabinet before the experiment to reduce the disturbance of air within the BSC during use.
- Work from a clean to a dirty side. Place all unused (clean) materials and reagents on one side of the work surface, and waste containers on the other (dirty) side.



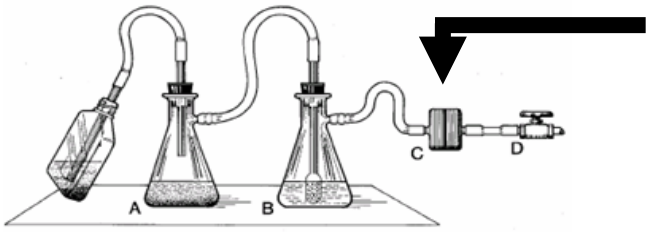
- Do not over-crowd your biosafety cabinets, which may interfere with proper laminar air flow required for BSC function.
- Do not block the grates in the front or the back of the BSC which would prevent proper laminar air flow required to maintain containment and sterility within the BSC. Work approximately 4 inches back from the front of the BSC work area.
- Allow the BSC to run for fifteen (15) minutes prior to use and fifteen (15) minutes after use to purge the air within the BSC of any contaminants.
- Clean all work surfaces, interior vertical surfaces and face shields before and after use with an appropriate disinfectant.
- Do not use open flames inside the BSC. Heat currents generated from the flame can damage the BSC components and may interfere with the airflow of the BSC. Additionally, flames pose a high flammability risk when used in the vicinity of alcohols, which are often used in tissue culture situations. Alternative devices or measures should be utilized, such as glass bead sterilizers, micro incinerators, flame-on-demand devices or use of disposable instruments or having multiple packets of sterile instruments on-hand. If no appropriate substitute can be found for a flame, only the use on flame-on-demand devices, such as properly-used touch-plate micro-burners will be permitted.

Glass bead sterilizer


Microincinerator


Touch-plate micro burner

- Do not use volatile chemicals or radiological materials in unducted biosafety cabinets. Please be aware that most BSCs at Augusta University are unducted and therefore not appropriate for work with these materials. Contact the Chemical Safety Office or the Radiation Safety Office for assistance in determining the appropriate location.
- Liquid wastes should be collected and decontaminated using an appropriate method which should be described in the laboratory SOPs.
- Do not allow vacuum traps to become overfull (recommended not greater than half-full). This not only prevent liquids from being inadvertently drawn into the vacuum line, but will allow for full decontamination of the liquid wastes prior to disposal.
- HEPA filters or equivalents should be placed on the vacuum lines that are connected to liquid waste containers to prevent contamination.




In-line HEPA vacuum filters

- Do not leave pipettes in the ends of the vacuum aspirator hoses. After use, remove them from the hose and place in disinfection tray/container prior to disposal.
- Rinse vacuum tubing with disinfectant after use.
- If the vacuum traps are outside of the Biosafety Cabinet, place in sufficient secondary containment to hold the volume of liquid which may be spilled if implosion of the vacuum flask should accidentally occur.
- Glassware/plasticware and other contaminated items should be disinfected or autoclaved before washing, reuse or disposal. Glassware should be thoroughly cleaned and rinsed by washing repeatedly with tap water and distilled water.
- Place dirty pipettes, tips and tubes in a decontamination tray or container in which disinfectant has been placed on the "dirty side" of the BSC rather than move hands in and out of the BSC to dispose of these. This will avoid disrupting the protective air curtain when hands are removed from the BSC. Discard empty tubes immediately into the disinfection tray or similar containment device; after the experiment, drain the disinfectant from the plastic wastes then dispose of the wastes in the biohazard waste containers.
- Keep open tubes parallel to the airflow.
- After transferring inoculums, always recap vials.
- Do not place tubes on work surface.
- Pipette gently along the sides of tubes to prevent production of aerosols
- Work with one specimen at a time; recap before going to the next.
- If a problem with contamination develops please contact the Biosafety Office for further assistance.

Vacuum Packed Tubes/Vials

When a vacuum-sealed tube or vial (e.g., Vacutainer blood tubes or septum bottles) are opened, the lyophilized material or liquid culture may become aerosolized due to the sudden influx of air within the tube/vial. Protective measures to protect personnel from exposures to these aerosols should be incorporated into the laboratory Standard Operating Procedures. Ideally, opening of vacuum-sealed tubes/vials should be done in biological safety cabinets. Covering the lid or plug with an disinfectant-soaked gauze pad will also provide a barrier against exposures to the aerosolized material that may be generated upon opening. Commercial "cap" devices are also available to limit the spread of aerosols generated when opening tubes or vials.

Transport of Biological Material on Campus (between Labs or Buildings)

To prevent exposure to non-authorized personnel (with unknown health status) and potential environmental release and contamination, biological materials which must be transported between laboratory areas must be properly packaged, contained and labeled:

- Biological materials must be contained inside a sealed, leakproof primary container. Utilize plastic containers whenever feasible. Avoid glass.
- The primary container must be placed inside a sealed, leakproof, puncture-resistant secondary container.
- Absorbent material (*e.g.,* paper towels) must be placed between the primary and secondary containers suitable for the volume transported.
- A biohazard sticker and label must be affixed on the outside of the secondary container with agent name, lab address and emergency contact phone number.
- The outside of the primary container should be decontaminated before placing into the secondary container. The outside of the secondary container should be decontaminated before leaving the laboratory.

Biological materials may not be transported through non-Augusta University areas (e.g., the Augusta University Medical Center or Augusta Veterans Administration Hospital) without prior permission from these entities. Transport of biological materials in a private vehicle is discouraged. Keep in mind that transport of hazardous materials (which may include biological material, dry ice and liquid nitrogen) is against the terms of most private automobile insurance policies. Check with your insurer. Any extramural transport of biological materials must

comply with the IATA/DOT shipping standards as described in Appendix D – Shipping, of the Augusta University Biosafety Guide.

Laboratory Equipment

In addition to safe practices, personal protective equipment (PPE) and safety equipment should be used to protect the researcher from contact with infectious, toxic or corrosive agents, excessive heat, cold, fire and other physical hazards. Clinical and laboratory staff should be trained by the Principal Investigator, Clinical Director or Instructional Course Director in the proper use of laboratory equipment.

Personal Protective Equipment (PPE)

Standard laboratory clothing should include items that cover bare skin to prevent contact with hazardous materials. Long pants/skirt and closed-toe shoes covering the foot and heel shall be worn in the laboratory setting. The minimum PPE requirements when working with biological materials are gloves, lab coat and eye protection. Additional PPE may be required based on a risk assessment.

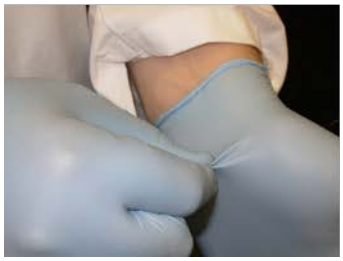
While PPE is an important component of any biological safety program, PPE is used with the understanding that PPE serves as a second line of defense. Good laboratory techniques, procedures and appropriate laboratory equipment are the primary barriers against potential exposure to hazardous agents:

- When skin is damaged or non-intact, waterproof bandages should be used to cover the open wound prior to putting on gloves.
- Contaminated or damaged PPE should be removed immediately and replaced with clean PPE
- PPE should be provided to visitors and maintenance or security personnel
- PPE worn within the laboratory should not be worn outside the facility to the library, cafeteria, or other places accessible to the public
- PPE should be placed in an appropriately designated area or container for storage, washing, decontamination or disposal
- Single use PPE (i.e. disposal gloves) should never be reused
- All PPE should be decontaminated before being sent to the laundry or discarded. Treat contaminated areas of PPE with an appropriate disinfectant. Lab coats with extensive contamination may be placed in a biohazard bag and autoclaved
- Do not take PPE home to launder; select a laundry service that follows universal precautions
- Wash hands whenever PPE is removed.
- Do not touch door handles, elevator buttons, telephones, computers or other clean surfaces or items with gloved hands.

Gloves: Gloves are designed to protect the hands and forearm from exposure to hazardous agents. Gloves should be comfortable, appropriately sized and the composition/design suitable for the task to be performed.

- Disposable (single use) gloves shall be:
    - Inspected prior to use for holes or tears
    - Changed frequently
    - Discarded after use (never reused)
    - Removed before exiting the laboratory. If materials must be transported between laboratory areas, use the one glove method or place the container in a clean secondary container.
- Avoid wetting or applying disinfectant on disposable gloves. This may compromise the integrity of the gloves and lead to wicking or leaking.
- Consider double gloving when working with cultures of infectious agents or handling spills.
- Beware of latex allergies (See Chapter 6 – Occupational Health).

When removing disposable gloves, the exterior of the gloves should be considered contaminated and exposure to skin should be avoided. Grip the outside of one glove at wrist with the other gloved hand, pull glove off and gather in palm of gloved hand. Place index or middle finger of the ungloved hand on wrist of gloved hand, slide finger under the glove opening and pull glove off inside out.




Temperature resistant gloves should be worn to protect hands from physical damage when working with very hot (autoclave) or cold (liquid nitrogen tank, -70°C freezer) materials. Kevlar gloves and sleeves are cut resistant and will help guard against slices, scratches or cuts, but will not prevent direct puncture or needlestick injuries. Steel mesh gloves also protect against slices, cuts, and scratches but will not eliminate punctures. Neoprene and other abrasive resistant gloves are cut resistant, but significantly reduce dexterity. For information on the types of gloves needed for various tasks, such as working with animals, dry ice, heat, acids, etc., contact Environmental Health and Safety.

Lab Coats: Lab coats protect the wearer's clothing and skin from contamination. Spills, splashes and sprays occur most often in the chest or lap area. Lab coats should be buttoned at all times while working in the laboratory. Lab coats are not 100% leakproof and must be changed when soiled. Long-sleeved garments with snug fitting cuffs are preferred over open cuffs or short sleeves. Snug fitting cuffs prevent splashes, splatters and aerosols from making contact with exposed skin on the lower arms. Longer single-use gloves can be pulled over snug fitting cuffs to seal out any infectious materials. Sleeve covers may be worn over lab coat and gown sleeves to provide protection to the sleeves and wrists from contamination when working in the biological safety cabinet. Disposable sleeve covers have tight fitting grips at both ends.

Face and Eye Protection: Protection of the face and eyes is of prime importance in laboratories. Safety glasses with side shields that meet American National Standards Institute (ANSI) standard Z87 are the minimum requirement when working in the laboratory. Additional protection (i.e. goggles, face shields or hoods may be required based on a risk assessment of the hazards. Regular eye glasses do not have side shields and therefore are not suitable eye protection. Contact lenses do not provide eye protection; in fact, they may present more risk to the eyes by holding hazardous materials in contact with the eye for a longer period of time until they can be removed. It is recommended that contact lenses not be in the laboratory.

Respiratory Protection: Protection of the respiratory system is a major concern of any biological safety program because infectious organisms can readily enter the human body through the respiratory tract. Engineering controls, such as the use of biological safety cabinets, should always be considered as a first line of defense against respiratory infection when working with infectious organisms. Respirators should only be considered as a second line of defense after feasible engineering controls have been put into place and additional controls are still needed.

Federal OSHA regulations (29 CFR 1910.134) require initial and annual training and fit-testing, and well as medical surveillance of all respirator wearers. If a respirator is to be used in the course of research with biological materials, the IBC will require adherence to these OSHA standards.

Employees who need to wear a respirator must enroll in the Respiratory Protection Program through the Industrial Hygiene Office (706-721-2663) before using a respirator. Proper selection of cartridges and respirators is very important and should not be made without input from the IH Office. The Employee Health and Wellness Office must also be notified (706-721-3418) so that medical evaluation/surveillance and clearance can be issued prior to wearing the respirator.

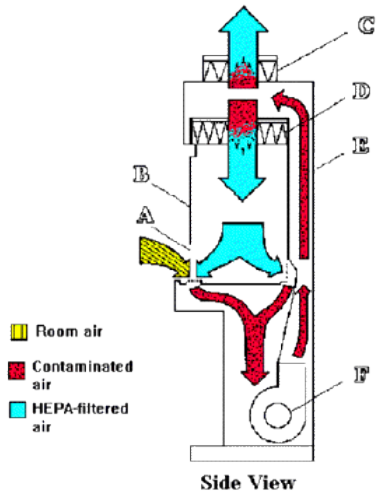
Biological Safety Cabinets (BSCs)

Biological Safety Cabinets (BSCs) isolate biohazards from personnel by confining the biohazardous material in the unit, primarily through the use of directional laminar airflow. The BSC removes aerosolized biohazardous material by moving air through high efficiency particulate air (HEPA) filters. The intake air coming from the front of the unit is drawn into the front grate of the BSC filtered through a HEPA filter before entering the BSC work area. Exhaust air also passes through a HEPA filter. Aerosols generated in the work area of the BSC are contained within the BSC. When a BSC is used properly, HEPA filters are very efficient at removing particles; however, HEPA filters will not filter out gases and vapors.

HEPA filters have a limited life span (approximately 5-7 years) and are relatively fragile; they can be easily dislodged or damaged during moves or repairs of the unit. For this reason, Biosafety Cabinet function must be certified at least annually or after any move or repair. The Division of Environmental Health and Safety and the Laboratory Equipment Service (LES) office jointly run a program that monitors the annual performance of biological safety cabinets at least annually. Contact LES to request certification of a new, moved or repaired BSC. The BSC certification program conforms to guidelines established by the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) in their publication Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm and OSHA's Bloodborne Pathogens Standard.

Biological safety cabinets (BSCs) are categorized by Classes:

1. Class I units provide personnel protection only
2. Class II units provide both personnel and product protection
3. Class III are glove-box units which provide personnel protection and optional product protection



Side View

Most BSCs at Augusta University are Class II units, which means, when used properly, they provide a clean work environment for research or patient care activities while offering personnel and environmental protection. The BSC provides primary containment for infectious materials. The efficacy of BSCs depends upon the behavior of the operator and the orientation of the unit in the facility. Class II BSCs fall into four types (A1, A2, B1 and B2), the most common of which is the Class IIA2 BSC at Augusta University. Class IIA2 BSCs recirculate 70% of filtered air and exhaust 30% into the room (see airflow diagram).
Class IIA2 cabinets can be either "ducted" or "unducted". The majority of BSCs in Augusta University facilities are unducted Class IIA2 BSCs. After HEPA filtration, the exhaust from a Class IIA2 Biosafety Cabinet can be expelled into the room, or it can be exhausted to an external area connected via a thimble or canopy connector through the buildings external exhaust system (i.e. a "ducted" Class IIA2 BSC). The great advantage of having a "ducted" Class IIA2 BSC is that it may be used with *minute quantities* of volatile toxic chemicals and tracer amounts of radionuclides, since the air from the BSC is exhausted through properly functioning exhaust canopies. Radionuclides and volatile chemicals may not be used in "unducted" Class IIA2 BSCs unless charcoal filter containment units are placed within the unit to capture any potentially volatilized radionuclides prior to circulation within the BSC. Contact the Radiation Safety Office for further information about these charcoal devices. Keep in mind: if the BSC is ducted using a thimble connection, because this is not an air-tight connection, if failure were to occur in the building exhaust system during use, the BSC would still function to filter particulates, but will expel the air exhaust into the room and may pose a hazard if radionuclides or volatile chemicals are in use.

Augusta University also has a small number of Class IIB2 BSCs in select areas on campus, which exhaust 100% of the filtered air (no air recirculation occurs). They are hard-connected to the building's external exhaust system (i.e., they are always "ducted"). Because the function of a Class IIB2 BSC is intricately connected to the function of the building external exhaust system, any failure in the building exhaust system will compromise the function of a Class IIB2 BSC. Therefore, audible or visual alarm systems must be installed to alert any users in fluctuations in the building exhaust system. However, because exhausts from Class IIB2 units are connected via air-tight connection and exhausted externally from the building and no recirculation of air occurs within the BSC, there are fewer restrictions for volatile chemicals or radionuclide use in these BSCs.

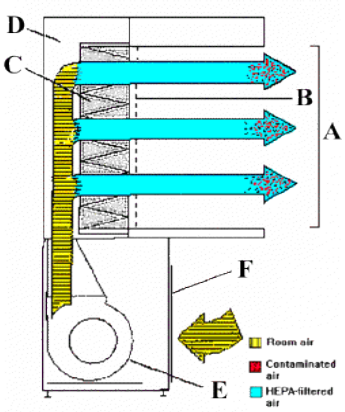
Operating Procedures for Class II Biological Safety Cabinet:

- If used, turn off UV light within the unit and switch on fluorescent light and blower.
- Disinfect all interior surfaces with 70% ethanol or suitable disinfectant.
- Place items required for procedure into cabinet; do not obstruct grills.
- Allow the unit to run approximately 15 minutes prior to use to purge contaminants from work area.
- Keep materials at least 4 inches inside work area.
- Work should proceed from clean to contaminated areas.
- After procedure, allow cabinet to run approximately 15 minutes before removing materials to purge contaminants from work area prior to shutting off motor.

- Wipe down all work surfaces with suitable disinfectant (as described in the laboratory SOPs)
- Turn off fluorescent light and blower if desired.

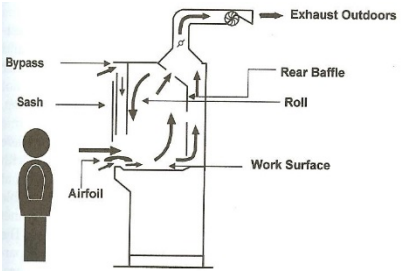
Many BSCs are equipped with germicidal ultraviolet (UV) lamps. Time of exposure, distance, presence of dust or debris and UV lamp intensity contribute to the germicidal effect of the UV lamp. The visible blue-violet glow of the UV lamp does not indicate there is germicidal effect; the efficacy of the UV lamp may decrease as the lamp grows older. The UV lamp needs to be cleaned periodically to remove dust. UV lamps may damage eyes, skin, and laboratory equipment. UV lamps should be turned off while the room is occupied. For these reasons, the Biosafety Office discourages the use of UV lamps inside of BSCs due to the potential damage which may result from UV lamp use, and the arguable reliability of UV decontamination over time.

Laminar Flow Hoods/Clean Benches:



Laminar Flow Hoods (a.k.a. Clean Benches) differ from Biosafety Cabinets in that they offer only product protection, not personnel protection. They function by blowing HEPA filtered air through the metal baffle in the back of the unit directly across the work surface *toward the user* (see airflow diagram, right). While this provides a sterile work surface, this may increase the exposure risk of the individual using the unit to the materials on the work surface. Therefore, LFHs should not be used for work with hazardous materials. These function well for media preparation or similarly low hazard operations which may require sterile conditions.

Chemical Fume Hoods:



Unlike Biosafety Cabinets or Laminar Flow Hoods, chemical fume hoods offer personnel protection to the user, but no product or environmental protection. Air drawn from the front of the unit passes directly across the work surface of the fume hood, thereby potentially compromising the sterility of any materials exposed on the work surface (see airflow diagram, right). In addition, the exhaust air from the fume hood is not filtered in any way before expelling the air via the building's exhaust systems. This may result in environmental contamination, and potential exposure of personnel who may be near the exhaust outtakes. However, typically fume hood exhausts are expelled at high velocity through an exhaust stack, reducing the latter risk. Fume hoods should be used for working with hazardous materials, such as biological toxins; however, not if sterility is needed.

Centrifuges

Centrifuge safety caps and buckets

All centrifugation of Risk Group 2 agents or higher shall be done using centrifuge safety buckets with safety caps or in sealed centrifuge tubes in sealed rotors. If a small centrifuge is used and centrifuge safety cups are not available, the centrifuge should be operated in the biological safety cabinet. The following safety measures are recommended when using biological materials in centrifuges:

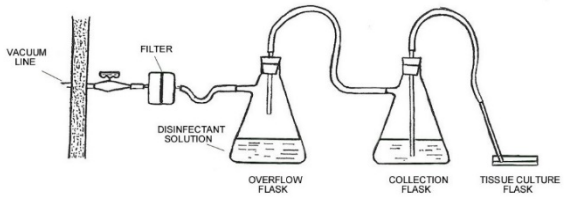
- Examine tubes and bottles for cracks or stress marks before using them.
- Fill and decant all centrifuge tubes and bottles within the biological safety cabinet.
- Never overfill centrifuge tubes as leakage may occur when tubes are filled to capacity. The maximum for centrifuge tubes is 3/4 full.
- Always cap tubes before spinning.
- Place all tubes in safety buckets with safety caps or in sealed rotors. Inspect the "O" ring seal of the safety bucket and the inside of safety buckets or rotors.
- Wipe exterior of tubes or bottles with disinfectant prior to loading into rotor or safety bucket. Wipe the exterior of the rotor or safety buckets before removal from Biosafety Cabinet.
- Never exceed safe rotor speed.
- Stop the centrifuge immediately if an unusual condition (noise or vibration) begins.

- Wait five to fifteen minutes after the run before opening the centrifuge. This will allow aerosols to settle in the event of a breakdown in containment.
- Decontaminate safety carriers or rotors and centrifuge interior after each use.
- Open safety buckets or rotors in a biological safety cabinet. If the rotor does not fit in the biological safety cabinet, use the fume hood.
- If construction of the centrifuge permits, the centrifuge chamber should be connected to a vacuum pump with a HEPA filter installed between the centrifuge and the vacuum pump.

Vacuum Line Traps and Filters:

Liquid wastes should be collected in order to decontaminate using an appropriate method which should be described in the laboratory SOPs. Typically, liquid wastes are collected in vacuum aspirators into which some full-strength disinfectant has been placed.

- When setting up a vacuum aspirator system, make sure the tubing inside the vacuum flasks extend far below the vacuum arm of the flask to prevent liquid wastes from being drawn through the flask's vacuum arm and contaminating the vacuum line (see, *e.g.*, "Collection flask" in figure below).
- Flexible vacuum tubing or Tygon® tubing used in aspirator systems should have walls thick enough to withstand the vacuum without collapsing, cracking or leaking.
- Periodically inspect and replace vacuum tubing which has become cracked over time.
- To ensure appropriate decontamination, subsequent disinfection measures should be followed prior to disposal.



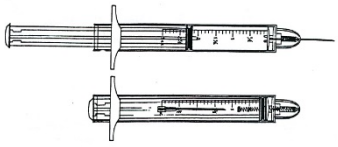
- Do not allow vacuum traps to become overfull (recommended not greater than half-full). This not only prevents liquids from inadvertently drawn into the vacuum line, but will allow for full decontamination of the liquid wastes prior to disposal.
- HEPA filters or equivalents (i.e. 2 flask system) should be placed on the vacuum lines to prevent contamination of vacuum pumps.
- Vacuum line filters shall be examined and replaced if clogged or if liquid makes contact with the filter. Used filters shall be discarded as biohazardous waste.
- Do not leave pipettes in the ends of the vacuum aspirator hoses. After use, remove them from the hose and place in disinfection tray/container prior to disposal. Leaving pipettes within the hoses only presents additional exposure or contamination risks.
- Rinse vacuum tubing with disinfectant after use. This will prevent backflow of contaminated liquids within the vacuum line and subsequent contamination.
- If the vacuum traps are outside of the Biosafety Cabinet, place in sufficient secondary containment to hold the volume of liquid which may be spilled if implosion of the vacuum flask should accidentally occur

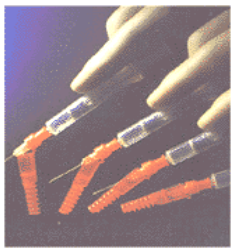
Syringes and Needles

The hypodermic needle is a dangerous instrument. To lessen the chance of accidental injection, aerosol generation, or spills, the use of syringes should be avoided when alternate methods are available (i.e. use a blunt needle or cannula on the syringe for oral or intranasal inoculations).

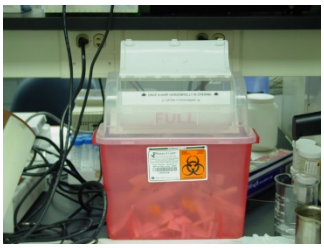
The following practices are recommended for hypodermic needles and syringes when used for parenteral injections:

- Use the syringe and needle in a biological safety cabinet only and avoid quick and unnecessary movements of the hand holding the syringe.
- Examine glass syringes for chips and cracks, and needles for barbs and plugs. This should be done prior to sterilization before use. Use needle-locking (Luer-lock) syringes only, and be sure that the needle is locked securely into the barrel. Replace glass syringes with plastic disposable syringes whenever possible.
- Whenever possible use safer needle systems such as retractable needle systems or shielded needle systems (see right).
- Wear latex or nitrile gloves for all manipulations with needles and syringes.
- Fill the syringe carefully to minimize air bubbles and frothing of the inoculum.





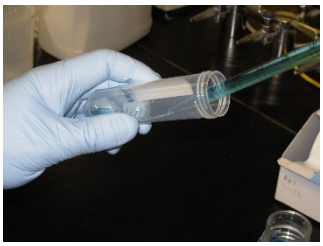
- Expel excess air, liquid and bubbles from a syringe vertically into a cotton pledget moistened with an appropriate disinfectant, or into a small bottle of sterile cotton.
- Do not use the syringe to forcefully expel a stream of infectious fluid into an open vial for the purpose of mixing. Mixing with a syringe is condoned only if the tip of the syringe is held below the surface of the fluid in the tube.
- If syringes are filled from test tubes, take care not to contaminate the hub of the needle, as this may result in the transfer of infectious material to the fingers.
- When removing a syringe and needle from a rubber-stoppered bottle, wrap the needle and stopper in a cotton pledget moistened with an appropriate disinfectant. If there is concern of the disinfectant contaminating sensitive experimental materials, a sterile pledget may be used and immediately discarded into a biohazard bag.
- When inoculating animals, position the hand that is holding the animal "behind" the needle or use a pair of forceps or other restraint to hold the animal in order to avoid puncture wounds.
- Be sure the animal is properly restrained prior to the inoculation and be on the alert for any unexpected movements of the animal; for higher risk agents, the IBC may require that animals be anesthetized for injection.
- Before and after injection of an animal, swab the injection site with an appropriate antiseptic.
- Immediately discard syringes into an authorized sharps container, which should always be kept near the site of use. DO NOT bend, shear, recap or otherwise manipulate the needle. If recapping is unavoidable, use a one handed method. DO NOT discard syringes into biohazard bags.



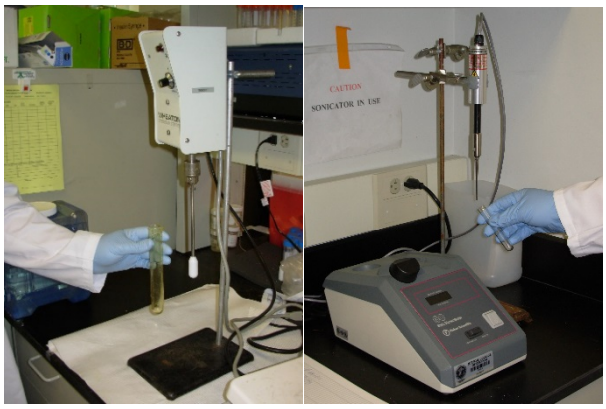
Pipettes

The following is excerpted from Laboratory Safety, Principles and Practices 2nd Ed., ASM Press.

- Never suction or pipette by mouth; always use some type of pipetting aid.
- When pipetting infectious materials, all activities should be confined to a biosafety cabinet.
- Pipetting of toxic chemicals should be performed in a chemical fume hood.
- Infectious or toxic materials should never be forcefully expelled from a pipette. Mark-to-mark pipettes are preferable to other types because they do not require expulsion of the last drop.
- Infectious or toxic fluids should never be mixed by bubbling air from a pipette through the fluid.
- Infectious or toxic fluids should never be mixed by alternate suction and expulsion through a pipette.
- Gently discharge from a pipette as close as possible to the fluid or agar level, and the contents should be allowed to run down the wall of the tube or bottle whenever possible, not dropped from a height.
- Pipettes used for transferring infectious or toxic materials should always be plugged with cotton, even when safety pipetting aids are used.
- Avoid accidentally dropping infectious or toxic material from the pipette onto the work surface. Place a disinfectant dampened towel or other absorbent material on the work surface, and discard as biohazardous waste. Plastic backed bench paper or "blue pads" are suitable for this purpose.
- Contaminated pipettes should be placed horizontally into a pan or tray containing enough suitable disinfectant, such as bleach, to allow complete immersion of the pipettes. Pipettes should not be placed vertically in a cylinder that, because of its height, must be placed on the floor outside the biosafety cabinet. Removing contaminated pipettes from the biosafety cabinet and placing them vertically in a cylinder provides opportunity for dripping from the pipette onto the floor, or the rim of the cylinder, thereby creating an aerosol, and the top of the pipettes often protrude above the level of disinfectant.



- Place discard pans for used pipettes within the biosafety cabinet; after suitable contact time, excess disinfectant can be carefully poured down the sink and pipettes can be placed in biohazard waste container for disposal.



Blenders, Mixers, Sonicators and Cell Disruption Equipment

Hazardous aerosols are created by most laboratory operations involving blending, mixing, stirring, grinding or disrupting biohazardous materials. Even the use of a mortar and pestle can be a hazardous operation. Other devices that may produce aerosols are ball mills, colloid mills, jet mills, tissue grinders, magnetic mixers, stirrers, sonic cleaning devices/sonicators, homogenizers, ultrasonic cell disintegrators, French Presses, and shakers. The laboratory practices generally required when using equipment that may generate aerosols with biohazardous materials are as follows:

- Operate blending, cell disruption, and grinding equipment in a biological safety cabinet; if these operations cannot be accomplished in a biosafety cabinet, the IBC may require additional PPE or other safety measures.
- Use safety blenders designed to prevent leakage from the rotor bearing at the bottom of the bowl. In the absence of a leakproof rotor, inspect the rotor for leakage prior to operation. A preliminary test run with sterile water, saline, or methylene blue solution is recommended prior to use.
- If the blender is used with infectious material place a towel moistened with an appropriate disinfectant over the top of the blender. Sterilize the device and residual contents promptly after use.
- Glass blender bowls are undesirable for use with infectious material because of the potential for glass bowls to break.
- Blender bowls sometimes require supplemental cooling to prevent destruction of the bearings and to minimize thermal effects on the product.
- Before opening the safety blender bowl, permit the blender to rest for at least one minute to allow settling of the aerosol cloud.

Lyophilizers:

The filling of ampules and vials with infectious specimens, the subsequent freeze-drying, and sealing or closing of ampules and vials in the preparation of dry infectious specimens should be performed in a biological safety cabinet. Safety precautions to be taken will depend on the agents, equipment, and containment available. Therefore, before initiating this procedure, the principal investigator should work out the protocol for each machine in consultation with the Biological Safety Office.

Microtome/Cryostat:

Due to the very sharp blade and the nature of the materials used with the microtome/cryostat, training is essential in the use of the equipment and in the hazards of the materials used with the equipment. Users should be informed of the need to prevent cuts and scrapes as well as protect the eyes, nose, mouth and skin from exposure to the materials being used. New personnel must be trained in the proper use and maintenance of the equipment, and demonstrate proficiency prior to use.

Fixatives take time to penetrate tissue; the fixatives may not inactivate pathogens deep in the tissue. Freezing and drying do not inactivate most pathogens, so, as with fixative use, the pathogens that may be present in the tissue should be considered capable of causing infection.

Things to remember when using and maintaining microtomes/cryostats:

- Never retrieve samples, change blades, or clean equipment by hand with the blade in place; always use appropriate engineering controls (i.e. forceps, tweezers, dissecting probes, and small brushes).
- Always keep hands away from blades.
- Use extreme caution when aligning blocks, the blocks may be close to the blades. If available, make sure block holder is in locked position when loading/aligning blocks.
- Use knife-edge protectors/guards. Do not leave knife-edges that may extend beyond microtome knife holder unprotected.
- Keep blocks wet when in the microtome to minimize airborne shavings during slicing.
- Use brushes to clean/brush equipment.

- Use engineering controls such as forceps when removing or changing the blade.
- Dislodge stuck blocks using mechanical means such as forceps and/or dissecting probes.
- Wear appropriate PPE such as a lab coat or gown, mask, safety glasses or goggles, surgical grade Kevlar gloves that provide dexterity and cut protection, and examination gloves to protect against biohazards.
- When changing blades, wear stainless steel mesh gloves to provide additional protection from cuts and scrapes.
- Avoid freezing propellants that are under pressure as they may cause splattering or droplets of infectious materials.
- Decontaminate equipment on a regular schedule using an appropriate disinfectant.
- Consider trimmings and sections of tissue as contaminated and discard in the appropriate waste stream.
- Do not move or transport microtome with knife in position.
- Do not leave knives out of containers when not in use.
- Do not leave motorized microtomes running unattended.

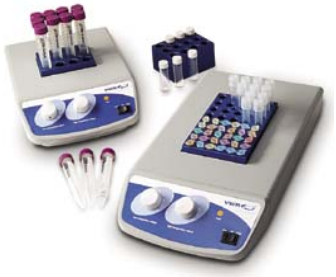
Fluorescence Activated Cell Sorters (FACS) and FACS analyzers:

In 1994 the International Society of Analytical Cytology (ISAC) first recognized the need to formulate safety guidelines for sorting and analysis of unfixed cells to provide laboratories with recommendations for practices to reduce the potential for biohazard exposure of instrument operators. These standards are periodically updated by ISAC, most recently in 2014 (See: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4117398/).

Jet-in-air technology utilized for cell sorting involves a liquid stream carrying the cells through a nozzle vibrating at high frequency. Owing to the high fluid pressure produced in high-speed cell sorters, large amounts of secondary aerosols can occur during instrument failures, for instance, when a partial clog in the nozzle causes a deflection in the fluid stream that is hitting a hard surface, e.g., the waste catcher. Because of the potential health risk to sorter operators and the environment if aerosols escape into the room, aerosol containment of a sorter, whether free standing or enclosed in a biological safety cabinet, must be verified routinely using appropriate testing methods, such as the use of highly fluorescent Glo-Germ® (5-µm melamine copolymer resin beads in a 5-ml volume of ethanol) under the same conditions as the cell sort.

All risks associated with materials being used or presented for sorting or analysis in any Augusta University FACS facility should be fully disclosed to the facility manager before use and documented on the PI's Biosafety Protocol for risk assessment.

Waterbaths:



Water baths and Warburg baths used to inactivate, incubate, or test infectious substances should contain a disinfectant. For cold water baths, 70% propylene glycol is recommended. Sodium azide should not be used as a bacteriostatic. It creates a serious explosion hazard. Whenever possible, the use of dry heat/incubator blocks and dry incubators should be considered instead of water baths since this may reduce the risks of water intrusion upon the samples and contamination of water in baths or shakers. Dry heat blocks come with modular adapters designed to fit tubes of multiple sizes as well as rectangular 12-, 24- or 96-well plates.

Cold Storage:

Deep freezer, liquid nitrogen, and dry ice chests as well as refrigerators should be checked, cleaned out periodically to remove any broken ampules, tubes, etc. containing infectious material, and decontaminated. Use rubber gloves and respiratory protection during this cleaning. All infectious or toxic material stored in refrigerators or deep freezers should be properly labeled. If equipment failure occurs, immediate action to prevent specimen loss and contamination of equipment and facilities may be required. Emergency contact information should be posted on the outside of critical cold storage containers.

CHAPTER 6 – OCCUPATIONAL HEALTH

All personnel with the potential for exposure to biological materials in the execution of Augusta University's research or educational missions are required to have access to Occupational Health services.

The purpose of an Occupational Health Program is to conduct periodic health assessments of personnel handling biological materials with particular attention devoted to factors or conditions associated with a particular biological agent that a given individual might handle. This may also include a number of precautionary measures, such as screenings, vaccinations or a periodic physical examination. During the final risk assessment performed by the Biosafety Office or the IBC, Occupational Health requirements may be recommended as a condition of approval.

Requirement for Occupational Health Services

The provision of Occupational Health services is a requirement defined in the CDC BMBL, OSHA BBP standard and the NIH Guidelines. Occupational Health services should be offered by the employer at no charge to personnel engaged in biological research, whose job may result in potential exposure. As Augusta University has no university-wide occupational health program (except for individuals enrolled in the Animal Occupational Health program), these costs are typically incurred at the departmental level. Therefore, an IDR may be required from the department for these services.

- For Augusta University employees, these services are provided by the Employee Health and Wellness Office (706-721-3418) located at the FG Building, room 1174 on 1515 Pope Avenue.
- Augusta University students who may be working with biological materials in the course of their education or as part of research, should seek health counseling and surveillance services from the Student Health Office (706-721-3487) located at 1040 AF (Pavilion II) Building, room 1040 on Laney Walker Blvd.
- For non-employees (i.e. volunteers, visitors) who may be working with biological materials, it is the responsibility of the PI, Clinic Director and/or Course Instructor to determine how these personnel will receive the appropriate health counseling, vaccination and post-exposure follow-up health care. This may involve utilization of a personal physician.

Tuberculosis (TB) Screening

New employees at risk for acquiring TB must be tested for exposure by a tuberculin skin test (PPD) at the time of hire (within 2 weeks of start date) to establish a baseline. The can be done at the Employee Health and Wellness Office or documentation can be submitted to the Employee Health and Wellness Office by a personal physician. All employees at risk must be PPD tested on an annual basis. Students who may encounter TB exposure as part of their educational operations should follow similar practices with Student Health Services.

In addition, any personnel working with non-human primates should be carefully monitored for potential exposures to tuberculosis. A TB infection causes an extremely rapidly fatal pneumonia in most Old World primate species which can devastate an entire NHP colony.

For more information, see the Tuberculosis Exposure Control Plan, Appendix B.

Immunizations

In certain situations, personnel engaged in particular research, educational or patient care activities should be immunized with appropriate vaccines. Vaccines not commonly available will be obtained, whenever possible, for those engaged in specific research with potential exposure to the agent in question.

Vaccine	Recommendations
Rabies Vaccine	Recommended for all personnel entering laboratories or animal facilities with rabies vaccination entrance requirements.
Hepatitis B Vaccine	Recommended for persons working with patients in a health care setting or persons working with human blood, body fluids, tissues or cell lines derived from human materials. See Bloodborne Pathogen Exposure Control Plan, Appendix A.
MMR (Measles, Mumps, Rubella)	Recommended for persons working with patients in a health care setting or persons working with human blood, body fluids, tissues or cell lines derived from human materials.

Td (Tetanus, diphtheria) or TDap (Tetanus, Diphtheria, Pertussis)	Recommended for persons working with patients in a health care setting or persons working with human blood, body fluids, tissues or cell lines derived from human materials. Current tetanus vaccination is required of all those who work with laboratory animals, including researchers and animal caretakers. In addition, anyone whose job responsibilities associated with an animal facility may place them at risk of exposure to tetanus.
Influenza	Recommended for persons working with patients in a health care setting or persons working with human blood, body fluids, tissues or cell lines derived from human materials.
Varicella Zoster Vaccine	Recommended for persons who have not previously had varicella zoster infection (*i.e.* chicken pox and/or shingles) who work with patients in a health care setting or persons working with human blood, body fluids, tissues or cell lines derived from human materials.
Vaccinia (Smallpox) Vaccine	Prior to working with vaccinia, employees are required to receive an independent medical counseling session from the Employee Health and Wellness regarding vaccinia immunization to discuss the risks and benefits of vaccinia vaccination. In cases where infected animals are not housed in filter-top cages or other primary containment devices, vaccination shall be required for room entry.
Arboviruses: Eastern and Western Equine Encephalitis Vaccines, Japanese Encephalitis Vaccine, Venezuelan Equine Encephalitis Vaccine, Yellow Fever Vaccine, Rift Valley Fever Vaccine	Prior to working with arboviruses, employees are required to receive a medical evaluation and counseling from Employee Health and Wellness regarding possible immunization.
Lyme Disease Vaccine	Recommended for persons working with the Lyme Disease agent or vectors in research laboratories, with animals, or in fieldwork.
Other vaccines such as Salmonella typhi (Typhoid),	To be determined by the Occupational Health Physician.

In some cases, appropriate follow-up serum samples will be collected at periodic intervals to measure vaccine-induced antibodies when indicated.

Respiratory Protection

Section 4.2.1.2, Federal OSHA regulations (29 CFR 1910.134) require initial and annual training and fit-testing, and well as medical surveillance of all respirator wearers. If a respirator is to be used in the course of research with biological materials, the IBC will require adherence to these OSHA standards as a stipulation of IBC approval. Please contact the Industrial Hygiene (IH) Office (706-721-2663) whenever the use of a respirator is being considered. IH staff will assist users in proper selection of cartridges and respirators and in obtaining the appropriate medical evaluation, annual training and fit testing.

Medical Restrictions

As previously described in Chapter 4, risk group classifications are based on the risks to healthy human adults. These recommendations do not account for individual health considerations, such as allergies, medication effects, a compromised immune system (due to illnesses or medical treatments such as steroids or chemotherapy) or other illnesses which may make individuals more susceptible to agents.

For this reason, for their own safety, any individual with special health concerns is strongly encouraged to discuss these with the Principal Investigator, Clinical Director or Instructional Course Director prior to initiation of work within the laboratory. In turn, PIs, Clinical Directors or Instructions Course Directors should offer the opportunity for the individual to seek Occupational Health Counseling through the Employee Health and Wellness or Student Health Offices to discuss their potential individual special risks.

Pregnancy

It is recognized that exposure to certain infectious agents may adversely affect a fetus during pregnancy (or when

breast feeding) if the mother is infected with the agent. Therefore, if pregnancy is possible while you are working in an infectious disease laboratory or laboratory engaged in work with infectious agents you should consult your Principal Investigator or supervisor.

The Employee Health and Wellness and Student Health Offices are resources for pregnant women to ask about any questions or concerns they may have regarding risks in their work environment. The Employee Health and Wellness and Student Health Offices may require additional information about the agents and on-going operations within the laboratory beyond what the laboratory personnel is able to offer. The Employee or Student Health Office may need to discuss these matters with the Principal Investigator, Clinic Director or Instructional Course Director, or they may contact the Biosafety Office to discuss the agents and operations documented in the laboratory's Biosafety Protocol. The Employee Health and Wellness or Student Health Office may also act as a liaison between pregnant laboratory personnel and their respective supervisors or PIs. Please contact the Employee Health and Wellness (706-721-3418) or Student Health Offices (706-721-3487) for further information on reproductive and fetal pathogens.

The Occupational Health Physician will offer confidential counseling to any woman or man of childbearing age working with reproductive pathogens or other potentially infectious materials. Reproductive biological hazards include, but are not limited to the following:

- Cytomegalovirus (CMV)
- Hepatitis B virus (HBV)
- Hepatitis E virus
- Human Immunodeficiency virus (HIV)
- Human parvovirus B19
- Rubella (German Measles)
- Lymphocytic Choriomeningitis virus
- Toxoplasma gondii (Toxoplasmosis)
- Listeria monocytogenes
- Varicella-zoster virus (chicken pox)
- Coxiella burnetii (Q fever)
- Vaccinia virus

Whenever necessary, the Employee Health and Wellness Office along with the Biosafety Office will offer an opportunity to review work procedures in the lab to ensure that potential exposure is minimized. Consideration for reassignment to other tasks that do not involve exposure to the reproductive hazard (generally with actual pathogens, not necessarily for only other potentially infectious materials such as blood or body fluids) should be given. Also, PIs actively working with reproductive hazards should explain these risks at the time of hire.

Work with Animals

Special hazards exist for workers who are exposed to animals (i.e. allergies), and therefore guidance is provided by the Institute for Laboratory Animal Research (ILAR) Commission on Life Sciences, National Research Council related to Occupational Health issues in:

- *Occupational Health and Safety in the Care of Research Animals* http://www.nap.edu/catalog.php?record_id=4988
- *Occupational Health and Safety in the Care and Use of Nonhuman Primates* http://www.nap.edu/catalog.php?record_id=10713#toc

Allergic reaction to animals is among the most common condition that adversely affects worker health. The estimated prevalence of allergic symptoms among workers exposed to animals is from 10% to 40%. Workers who are continually exposed to animal allergen tend to have progressively more frequent and severe symptoms, and an estimated 10% develop asthma. Studies have shown that about 50% of those with symptoms will eventually stop working with animals permanently or temporarily because of the discomfort involved in ALA. Initial allergy symptoms are usually runny nose (allergic rhinitis), itchy eyes (allergic conjunctivitis), and/or rashes (contact urticaria, atopy). Symptoms usually evolve over a period of 1-2 years and may lead to acute anaphylaxis in a small number of individuals.

Prudent efforts to prevent allergen exposure and reduce the frequency of sensitization in animal workers require strict work practices and consistent use of PPE. Housing animals in filter-top cages, working in well-ventilated areas, and using ventilated hoods for soiled bedding disposal will minimize exposure to animal allergens.

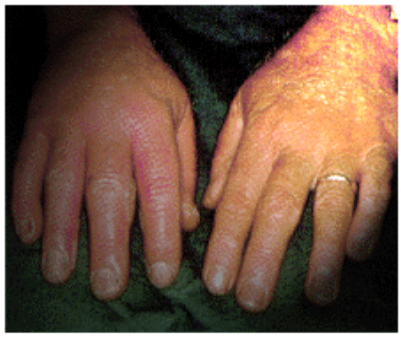
The work area must be maintained clean to prevent inhalant and contact exposure. Procedures should be adopted that minimize release of airborne materials, including bedding dust and antibiotic aerosols, and the contamination of hands, arms, body and face. Workers should adopt the use of PPE during each and every

animal contact or allergen exposure.

Of particular importance is wearing a face mask to reduce inhalation and hand-to-face spread of allergens and covering all exposed skin (i.e. gloves, lab coat, sleeve protectors) to prevent allergen contact. In some cases, respirators may be recommended; in which case the employee must be enrolled in Augusta University's respirator program, and undergo annual fit-testing as per OSHA standards (29 CFR 1910.134).

It is also important that once animal procedures are complete, all contaminated PPE and clothing are removed and properly disposed of to prevent repeated exposure while performing subsequent duties. Contact your supervisor, LAS supervisors or biosafety further information regarding PPE.

Latex Gloves and Related Allergies



Allergic reactions to natural rubber latex have been increasing since 1987, when the Center for Disease Control recommended the use of universal precautions to protect against potentially infectious materials, bloodborne pathogens and HIV. Increased glove demand also resulted in higher levels of allergens due to changes in the manufacturing process. In additional to skin contact with the latex allergens, inhalation is another potential route of exposure. Latex proteins may be released into the air along with the powders used to lubricate the interior of the glove.

In June 1997, the National Institute of Occupational Safety and Health (NIOSH) issued an alert, "Preventing Allergic Reactions to Latex in the Workplace" (publication number DHHS (NIOSH) 97-135). The full text of this publication is available at the NIOSH web site, http://www.cdc.gov/niosh/topics/latex/.

NIOSH studies indicate that 8-12% of healthcare workers regularly exposed to latex are sensitized, compared to 1-6% of the general population. Latex exposure symptoms include skin rash and inflammation, respiratory irritation, asthma and shock. The amount of exposure needed to sensitize an individual to natural rubber latex is not known, but when exposures are reduced, sensitization decreases.

NIOSH recommends the following actions to reduce exposure to latex:

- If latex gloves must be used, choose reduced-protein, powder-free latex gloves
- Whenever possible, substitute another glove material (for instance, nitrile gloves)
- Wash hands with mild soap and water after removing latex gloves

Antibiotic Allergies

Allergic reactions have been described to a large number of medicines, and those against antibiotics are among the most common of these. Reactions to antibiotics can range from a rash or hives starting a few days after exposure to sudden onset of rashes, difficulty breathing, stomach upset and anaphylaxis soon after exposure. Because of the potential severity of these reactions, any personnel with known allergies to antibiotics should discuss their personal health risks in working in a laboratory with the Employee Health and Wellness or Student Health Offices.

Should exposures occur to biological materials for which the medical treatment modality is administration of an antibiotic against which the laboratory personnel is allergic, an alternate post-exposure treatment plan should be made prior to exposure in conjunction with the Principal Investigator, Clinical Director and/or Instructional Course Director. These supervisors should be also be made aware of the potential for allergic reaction, so this can be communicated to health care providers in an emergency situation.

Biomedical laboratories often use antibiotics for research purposes. For instance, antibiotic selection is often used during culture operations in both microbiological and mammalian cell/tissue culture settings. The risks of exposure of allergic personnel to the antibiotic should be communicated to the Principal Investigator, Clinic Director and/or Class Instruction to enable development of any operating practices which would help limit the exposure any allergic personnel to the antibiotic and to Eenable communication of the exposure risks to others in the laboratory to consider the exposure risks to the allergic personnel.

CHAPTER 7 – ACCIDENTS, EXPOSURES, SPILL RESPONSE

Emergency response procedures can be found in the laboratory-specific SOPs or the (flip chart) "Critical Event and Emergency Response Guide" located on the wall in your lab /clinicfor medical emergency guidance. The following sections will discuss exposure response, incident reporting, medical assistance and spill cleanup procedures.

Exposure Response

1. REMOVE contaminated PPE.
2. EXPRESS wounds or injury site to encourage bleeding.
3. WASH site thoroughly with antiseptic soap and warm water or FLUSH eyes or mucous membranes continuously under running water (sink or eye wash) for 15 minutes
4. ALERT others to avoid the area if hazards are present (post spill sign, secure sharps).
5. For inhalation hazards, leave the room, ALERT others to avoid the area (post spill sign, close door and wait 30 minutes if aerosol involved). The PI must clear the laboratory before re-entry and spill clean-up to commence. For extensive contamination (*i.e.* an incident involving a centrifuge) or incidents involving agents contained at BSL2+/BSL3, the Biosafety Office must be notified immediately (706-721-2663) and will assume responsibility, in conjunction with the PI, to clear the laboratory for re-entry.
6. REPORT incident to supervisor. Supervisors should initiate the Incident Reporting Procedure (see below).
7. SEEK MEDICAL ATTENTION (see instructions below).
8. NOTIFY the Biological Safety Office (706-721-2663) as soon as possible to assure that the appropriate treatment and post-exposure follow-up measures are implemented.

Incident Reporting

The employee must report the incident to his/her supervisor. Because the health and safety issues of the injured personnel is of primary importance, if the injury is emergent, the supervisor should take (or make arrangements for the injured person to be taken) to the nearest emergency room and reporting requirements should be completed *post-hoc*. The supervisor should take measures to ensure that additional personnel are restricted from areas to prevent further inadvertent exposures.

Any incident, accident, exposure, possible exposure, illness which may have resulted from exposure, releases from primary containment or environmental contamination involving biological materials which occurred in the course of accomplishing the research and/or educational missions of the university should be reported as soon as possible to the Biosafety Office. It is the responsibility of the Biosafety Office to assist PIs, Clinical Directors and/or Course Instructors in completion of any funding agency-specific, public health or environmental safety reporting requirements and to review the incident with the supervisor and the injured person to discuss whether alterations in the laboratory's or institution's Standard Operating Procedures would be prudent to prevent future similar occurrences.

Principal Investigators and employees are also encouraged to report incidents that did not result in an exposure ("near misses") to the Biosafety Office. Evaluation of near misses can lead to alternative work practices and implementation of engineering controls to minimize future incidents.

Medical Assistance

Faculty/Staff:

- If an emergency, ensure the employee goes to the nearest emergency room for assistance.
- If it is not an emergency, exposures such as non-human primate bites, scratches or splashes, tick or insect bites, or exposure to infectious agents should be evaluated by the Employee Health and Wellness Office. When Employee Health is not available or if more extensive treatment is required, the employee will likely be referred to the nearest Emergency Room, and asked to follow up with visit(s) with the Employee Health and Wellness Office.

Students:

- If an emergency, ensure the student goes to the nearest emergency room for assistance.
- If it is not an emergency, students should report immediately to Student Health Services. When Student Health is not available or if more extensive treatment is required, the student will likely be referred to the nearest Emergency Room, and asked to follow up with visit(s) with the Student Health Office.

Visitors, Patients, Non-AU Employees: If you have an accident, injury, or exposure while on Augusta University property, report injury to any Augusta University employee who should notify Public Safety and await their arrival.

Spill Cleanup Procedures

A spill kit is an essential safety item for labs working with agents which require Biosafety Level 2 or higher containment and for groups working with large volumes (> 1 liter) under Biosafety Level 1 containment. PPE specific to your laboratory will need to be added, as necessary (i.e. gloves, eye protection, or disposable gowns) in appropriate sizes for your staff, and supplies should be restocked as they are used. Decontaminate any reusable items before returning them to the kit using a decontamination method suitable for the agents used in your laboratory or involved in the spill.

The kit should contain the following items:

- Paper towels or other absorbent materials (diapers or disposable shop towels)
- Concentrated Bleach (or other disinfectant per laboratory SOPs) (<1 year old)
- Broom and dustpan (or other device for removing solid objects within a spill)
- Tongs (or other mechanical device for handling sharps)
- Biohazard bags for the collection of contaminated spill clean-up items
- Biological Spill sign for warning others to avoid the area
- Spill clean-up instructions
- PPE (provided by the researcher)
- A spray bottle or other container for making 10% bleach solutions

Although household bleach is recommended as a standard disinfectant in the spill kit, other suitable disinfectants may be used provided the disinfectant is effective against the agents in use at the appropriate dilutions and contact time.

Spills Occurring Outside of Laboratory Areas:

Because laboratory facilities are designed to contain hazards within the confines of the laboratory, where all who are likely to encounter the material have knowledge of the risks, any spill outside of the laboratory area poses a particular risk for exposure of the general public or environmental contamination. Therefore, the procedures for addressing a spill which occurs outside the confines of a laboratory are:

1. Attend to any injuries or exposures
2. Alert others to avoid the area to prevent contamination of additional personnel and environment
3. Contact the Biosafety Office immediately to assist in spill clean-up. If after hours, contact Public Safety Office, who has the 24/7 on-call numbers for EHS staff members.

Spills within the Laboratory Areas:

Because laboratory facilities are designed to contain hazards within the confines of the laboratory, spills within the laboratory are generally not as potentially problematic as those which occur outside the laboratory. Of course, the overall risk will depend on the agents, operations and personnel involved in the spill and clean-up measures.

Biosafety Level 1 (BSL1) Spills

1. Notify others in the area, to prevent contamination of additional personnel and environment.
2. Remove any contaminated clothing and wash exposed skin with soap and water.
3. Wearing gloves, lab coat, and face protection, cover spill with paper towels, pour concentrated disinfectant around the spill allowing it to mix with spilled material. Allow suitable contact time, at least 15 min.
4. Pick up any pieces of broken glass with forceps or other mechanical device(s) (not with your hands!) and place in a sharps container.
5. Discard all disposable materials used to clean up the spill into a biohazard bag.
6. Wash hands with soap and water.

Biosafety Level 2 (BSL2) Spills

1. Avoid inhaling airborne material, while quickly leaving the room. Notify others to leave.
2. Close door, and post with a warning sign.
3. Remove contaminated clothing, turning exposed areas inward, and place in a biohazard bag.
4. Wash all exposed skin with soap and water.
5. Inform Supervisor, and, if assistance is needed, consult the Biosafety Office.
6. Allow aerosols to disperse for at least 30 minutes before reentering the laboratory. Assemble clean-up materials (disinfectant, paper towels, biohazard bags, and forceps).
7. Put on protective clothing (lab coat, face protection, gloves, and booties if necessary).

8. Cover the area with disinfectant-soaked towels, and then carefully pour disinfectant around the spill. Avoid enlarging the contaminated area. Use more concentrated disinfectant as it is diluted by the spill. Allow at least a 30 minute contact time.
9. Pick up any sharp objects with forceps or other mechanical devices (not your hands!) and discard in a sharps container.
10. Soak up the disinfectant and spill using mechanical means, such as an autoclavable broom and dustpan, since there may be sharps under the paper towels, and place the materials into a sharps container. Smaller pieces of glass may be collected with cotton or paper towels held with forceps. If no sharps were involved in the spill discard the materials into an autoclave bag.
11. Wipe surrounding areas (where the spill may have splashed) with disinfectant.
12. Spray the area with freshly prepared 10% household bleach solution and allow to air-dry (or wipe down with disinfectant-soaked towels after a 30-minute contact time).
13. Place all contaminated paper towels and any contaminated protective clothing into a biohazard bag and autoclave or dispose in the appropriate Stericycle waste box.
14. Wash hands and exposed skin areas with soap and water.

For blood or other material with a high organic content and low concentration of infectious microorganisms:

1. Wear gloves, eye protection, and a lab coat.
2. Absorb blood with paper towels and place in a biohazard bag. Collect any sharp objects with forceps or other mechanical device and place in a sharps container.
3. Using a detergent solution, clean the spill site of all visible blood.
4. Spray the spill site with 10% household bleach and allow to air-dry for 30 minutes.
5. After the 30 minute contact time, wipe the area down with disinfectant-soaked paper towels.
6. Discard all disposable materials used to decontaminate the spill and any contaminated personal protective equipment into a biohazard bag.
7. Wash your hands with soap and water.

Spill in a Biological Safety Cabinet

1. Leave the biological safety cabinet blower on and begin cleanup immediately.
2. While wearing PPE (gloves, gown and eye protection) cover the spill area with paper towels or disinfectant soaked paper towels. Do not place your head in the cabinet to clean the spill, keep your face behind the viewscreen.
3. If necessary, flood the work surface as well as the drain pans and catch basins below the work surface, with disinfectant. Be sure the drain valve is closed before flooding the area under the work surface.
4. Wipe cabinet walls, work surfaces, and inside the viewscreen with disinfectant.
5. Lift the front exhaust grill and work surface; wipe all surfaces with disinfectant. Be sure no paper towels or soiled debris are blown into the area under the spill tray
6. If the work surface, as well as drain pans and catch basins under the work surface, have been flooded with disinfectant soak up the disinfectant in the work surface. Place a container under the drain valve and drain the disinfectant under the work surface into the container.
7. Wipe the areas under the work surface to remove residual disinfectant.
8. Wash hands and exposed skin with soap and water.
9. Autoclave all cleanup materials and protective clothing.
10. Notify your PI or supervisor.
11. If the spill overflows the drain pan/catch basin under the wok surface into the interior of the biological safety cabinet notify the Biosafety Office. A more extensive decontamination of the biological safety cabinet may be required.

Centrifuge Spill

1. If a spill/broken centrifuge tube is suspected, do not open the lid. Contact the Biosafety Office for assistance.
2. If a spill is identified after the centrifuge lid is opened, carefully close the lid and evacuate the laboratory and close the laboratory door. Remain out of the laboratory for at least 30 minutes. Post a sign on the laboratory door indicating there is a biohazard spill and do not enter.
3. Remove any contaminated protective clothing and place into a biohazard bag. Wash hands and any exposed skin surfaces with soap and water.
4. Notify your supervisor and the Biosafety Office.

After 30 minutes...

5. Enter the lab with personal protective equipment and spill cleanup materials. Full-face protection, lab coat and utility gloves should be worn.
6. Transfer rotors and buckets to a biological safety cabinet. Immerse rotor/buckets in 70% ethanol or a non-corrosive disinfectant effective against the agent in use. Allow at least a one hour contact time. Intact tubes may be wiped down and placed into a new container. Handle any broken glass with forceps and discard into a sharps container.
7. Carefully retrieve any broken glass from inside the centrifuge using forceps and discard into a sharps container. Smaller pieces of glass may be collected with cotton or paper towels held with forceps. Carefully wipe the inside of the centrifuge with disinfectant.
8. Spray the inside of the centrifuge with disinfectant and allow to air dry. If bleach is used, follow by wiping with 70% ethanol to remove any corrosive residues.
9. Place contaminated items and disposable personal protective equipment in an autoclave bag and autoclave.
10. Wash hands with soap and water.

Spill of a Biohazardous Radioactive Material

A biohazardous spill involving radioactive material requires emergency procedures that are different from the procedures used for either material alone.

1. Avoid inhaling airborne material, while quickly leaving the room and closing the door.
2. Notify others to leave the room.
3. Close door, and post a warning sign.
4. Anyone that was in the room at the time of the spill should remain at the scene until monitored for contamination and cleared by Radiation Safety Office.
5. Remove contaminated clothing, turning exposed areas inward, and place in a biohazard bag labeled with a radioactive materials label or a radioactive waste container labeled with a biohazard label.
6. Wash all exposed skin with soap and water; follow with a three-minute water rinse.
7. Inform supervisor and Radiation Safety Office of spill, and monitor all exposed personnel for radiation.

CHAPTER 8 – DECONTAMINATION/DEACTIVATION OF BIOLOGICALS

This section describes basic strategies for decontaminating surfaces, items, and areas in laboratories to eliminate the possibility of transmission of infectious agents to laboratory workers, the general public, and the environment. Factors necessary for environmentally mediated infection transmission are reviewed as well as methods for sterilization and disinfection and the levels of antimicrobial activity associated with liquid chemical germicides. General approaches are emphasized, not detailed protocols and methods. The principles of sterilization and disinfection are stated and compared.

Decontamination methods fall into three main categories: heat, application of chemical decontaminants (including vapors and gases) and physical methods (such as filtration or irradiation).

Heat

The application of heat, either moist or dry, is an effective method of sterilization. Steam at 121°C under pressure in the autoclave is the most convenient method of rapidly achieving sterility under ordinary circumstances. Dry heat at 160°C to 170°C for periods of two to four hours is suitable for destruction of viable agents on an impermeable non-organic material such as glass, but is not reliable in even shallow layers of organic or inorganic material that can act as insulation. Incineration is another use of heat for decontamination. Incineration serves as an efficient means of disposal for human and animal pathological wastes.

Autoclave Use and Maintenance

Moist heat causes the denaturation of proteins at lower temperatures and shorter times than dry heat. One of the most effective physical decontamination controls is steam sterilization (autoclave) which generates moisture and high temperature pressurized steam within a sealed chamber. Autoclaves can sterilize all items that are heat stable. In gravity autoclaves, a cycle of 250°F (121°C) at 15 to 18 pounds per square inch (psi) of pressure for one hour may be required for decontamination. In the newer vacuum autoclaves, decontamination may require a cycle of 270°F (132°C) at 27 to 30 psi for 45 minutes.

Laboratory personnel should be cautioned that steam under pressure, such as that found in autoclaves, could be a source of scalding jets if the equipment is misused. When preparing to use an autoclave, check the door seal gaskets each time to ensure these are intact prior to using the autoclave. Also, before use, check to make sure the drain at the bottom of the autoclave is unobstructed. Prepare to autoclave loads of manageable size only. Do not overfill autoclaves.

Fluids treated by steam under pressure may be superheated if removed from the sterilizer too soon after treatment; which may cause a sudden and violent boiling of contents from the containers that can splash scalding liquids onto personnel handling the containers. Therefore slow exhaust cycles should be used to autoclave liquids. In addition, bottles with liquids should allow for the liquid expansion during autoclaving; “head room” should be left in the vessels before autoclaving. Similarly, to avoid over-pressurization will occur inside of vessels with liquids if gas is not able to freely enter/exit the bottle during the cycle. Therefore, only loosely fit covers or caps on these vessels prior to autoclaving.

For solid materials, keep in mind that steam must be in contact with the materials to efficiently sterilize them. Therefore autoclave bags should be left partially opened and/or some additional water should be placed on the inside of the bag prior to autoclaving.

Because of the air and liquid exchange inside of bags or vessels, other hazardous materials should not be included in autoclave loads. Mixed waste—either chemicals (such as phenol: chloroform) or radiological material mixed with biological materials should never be autoclaved due to the chemical and radiological hazards present.

In addition, some materials should never be autoclaved. Nitrocellulose materials (tubes/filters), for instance, can explode under autoclave temperatures. Make sure any plastic materials that are autoclaved are guaranteed “autoclavable” by the manufacturer. Most plastics will melt inside the autoclave and produce irritating odors.

Always place materials to be autoclaved inside of a metal or *autoclavable* plastic autoclave tray to prevent spillage of agar or melted plastics into the bottom of the autoclave. (Note: most plastics are **not** autoclavable unless specially formulated, so check the manufacturer’s specifications to ensure your plastics are autoclavable!). Melted and re-solidified agar or plastic plugs the drain at the bottom of the autoclave, which prevents proper function of the autoclave and often requires maintenance to repair.

Wear closed toe shoes, pants, lab coat, face shield and long sleeved insulated gloves when operating an autoclave. A heavy, rubberized insulated apron is further recommended for those who autoclave frequently. Allow time for loads to cool before removing them from autoclaves after a run. Take proper precautions when first

opening the door; first crack the seal on the door sufficiently to allow the initial burst of steam to escape, then leave the door open about ½ inch to vent the autoclave for about 5-10 before fully opening the door.

All autoclaves should be on a preventative maintenance program and certified regularly to ensure proper function. Heat-sensitive autoclave tape can be used to ensure that an autoclave got warm; however, this is insufficient to tell the user that the appropriate temperature and pressure were maintained over a sufficient period of time to provide full decontamination. Please note: Augusta University does not have a campus-wide autoclave certification and maintenance program. Responsibility for certifying and maintaining autoclaves falls to the owner—the department or Principal Investigator who owns the autoclave. Autoclaves should be certified using bioindicators for steam autoclaves. Typically, these are vials containing spores of *Geobacillus stearothermophilus* in growth media with a colored indicator. To certify that an autoclave is functioning properly, a vial is placed in the middle of a typical autoclave load (attaching a string to the vial prior to placement allows for later retrieval). The autoclave load is run as usual, and the vial is retrieved from the load after autoclaving. The vial is cultured to determine whether the spores are capable of germinating, which would cause a color change in the indicator. Germination of the spores would indicate that the autoclave is not decontaminating the loads sufficiently, and maintenance should be performed on the autoclave.

If you experience any problems or unusual occurrences during autoclave use, please report these to your supervisor and/or building/department manager to enable them to contact the autoclave maintenance provider. For autoclaves attached to "house" steam lines, ensure that steam pressure is sufficient to operate the autoclave prior to contacting external repair offices. Insufficient steam pressure should be reported to the Facilities Management Office for repair.

Chemical Decontaminants

In general, chemical decontaminants find their most practical use in surface decontamination and, at sufficient concentration, as decontaminants of liquid wastes for final disposal in sanitary sewer systems.

Liquid Chemical Decontaminants

There are many liquid decontaminants available under a wide variety of trade names. In general, these can be categorized as halogens, acids and alkalis, heavy metal salts, quaternary ammonium compounds, phenols, aldehydes, ketones, alcohols, and amines. Unfortunately, the more active the decontaminant, the more likely it will possess undesirable characteristics such as corrosiveness. In addition, some of the chemical disinfectants will require disposal as chemical waste.

Small variations in temperature, contact time, pH, the presence and state of dispersion, penetrability and reactivity of organic material at the site of application may make large differences in the effectiveness of liquids for decontamination. None is equally useful or effective under all conditions for all infectious agents. It is the responsibility of the Principal Investigator to work with the Biosafety Office and/or IBC to identify the appropriate chemical decontaminant for use with the agents and experiments described in the Biosafety Protocol and to outline decontamination procedures in laboratory SOPs. Decontamination procedures should not be modified without review and approval from the Biosafety Office and/or IBC.

Particular care should be observed when handling concentrated stock solutions of chemical decontaminants. Personnel assigned to the task of making up use-concentrations from stock solutions must be informed of the potential hazards and trained in the safe procedures to follow and appropriate personal protective equipment to use as well as the toxicity associated with ocular, skin and respiratory exposure.

Vapors and Gases

A variety of vapors and gases possess decontamination properties. The most useful of these are formaldehyde, vapor-phase hydrogen peroxide (VHP), chlorine dioxide and ethylene oxide. When these can be employed in a closed system and under controlled conditions of temperature and humidity, excellent decontamination can result. Vapor and gas decontaminants are primarily useful in decontaminating biological safety cabinets and associated air-handling systems and air filters; bulky or stationary equipment that resists penetration by liquid surface decontaminants; instruments and optics that may be damaged by other decontamination methods; and rooms, buildings and associated air-handling systems.

Only those who have received appropriate training in vapor and gas decontamination should attempt these operations. Mutagenic potential has been attributed to ethylene oxide; toxic and hypersensitivity effects are well-documented for formaldehyde. Ethylene oxide use is very limited and is generally used in surgical and clinical areas. Use of vapor and gas disinfection methods is monitored closely by the Division of Environmental Health and Safety. Please contact EHS for information regarding the exposure monitoring program.

Selecting Chemical Disinfectants

No single chemical disinfectant or method will be effective or practical for all situations in which decontamination is required. The following issues should be considered when selecting the appropriate chemical decontamination method:

- What is the target organism(s)?
- What disinfectants (and in what form/concentration), are known to inactivate the target organism(s)?
- What degree of inactivation is required (i.e. is total sterility necessary?
- In what medium is the organism suspended (i.e. simple or complex, on solid or porous surface, and/or airborne)?
- What is the highest concentration of organisms anticipated to be present?
- Can the disinfectant, either as a liquid, vapor, or gas, be expected to contact the organism and can effective duration of contact be maintained?
- What restrictions apply with respect to compatibility of materials?
- What is the stability of the disinfectant in concentrated form and once diluted for use?
- Will conditions permit safe use of some disinfectants (*e.g.*, is ventilation sufficient to safely use aldehydes)?

The primary target of decontamination in the laboratory is the organism(s) under investigation. Laboratory preparations or cultures usually have titers in excess of those normally observed in nature. Inactivation of these materials presents other problems since agar, proteinaceous nutrients, and cellular materials can effectively retard or chemically bind the active moieties of chemical disinfectants. Such interference with the desired action of disinfectants may require higher concentrations and longer contact times than those shown to be effective in the test tube.

Organisms exhibit a range of resistance to chemical disinfectants. In terms of practical decontamination, most vegetative bacteria, fungi, and lipid-containing viruses are relatively susceptible to chemical disinfection. The non-lipid-containing viruses and bacteria with a waxy coating, such as tubercule bacillus, occupy a mid-range of resistance. Spore forms and unconventional (slow) viruses are the most resistant. A disinfectant selected on the basis of its effectiveness against organisms on any range of the resistance scale generally will be effective against organisms lower on the scale. Therefore, if disinfectants that effectively control spore forms are selected for routine laboratory decontamination, it can be assumed that any other organism generated by laboratory operations, even in higher concentrations, would also be inactivated.

Chlorine/Hypochlorites: This halogen is a universal decontaminant active against a broad spectrum of microorganisms, including bacterial spores. Chlorine combines with protein and rapidly decreases in concentration in the presence of protein. Free available chlorine is the active element. Chlorine solutions must be prepared frequently because of its instability in water. Sodium hypochlorite is usually used as a base for chlorine decontaminants. An excellent decontaminant can be prepared from household or laundry bleach. These bleaches usually contain 5.25%, or 52,500 ppm, available hypochlorite. If diluted 1 to 10, the resulting solution will contain 0.525% or 5,250 ppm of available hypochlorite. Because hypochlorite is a strong oxidizing agent, it can be corrosive to metals. A rinse step (i.e. with water or 70% ethanol should be included for stainless surfaces decontamination with bleach solutions.

Alcohols: Ethyl or isopropyl alcohol in a concentration of 70-85% by weight is often used; however, both lose effectiveness at concentrations below 50% and above 90%. Alcohols denature proteins and are somewhat slow in germicidal action. However, alcohols are effective decontaminants against lipid-containing viruses. Due to the high evaporation rate of alcohols, repeated applications may be required to achieve the required ten-minute contact time for decontamination. Because of this, the OSHA Bloodborne Pathogens Standard does not recognize alcohol as an effective decontaminant for surfaces. Alcohols are also very flammable, so precautions should be taken to prevent exposure to spark or flame sources.

Aldehydes (Formaldehyde, Glutaraldehyde): Aldehydes are commonly-used fixative agents in laboratories; however, during the process of fixation, materials are decontaminated. Formaldehyde for use as a decontaminant is usually marketed as a solution of about 37% concentration referred to as formalin, or as a solid polymerized compound called paraformaldehyde. Glutaraldehyde is commonly used in concentrations of 2-4%. Formaldehyde at a concentration of 5% active ingredient is an effective liquid decontaminant. A glutaraldehyde-based commercial disinfectant (Cidex®) is used in some hospital settings. All materials disinfected with aldehydes must be disposed as chemical wastes to adhere to EPA standards.

Phenols: Phenol homologs and phenolic compounds are basic to a number of popular decontaminants, such as the original Lysol® and Amphyl®. Phenolic compounds are effective decontaminants against some viruses, fungi, and vegetative bacteria, including rickettsiae. Phenolics are not effective in ordinary use against bacterial spores.

Quaternary Ammonium Compounds (a.k.a. "Quats"): These cationic detergents are strongly surface-active and are effective against lipid-containing viruses and often vegetative gram positive bacterial however, they have variable activities against gram negative bacteria and fungi, and are not very effective against non-lipid enveloped viruses. The Quats will attach to protein so that dilute solutions will quickly loose effectiveness in the presence of proteins. Many common household and laboratory disinfectants are Quats (e.g., Roccal®, Germex®, Coverage Plus®).

Iodine: The characteristics of chlorine and iodine are similar. One of the most popular groups of decontaminants for laboratory use are the iodophors, including Wescodyne®, Betadyne® and Providone®. The range of dilution of Wescodyne® recommended by the manufacturer is 1 oz. in 5 gal. of water (25 ppm available iodine) to 3 oz. in 5 gal. of water (75 ppm available iodine). The small amount of free iodine available in this range can rapidly be taken up by extraneous protein that may be present. Clean surfaces or clear water can be effectively treated with 75-ppm available iodine, but difficulties may be experienced if any appreciable amount of protein is present. For iodophors such as Wescodyne®, it is critical that the manufacturer's written instructions are followed. Higher concentrations of iodophores are actually less effective, as the iodine is bound to itself or the carrier molecule.

Peroxygens: Liquid peroxygen disinfectants, such as Virkon-S® are available as surface decontamination methods. Peroxygens have broad-spectrum disinfectant properties and are generally effective against vegetative bacteria, viruses and some spores. Peroxygens have variable efficacy in the presence of organic matter. However, peroxygens can be incompatible with some materials (such as Aluminum, Copper, Zinc, Brass, Natural rubber and some plastics), which should be considered when selecting disinfectants.

Deactivation of Biological Toxins

Toxins of biological origin may be inactivated by physical or chemical methods. General guidelines for inactivation of selected toxins are summarized in Tables 8.1, 8.2 and 8.3. It is the responsibility of the Principal Investigator to develop specific inactivation and/or disposal procedures for any toxins that are present in the laboratory. This should be done in collaboration with the Biosafety Office and the IBC. The IBC approved procedures should be included in laboratory SOPs, and the PI should train all research personnel on the approved procedure. Inactivation or disposal methods should not be altered without review and approval of the IBC.

Many toxins are susceptible to inactivation with dilute sodium hydroxide (NaOH) at concentrations of 0.1-0.25N, and/or sodium hypochlorite (NaOCl) bleach solutions at concentrations of 0.1-0.5% (w/v). Use freshly prepared bleach solutions for decontamination; undiluted, commercially available bleach solutions typically contain 3-6% (w/v) NaOCl. Special care should be taken while deactivating acute biological toxins to protect the handler, but also to ensure thorough decontamination.

To chemically decontaminate toxins, perform all operations in a fume hood or biosafety cabinet with the sash at the lowest reasonable sash height for safe and effective work. Place plastic-backed absorbent paper (e.g. Benchkote or diaper) on the work surface of the fume hood or BSC to protect the surfaces. Wear long-sleeved protective clothing (lab coat, gown), gloves and eye protection while decontaminating toxins. Place toxin into solution in a non-glass primary container, which can be placed in a secondary container, such as a beaker or rack. Slowly dispense equal volume of the concentrations of NaOCl and/or NaOH or similar disinfectant to deactivate the toxin. Do not replace the cap on the primary container and allow for a minimum of 30 minutes exposure time or as recommended in the tables below.

Depending upon the toxin, contaminated materials and toxin waste solutions can be inactivated by incineration or extensive autoclaving, or by soaking in suitable decontamination solutions (See Table 8.2). Autoclaving should not be used for destruction of any low molecular weight toxins (e.g., mycotoxins, marine and reptile venoms). To autoclave, the cap on the primary container should be loosened in a fume hood or BSC to allow for steam penetration, then placed in secondary containers before autoclaving at 121°C for 1 hour on liquid cycle (slow exhaust). Allow time for the materials to cool before handling and dispose materials as of as toxic waste.

Contaminated or potentially contaminated protective clothing and equipment should be decontaminated using suitable chemical methods or autoclaving before removal from the laboratory for disposal, cleaning or repair. If decontamination is impracticable, materials should be disposed of as toxic waste.

Table 8.1
PHYSICAL INACTIVATION OF SELECTED TOXINS
(Reproduced from Appendix I, CDC/NIH BMBL http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_appendixI.pdf)

TOXIN	STEAM AUTOCLAVE	DRY HEAT (10 MIN)	FREEZE-THAW	GAMMA-IRRADIATION
Botulinium neurotoxin (BoNT)	Yes[a]	> 100°C[b]	No[c]	Incomplete[d]
Staphylococcal Enterotoxin	Yes[e]	> 100°C; refolds[f]	No[g]	Incomplete
Ricin	Yes[i]	> 100°C[i]	No[j]	Incomplete[k]
Microcystin	No[l]	> 260°C[m]	No[n]	ND
Saxitoxin	No[l]	> 260°C[m]	No[n]	ND
Palytoxin	No[l]	> 260°C[m]	No[n]	ND
Tetrodotoxin	No[l]	> 260°C[m]	No[n]	ND
T-2 mycotoxin	No[l]	> 815°C[m]	No[n]	ND
Brevetoxin (PbTx-2)	No[l]	> 815°C[m]	No[n]	ND

ND indicates “not determined” from available decontamination literature

[a]Steam autoclaving should be at ≥ 121°C for 1 h. For volumes larger than 1 liter, especially those containing Clostridium botulinum spores, autoclave at ≥ 121°C for 2 h to ensure that sufficient heat has penetrated to kill all spores.
[b]Exposure to 100°C for 10 min. inactivates BoNT. Heat denaturation of BoNT as a function of time is biphasic with most of the activity destroyed relatively rapidly, but with some residual toxin (e.g., 1-5%) inactivated much more slowly.
[c]Measured using BoNT serotype A at -20°C in food matrices at pH 4.1-6.2 over a period of 180 days.
[d]Measured using BoNT serotype A and B with gamma irradiation from a ^{60}Co source.
[e]Protracted steam autoclaving, similar to that described for BoNT, followed by incineration is recommended for disposal of SE-contaminated materials.
[f]Inactivation may not be complete depending upon the extent of toxin re-folding after denaturation. Biological activate of SE can be retained despite heat and pressure treatment routinely used in canned food product processing.
[g]SE toxins are resistant to degradation from freezing, chilling or storage at ambient temperature. Active SEB in the freeze-dried state can be stored for years.
[i]Dry heat of ≥100°C for 60 min in an ashing oven or steam autoclave treatment at >121°C for 1 h reduced the activity of pure ricin by >99%. Heat inactivation of impure toxin preparations (e.g., crude ricin plant extracts) may vary. Heat-denatured ricin can undergo limited refolding (<1%) to yield active toxin.
[j]Ricin holotoxin is not inactivated significantly by freezing, chilling or storage at ambient temperature. In the liquid state with a preservative (sodium azide), ricin can be stored at 4°C for years with little loss in potency.
[k]Irradiation causes a dose-dependent loss of activity for aqueous solutions of ricin, but complete inactivation is difficult to achieve; 75 MRad reduced activity 90%, but complete inactivation was not achieved even at 100MRad. Gamma irradiation from a laboratory ^{60}Co source can be used to partically inactivate aqueous solutions of ricin, but dried ricin powders are significantly resistant to inactivation by this method.
[l]Autoclaving with 17 lb pressure (121-132°C) for 30 min failed to inactivate LMW toxins. All burnable waste from LMW toxins should be incinerated at temperatures in excess of 815°C (1,500°F).
[m]Toxin solutions were dried at 150°C in a crucible, placed in an ashing oven at various temperatures for either 10 or 30 min, reconstituted and tested for concentration and/or activity; tabulated values are temperatures exceeding those required to achieve 99% toxin inactivation.
[n]LMW toxins are generally very resistant to temperature fluctuations and can be stored in the freeze-dried state for years and retain toxicity.

Table 8.2
CHEMICAL INACTIVATION OF SELECTED TOXINS
(Reproduced from Appendix I, CDC/NIH BMBL http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_appendixI.pdf)

TOXIN	NaOCl (30 MIN)	NaOH (30 MIN)	NaOCl + NaOH (30 MIN)	OZONE TREATMENT
Botulinium neurotoxin	>0.1%[a]	>0.25 N	ND	Yes[b]
Staphylococcal Enterotoxin	>0.5%[c]	>0.25 N	ND	ND
Ricin	>1.0%[d]	ND	>0.1% + 0.25 N[e]	ND
Microcystin	≥0.1%[e]	ND	0.25% + 0.25 N[e]	ND
Saxitoxin	≥0.1%[e]	ND	0.25% + 0.25 N[e]	ND
Palytoxin	≥0.5%[e]	ND	0.25% + 0.25 N[e]	ND
Tetrodotoxin	≥0.5%[e]	ND	0.25% + 0.25 N[e]	ND
T-2 mycotoxin	≥2.5%[f]	ND	0.25% + 0.25 N[e]	ND
Brevetoxin (PbTx-2)	≥2.5%[e,f]	ND	0.25% + 0.25 N[e]	ND

ND indicates “not determined” from available decontamination literature

[a]Solutions of NaOCl (≥0.1%) or NaOH (>0.25 N) for 30 min inactivate BoNT and are recommended for decontaminating work surfaces and spills of *C. botulinum* or BoNT. Chlorine at a concentration of 0.3-0.5 mg/L as a solution of hypochlorite rapidly inactivates BoNT (serotypes B or E tested) in water. Chlorine dioxide inactivates BoNT, but chloramines are less effective.
[b]Ozone (>2 mg/L) or powdered activated charcoal treatment also completely inactivate BoNT (serotypes A, B tested) in water under defined condition.
[c]SEB is inactivated with 0.5% hypochlorite for 10-15 min.
[d]Ricin is inactivated by a 30 min exposure to concentrations of NaOCl ranging from 0.1-2.5%, or by a mixture of 0.25% NaOCl plus 0.25 N NaOH. In general, solutions of 1.0% NaOCl are effective for decontamination of ricin from laboratory surfaces, equipment, animal cages, or small spills.
[e]The minimal effective concentration of NaOCl was dependent on toxin and contact time; all LMW toxins tested were inactivated at least 99% by treatment with 2.5% NaOCl, or with a combination of 0.25% NaOCl and 0.25N NaOH.
[f]For T-2 mycotoxin and brevetoxin, liquid samples, accidental spills, and nonburnable waste should be soaked in 2.5% NaOCl with 0.25% N NaOH for 4 h. Cages and bedding from animals exposed to T-2 mycotoxin or brevetoxin should be treated with 0.25% N NaOCl and 0.025 N NaOH for 4 h. Exposure for 30 min to 1.0% NaOCl is an effective procedure for the laboratory (working solutions, equipment, animal cages, working area and spills) for the inactivation of saxitoxin or tetrodotoxin.

Alternate methods of chemical decontamination:
1 N sulfuric or hydrochloric acid did not inactivate T-2 mycotoxin and only partially inactivated microcystin-LR, saxitoxin, and brevetoxin (PbTx-2). Tetrodotoxin and palytoxin were inactivated by hydrochloric acid, but only at relatively high molar concentrations. T2 was not inactivated by exposure to 18% formaldehyde plus methanol (16 h), 90% Freon-114+ 10% acetic acid, calcium hypochlorite, sodium bisulfate, or mild oxidizing. Hydrogen peroxide was ineffective in inactivating T-2 mycotoxin. This agent did cause some inactivation of saxitoxin and tetrodotoxin, but required 16 h contact time in the presence of ultraviolet light.

Table 8.3
INACTIVATION PROCEDURES FOR SELECT AGENT TOXINS

Allow at least a 30-minute chemical contact time for complete inactivation of toxin. Any procedure labeled "yes" is an approved procedure for inactivation of the toxin specified.

Select Agent Toxin	Autoclave (1 hour @ 121° C, liquid exhaust)	2.5% NaOCL + 0.25 N NaOH	0.1% NaOCl	1.0% NaOCl	2.5% NaOCl
Abrin	Yes	N/A	N/A	N/A	N/A
Botulinum Neurotoxin	Yes	Yes	Yes	Yes	Yes
Clostridium perfringens epsilon toxin	Yes	N/A	N/A	N/A	N/A
Diacetoxyscirpenol	No	Yes	No	No	Yes (3-5%)
Ricin	Yes	Yes	Yes	Yes	Yes
Saxitoxin	No	Yes	Yes	Yes	Yes
Shigatoxin & Shiga-like ribosome inactivating proteins	Yes	Yes	Yes	Yes	Yes
Staphylococcal Enterotoxins	Yes	Yes	Yes	Yes	Yes
Tetrodotoxin	No	Yes	No	Yes	Yes
T-2 Toxin	No	Yes	No	No	No
Conotoxin	Glutaraldehyde (according to manufacturer's specifications) or thiol reagents (e.g. BAL) if aerosolized.				

Deactivation of Prions

Work with neural tissues presents the possible risk for the presence of prions. Prions are characterized by resistance to conventional inactivation procedures including irradiation, boiling, dry heat, and chemicals (formalin, betapropiolactone, alcohols). While prion infectivity in purified samples is diminished by prolonged digestion with proteases, results from boiling in sodium dodecyl sulfate and urea are variable. Likewise, denaturing organic solvents such as phenol or chaotropic reagents such as guanidine isothiocyanate have also resulted in greatly reduced but not complete inactivation. The use of conventional autoclaves as the sole treatment has not resulted in complete inactivation of prions.

Formalin-fixed and paraffin-embedded tissues, especially of the brain, remain infectious. Some investigators recommend that formalin-fixed tissues from suspected cases of prion disease be immersed for 30 min in 96% formic acid or phenol before histopathologic processing, but such treatment may severely distort the microscopic neuropathology.

The safest and most unambiguous method for ensuring that there is no risk of residual infectivity on contaminated instruments and other materials is to discard and destroy them by incineration. Current recommendations for inactivation of prions on instruments and other materials are based on the use of sodium hypochlorite, NaOH, Environ, and the moist heat of autoclaving with combinations of heat and chemical being most effective:

- Immerse in 1 N NaOH, and heat in a gravity displacement autoclave at 121□C for 30 minutes. Clean and sterilize by conventional means.
- Immerse in 1 N NaOH or sodium hypochlorite (20,000 ppm) for 1 hour. Transfer into water and autoclave (gravity displacement) at 121□C for 1 hour. Clean and sterilize by conventional means.
- Immerse in 1N NaOH or sodium hypochlorite (20,000 ppm) 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.
- Surfaces or heat-sensitive instruments can be treated with 2N NaOH or sodium hypochlorite (20,000 ppm) 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.
- 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 or other liquids). This product is currently

being used under FIFRA Section 18 exemptions in a number of States. Users should consult with the State environmental protection office prior to use.

Unfortunately, these solutions are corrosive and require suitable personal protective equipment and proper secondary containment. These strong corrosive solutions require careful disposal in accordance with local regulations. 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. Persons who use this procedure should be cautious in handling hot NaOH solution (post-autoclave) and in avoiding potential exposure to gaseous NaOH, exercise caution during all sterilization steps, and allow the autoclave, instruments, and solutions to cool down before removal. Immersion in sodium hypochlorite bleach can cause severe damage to some instruments.

CHAPTER 9 **– BIOLOGICAL WASTE MANAGEMENT**

The Augusta University Biological Waste Management Program is designed to protect:

- Personnel who handle, transport and dispose of biological waste,
- The environment, and
- The public perception of the Institution.

Definition of Biomedical Waste

"Biological waste," "biohazardous waste," and "biomedical waste" are terms commonly used interchangeably on Augusta University's campus. These materials must be excluded from the general waste stream unless appropriately decontaminated or deactivated. These include:

- Cultures and stocks of microorganisms
- Cultures/specimens from medical and pathological laboratories
- Materials that may have been contaminated with biological materials (including all tissue culture materials)
- Live and attenuated vaccines.
- Human tissues and fluids, including items that have come into contact with human tissues and fluids
- Sharps waste, including includes needles, Pasteur pipettes, scalpel/razor blades, blood vials, etc.
- Unused sharps, including items which have never been in contact with any biological materials
- Animal carcasses, tissues, and bedding
- Chemotherapy waste

The biological waste management program does not supersede the requirements for radioactive and/or hazardous chemical waste programs. Radioactive or hazardous chemical wastes shall be disposed of through the radioactive waste stream or the hazardous chemical waste stream respectively. In mixed waste situations (biological/chemical or biological/radiological), the waste disposal requirements of the chemical or radiological waste disposal procedures will take precedence over the biological, particularly, since biological wastes can usually be decontaminated/deactivated prior to placing the waste in the chemical or radiological waste streams.

Solid Biomedical Waste

Following collection from the laboratories and clinics, all solid biological waste generated by Augusta University is congregated in a trailer for eventual transportation by a professional biomedical waste handling company (as of June 2008, that contractor is Stericycle®). Stericycle® will transport the waste containers to their facilities for incineration.

Even though the waste is transported away from Augusta University for disposal, the institution is still liable for the environmental repercussions of inappropriate transport or disposal of any waste generated at Augusta University; therefore it is crucial that all personnel who may handle biologicals understand the appropriate waste disposal procedures.

Solid Biomedical Waste Procedures:

- Liquids or soggy materials should NOT be placed inside the Stericycle red-bag lined boxes; leaking waste containers pose a risk to Augusta University and/or Stericycle staff and violate U.S. Department of Transportation regulations.
- No chemicals or radiological materials should be placed in the general biomedical waste stream due to the potential risk posed to Augusta University and Stericycle® handlers and to the environment.
- Biohazard waste must be secured at all times; boxes or containers should not be left in unsecured areas (*e.g.,* in hallways or on loading docks) where non-trained personnel or personnel with unknown health status may encounter them.
- Staging of waste in secondary accumulation areas (*e.g.,* closets within buildings) is not permitted; waste containers should be removed from the laboratories and clinics and directly transferred and secured in the Stericycle® trailer.
- Care should be taken to not allow the boxes to become wet or damaged or exposed to vermin.
- Never remove a leaking biohazard waste box from a laboratory; notify the laboratory staff and/or the Biosafety Office to enable the staff to safely re-package the wastes prior to removal.
- If leakage is noticed after removal from the laboratory, the Environmental Services staff should contact the Environmental Health and Safety Office immediately and provide relevant information to identify the laboratory of the waste's origin.

- Because it is significantly more costly to dispose of biomedical waste than regular trash, items which are not biological waste or potentially contaminated with biological materials should NOT be placed in the biohazardous waste containers (i.e. pipette wrappers, notebook papers, paper towels which have not been in contact with any biological material). However, if one is unsure whether a particular item is contaminated with biological material, one should default to the biohazardous waste container. Since food items are not permitted in the laboratory, soda cans, candy wrappers, etc. should never be found in biohazard waste containers.
- Biohazardous waste bags/boxes/sharps containers should NOT be used for alternate purposes other than for collection of biohazardous wastes. These are provided by the biohazardous waste contractor and should be used expressly for collection of biohazardous wastes.
- Environmental Services (a.k.a. housekeeping) staff is responsible for providing the appropriate biohazardous waste containers and removing these items from the laboratory and clinics. To request additional biohazardous waste containers, or to request waste pick-ups, please contact 706-721-2434.
- Biowaste boxes, red bags, sealing tape and animal carts are delivered in each arriving empty truck from Stericycle®. Environmental Services staff is responsible for removing these materials from the truck prior to loading any biohazard waste containers into the trailer for disposal. Supplies should be stored in the Environmental Services supply areas throughout campus.
- The Environmental Services Office will provide authorized biohazardous waste containers, shown below. Alternate waste containers provided by the laboratory must be placed into one of the authorized Stericycle® waste containers by the laboratory staff for removal by the Environmental Services staff.

Biohazard "Red Bag" Box Procedures:

- No liquids or soggy materials should be placed in these containers.
- No loose sharp items should be placed in these containers
- These containers have a **50 lb. maximum weight** limit.
- Any material of higher hazard (≥BSL-2) should be decontaminated prior to placement into these containers to prevent exposure to personnel who may close the bag.
- The box should be closed and removed before the contents leak or spill over the edge. Do not overfill boxes.
- When preparing these boxes, Environmental Services Staff should use at least three (3) strips of packing tape to secure the bottoms of the boxes, each overlapping the edges by at least six (6) inches on either side. One strip of tape should be placed across the seam of the box; the other two strips should be placed perpendicular to the first strip of tape to secure it. The box is turned upright, and the top flaps bent backwards. Each box should be lined with one red biohazard plastic bag, folded over the box flaps, as shown above.
- After filling, while wearing appropriate PPE, Environmental Services personnel should carefully gather the edges of the bag together to avoid production of aerosols, and grasp the bag approximately 10 inches below the edges and twist the bag closed. The twisted bag should be secured with several pieces of packing tape.
- After the bags are securely closed, before removal from the laboratory, while wearing PPE (gloves, eye protection, coat/gown) the Environmental Services staff should tape the top box flaps closed with three strips of tape, overlapping each edge by at least six (6) inches (similarly to the way the bottom of the box was closed). They should place a Stericycle® label on the box. The label should include the date the waste was removed from the laboratory and the building and room number where the waste originated. The boxes should be removed by Environmental Services staff and placed on the Stericycle® truck for transport to their facilities for decontamination and disposal.
- Should laboratory staff notice waste that requires disposal, please contact Environmental Services (706-721-2434).

Laboratory staff may choose to use alternate intermediary biohazard waste containers. Use of these alternative containers must meet the following requirements:

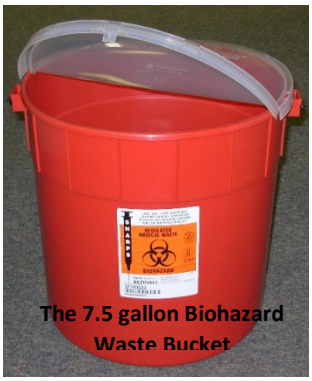
- Containers must be clearly demarked as biohazardous waste with color-coded labels (e.g., by using red bags or biohazard stickers).
- Waste in these containers are removed as promptly after use.
- Containers must be capable of being decontaminated and are decontaminated often.
- No sharps are disposed in these intermediary containers (sharps must be directly placed into authorized sharps containers).
- The waste is transferred to the authorized waste receptacle by the laboratory staff (not the Environmental Services staff).

A word of caution about the use of lifting biohazard bags: The act of lifting a bag containing biohazardous materials can increase ones risks of exposure to biohazardous materials. First, the act of lifting may generate aerosols; therefore staff should be fully protected with PPE (at least lab coat, gloves and eye protection), and the bag should be tightly closed before lifting. In addition, any pointed items that may penetrate the bag (*e.g.,* pipettes, micropipette tips) should not be placed in bags that are to be lifted, since they may also increase the exposure risks if the bag were to be punctured during lifting. Care should be taken by any staff member lifting a bag. These should be placed in the red bag/box for eventual disposal.

Sharps Container Procedures:

There are two types of sharps containers available upon request through Environmental Services (706-721-2434). These are shown below:

The Small Sharps Container



The 7.5 gallon Biohazard Waste Bucket

Each of these containers complies with OSHA BBP standard requirements dictated for sharps containers:

- Closable, puncture-resistant, leakproof on the sides and bottom, labeled and/or color-coded.
- Easily accessible and located close to work areas where sharp materials are used (place containers near sharps; do not walk across rooms handling sharps to dispose into the containers).
- The containers must be maintained upright.
- These containers need to be replaced routinely. Do not allow these containers to become overfull. As a rule, no sharps container should be allowed to become >2/3 full. Many sharps containers have handy "Full" arrow marks on the containers to remind users to replace the containers once they have reached ~2/3 full.

Any item that may puncture a trash bag or red bag liner should be placed in a sharps container for disposal, **regardless of biohazard contamination**. Hypodermic needles, syringes (with or without the attached needles), pasteur pipettes, disposable plastic pipettes, scalpel blades, razor blades, blood vials, test tubes, needles with attached tubing, broken plastic culture dishes, unbroken glass culture dishes, and other types of broken and unbroken glassware, including microscope slides and coverslips, should be placed in a sharps container for disposal.

Because these containers have leak-proof sides and bottoms, soggy items and **small amounts** of liquids (e.g., a few ml of blood remaining in a tube) can be disposed in these containers. However, larger volumes of liquids should be handled as liquid waste.

Environmental Services is responsible for closing and removing these containers from the laboratories. These are typically placed UPRIGHT in the red bag/boxes prior to sealing the box as described above.

Non-Contaminated Glass

Unbroken glass which has not been contaminated with any hazardous materials should be placed in a closed heavy duty cardboard carton before disposal in the general waste stream.

Improper Solid Biohazardous Waste Disposal

Environmental Services Staff members are to handle only the authorized waste containers above. They are not to:

- Lift any biohazard (red) bag from any waste receptacle (lifting only increases the Environmental Services staff members' potential exposure risk to biohazardous aerosols which may be generated while lifting or materials which may leak from the bag should the bag puncture).
- Combine the contents of multiple waste containers in order to compile one full container for disposal (combining only increases the risk of exposure to biohazardous aerosols, but also risks contaminating floors and surrounding areas).
- Leave any waste container unsecured or unprotected outside of the laboratory/clinic.
- Leave the Stericycle® truck unsecured.
- Accumulate wastes in any secondary waste collection sites (e.g., closets). The waste should be removed from the laboratory or clinic and taken to the Stericycle® truck.
- Please note: like all sharps containers, the 7.5 gallon biohazard buckets are **not** intended to be re-usable waste receptacles. Bag liners are not to be used in conjunction with these buckets, and they should **always** be used with their fitted plastic lids.

Pathological Wastes

Any item which is identifiable as a human or animal body part or an animal carcass needs to be disposed pathological waste. These items must be appropriately labeled for incineration. At Augusta University, the majority of the pathological waste is generated through animal waste disposal procedures. All animal carcasses be packaged and labeled according to LAS/IACUC compliant procedures and placed in one of the necropsy freezers (*e.g.*, in CB-1344, CA-1105, CA-1126, CA-1135, BG-1135A, CL-1119 or CL-1133) or in the cold storage room (CB-3100). Contact LAS for further information about labeling procedures. These wastes will be placed in the animal waste carts and placed on the Stericycle® trailer just prior to departure. Contact the Division of Environmental Health and Safety if you will be generating any pathological waste that is identifiable as human remains or if you have any other questions related to pathological waste disposal.

Liquid Biological Wastes

Liquids which are derived from biological organisms (*e.g.,* blood) or have been exposed to biological materials (e.g., tissue culture media, cell extracts) must be decontaminated prior to disposal. Liquid waste decontamination and disposal methods must be documented in each laboratory's or clinic's Standard Operating Procedures (SOPs).

The sanitary sewer was designed for the disposal of certain liquid wastes. Use of the sanitary sewer reduces the chance for leaks or spills during transport and reduces disposal costs. Whenever possible, decontamination of liquids by autoclaving or use of chemicals (namely, bleach) which can be disposed in the sewer system, is highly recommended. Remember to rinse sink with copious water after disposal of decontaminated/deactivated

biological materials.

Other chemical disinfectant methods may require subsequent disposal of the wastes through the chemical waste stream. Similarly, if the biological wastes are contaminated with chemicals or radiological materials, disposal procedures will have to be modified to comply with disposal requirements for these materials. Caution must be paid to disposal of any material which may clog or clog sewer disposal pipes. This would include large amounts of blood or agar. Disinfection of large amounts of blood may be accomplished by treatment with Isolyzer Plus®. This chlorine-based granular product solidifies and disinfects the blood or body fluids so they may be placed in general (clear), not biowaste (red) waste bags. Agar should be allowed to solidify prior to disposal in the regular waste stream (if not used in conjunction with biological materials), or placed in solid-sided waste containers, such as the 7.5 gallon biohazard waste bucket (if potentially contaminated with biological materials).

Chemotherapy Wastes

Chemotherapy agents need to be segregated from the general biohazardous waste, as per Georgia EPD Chapter 391-3-4-.15 http://rules.sos.state.ga.us/docs/391/3/4/15.pdf. While these agents are often used in clinical therapy, many of these agents may also be used for in vitro and *in vivo* animal research applications (*e.g.,* Actinomycin D, Mitomycin-C, Bleomycin, GM-CSF, Interleukin-2, INF-α, Gleevec) and must be disposed as chemotherapy waste. A list of chemotherapy agents can be found at: http://www.chemocare.com/bio/

According to GA EPD, chemotherapy wastes include 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 the growth and spread of tumors or malignant cells) during the preparation, handling, and administration of such agents. Such waste includes, but is 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 prior to being handled as biomedical waste. (Note: "Empty" is generally defined as containing less than 3% by weight of the total capacity of the container).

Stock solutions of these chemicals and items that are heavily contaminated are disposed of through the Chemical Hazardous Waste Program. Call the Chemical Safety Office for guidelines concerning the disposal of chemical hazardous waste.

Mixed Waste

“Mixed waste” are those wastes which are contaminated with more than one type of hazardous material. For the purposes of this Guide, focus will be on those materials which are contaminated with biologicals and either chemical or radiological materials.

Biological/Chemical Mixed Waste

Many chemicals serve to disinfect biological materials through lysis, dehydration or protein-crosslinking. Common chemical fixatives (formalin, glutaraldehyde) may serve to decontaminate a biological material, leaving only the chemical waste disposal issues to address. Whenever possible, in biological/chemical mixed waste situations, efforts should be made to determine whether the chemicals have adequately decontaminated the biologicals. If they have not, seek assistance from the Biological and Chemical Safety Offices to determine whether a chemically-compatible decontamination method can be devised which would then allow these items to be disposed as chemical waste. These should be documented in your laboratory SOPs prior to initiation of any experiment which would produce the mixed waste.

Items contaminated with ethidium bromide, diaminobenzidine (DAB), phorbol, or phenol-chloroform mixtures should not be mixed with other biomedical waste. These are already chemically decontaminated and should not be autoclaved or bleached. These items should be segregated into their own containers and disposed as chemical waste.

Do not dispose of biological items which contain mercury in the biowaste. Biological items which may contain mercury (*e.g.*, extracted teeth which contain mercury amalgams fillings) should first be decontaminated using a broad-spectrum chemical disinfectant (*never* autoclave mercury!) and disposed as mercury waste through the IH office.

Biological/Radioactive Mixed Waste

All Radioactive wastes are required to be disposed through the Radiation Safety Office. Any biological materials that can be decontaminated with bleach, first, should be decontaminated and the pH of the resultant waste adjusted by the addition of non-hazardous buffering agents (sodium bicarbonate, Tris) prior to disposal as radioactive waste.

Radioactive sharps waste should be disposed of in sharps containers to which Radioactive warning labels have

been clearly affixed. These should be disposed through the Radiation Safety Office.

Animal carcasses, tissue/parts, and excreta containing/contaminated with radioactive materials shall be handled and collected by those with proper radioactive material training and exposure badging.

Requisitions for New or Additional Biohazardous Waste Containers

Extra Stericycle box-bag units or authorized sharps containers can be obtained from Environmental Services at no cost to your laboratory. Any alternate required intermediary waste containers (small biohazard bags, small sharps containers) must be provided by the laboratory director.

If an unusual situation arises which requires disposal of large amounts (>15 gallons) of soggy materials or liquid materials, please contact the Environmental Health and Safety Office for assistance.

Requisition for Biohazardous Waste Pick-Up

The Environmental Services staff (a.k.a. Housekeeping) is responsible for removal of any full authorized waste containers. If laboratory staff members notice containers that are full and require removal, please contact the Environmental Services Office.

All animal carcasses, bedding and body parts are to be disposed through the Division of Laboratory Animal Services (LAS). As per LAS policies any animal bedding, caging or carcasses which have been purposely infected or known to have been exposed to Risk Group 2 agents shall be autoclaved prior to disposal in Biowaste containers. All animal carcass and body parts will be stored in the appropriate DLAS freezers and placed in the Stericycle® waste carts for transport to Stericycle® and incineration.

CHAPTER 10 – PLACARDS, SIGNS AND LABELS

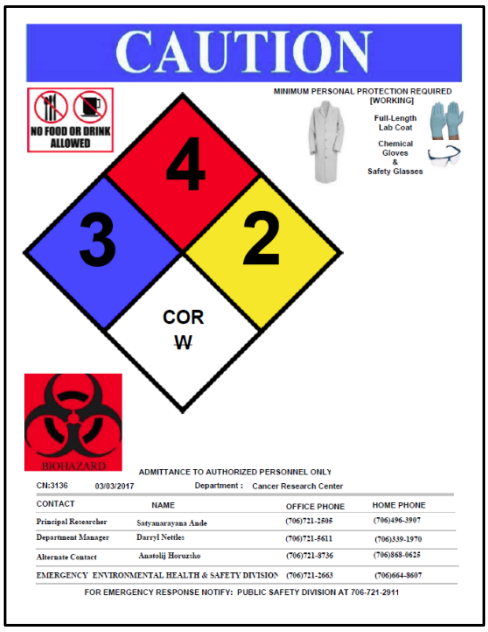
Placards, signs and labels which identify areas and equipment where biohazardous materials are stored or used are required by OSHA, CDC, and the NIH as a form of hazard communication.

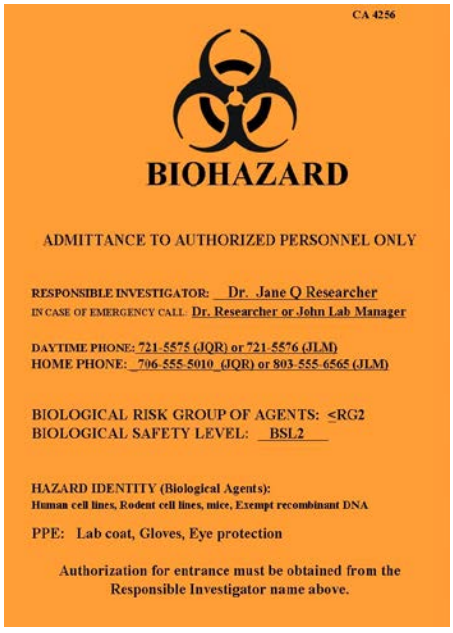
Door Placards

The purpose of the door placard is to advise all persons entering the laboratory or clinic area of potential hazards and the specific entry/exit requirements that must be met prior to entry. Entryways into any laboratory or animal facility in which biological materials are handled must be posted with an EH&S placard that contains a biohazard symbol. The EH&S placard is posted by EH&S and is used for areas requiring ≤ BSL2 containment measures.

A small number of laboratories at Augusta University require BSL2 enhanced/BSL2+ containment. In these facilities there may be specific vaccinations or PPE requirements. These areas will be posted with an orange biosafety placard in addition to the EH&S placard. These signs are available through the Biosafety Office. Contact the Biosafety Office if your area does not have a door placard or if the information on the placard needs to be updated. Biohazard door placards must be fluorescent orange-red with lettering or symbols in a contrasting color and include the following information:

- The universal biohazard symbol with the legend “BIOHAZARD”.
- The building and room number.
- The name of the responsible investigator, laboratory director, or clinic director. This person must have knowledge of the types of biological material, the hazards they pose, and the appropriate laboratory incident emergency response standard operating procedures.
- The name of an alternate contact person who may be contacted in the case of an emergency.
- The daytime phone numbers and emergency after-hours contact numbers for the responsible investigator, laboratory or clinic direction and those of the alternate contact person.
- The Biosafety Level (BSL) of the room.
- A description of the biological hazards within the laboratory.
- The appropriate PPE that must be worn by all personnel within the laboratory.
- Any additional entry requirements or special provisions for entry as established in the laboratory SOPs (e.g. required vaccination, respirators, authorizations, etc.)





Labels

Laboratory equipment or any containers exposed to biohazardous materials require warning labels. Labels must be fluorescent orange-red with lettering or symbols in a contrasting color, have the international biohazard symbol and bear the legend "Biohazard". Labels of various sizes are available from the Biosafety Office upon request.

Laboratory equipment (i.e. refrigerators, freezers, incubators, cryotanks, centrifuges) require warning labels that are affixed to an easily visible surface. Equipment that is decontaminated after use do not require a permanent label (i.e. biosafety cabinets). Equipment where biological materials are stored should have contact information for a person responsible for the contents of the equipment.

Transport containers used to transport biological materials require a biohazard warning label and contact information. The label shall be affixed to the outermost transport container and the contact information shall indicate a person responsible for the contents of the container.

Biohazardous waste containers, sharps containers or secondary containers (i.e. beakers placed in a biosafety cabinet to collect waste or small containers placed on a bench top to collect waste) require a biohazard warning label. The biohazardous waste containers and sharps containers provided by the Institution have the biohazard symbol printed on the container. All other containers will require an affixed label.

CHAPTER 11 – TEACHING LABORATORIES

Teaching laboratories present unique challenges for maintaining compliance with biological safety standards. The purpose of this chapter is to address those areas of laboratory safety that are unique to the teaching laboratory setting. This chapter does not negate the Instructor's responsibility for the entire Biosafety Guide as indicated in the Introduction to the Biosafety Guide; however, it does lend itself to the flexibility required to mitigate risks in these areas. This guidance is based on the American Society for Microbiology, Guidelines for Biosafety in Teaching Laboratories, 2012.

Educators need to be aware of the risks inherent in using microorganisms or cells/tissues that may harbor microorganisms in the laboratory and must use best practices to minimize the risk to students and the community. Biosafety Levels (BSL) are a combination of facilities, practices and equipment used to contain pathogens. Even though the majority of the organisms handled in undergraduate laboratories can be manipulated a BSL1, many of these organisms are capable of causing an infection given the appropriate circumstances. Organisms requiring BSL2 containment are capable of causing disease in humans, which is rarely serious and for which preventative and therapeutic interventions are often available. The guidance set forth in this chapter is applicable to faculty, staff and students.

Registration of Biological Materials

All Course Directors/Instructors working with biological materials are required to register their biological materials by completing and submitting a Course-based teaching application. This allows the Biosafety Office to evaluate the risks and assist the instructor with mitigation strategies. The application is available on the Biosafety website and must be submitted electronically. Amendments are not required unless there are changes affecting the biological risks associated with the course. In that case, the Course Director/Instructor will edit the original application to reflect the change and submit it to the Biosafety Office for review. A course that is taught multiple semesters does not require a new application each semester. New courses will require a new application. Note: This applies to teaching laboratories only, Course Directors/Instructors who will engage in research using the same materials or even in the same space must comply with the Biosafety Requirements indicated in Chapter 2 of the Biosafety Guide.

Occupational Health Requirements

- Advise immune-compromised students (including those who are pregnant or may become pregnant) and students living with or caring for an immune-compromised individual to consult physicians to determine the appropriate level of participation in the laboratory.
- Advise students of agent-specific precautions (e.g., cystic fibrosis patients should avoid work with *Pseudomonas aeruginosa*)

Minimum Apparel Requirements

- Ankle length pants or skirt;
- Enclosed shoes - must cover the toes, heel, and top of foot; and
- Long hair, loose jewelry and loose clothing must be confined.

Personal Protective Equipment (PPE) Requirements

- PPE in laboratories must include lab coat, gloves and safety glasses for all procedures/experiments involving biological materials, along or in conjunction with chemicals.
- Students may use the same lab coat for more than one class, including chemistry labs.
- Lab coats should be sealed in an airtight container (i.e. large Ziploc bag) when removed from the laboratory to prevent contamination of personal items or food and drink.
- The Biosafety Office will provide guidance for decontamination and laundering of lab coats.
- Laboratories that are engaging in research must adhere to the minimum PPE requirements for all research laboratories (i.e. lab coat, gloves and eye protection) regardless of the level of PPE worn during instructional activities. See Chapter 4 for more information.

Laboratory Facility Requirements

- EH&S placard at the entrance to the lab, as shown in Figure 11.3.
- Nonporous floor, bench tops, chairs, and stools.
- Sink for hand washing.

- Eyewash station.
- Lockable door to the room.
- Pest control practices (i.e. pest control program, fly screens on windows that open)
- Keep personal belongings in an area separate from work areas.

Laboratory Equipment Requirements

Recommended: Biosafety Cabinet for work with large volumes, procedures that will generate potentially infectious aerosols or agents that require BSL2 containment.

Standard Laboratory Practices

- Use cultures, cells and tissues from reputable sources (e.g., an academic laboratory, USDA-approved source, ATCC).
- No eating, drinking or applying cosmetics in the laboratory.
- Do not store food/beverage in refrigerators in the laboratory.
- Do not mouth pipette.
- Label all containers clearly, in English.
- Label all equipment (e.g., refrigerators, incubators) and containers where biohazardous materials are stored with a biohazard sticker (provided by the Biosafety Office).
- Minimize the use of sharps and handle sharps safely. Do not handle broken glass with hands, use forceps.
- Disinfect surfaces with a disinfectant known to kill the microorganisms present.
- Keep hands away from your face, eyes, mouth and body while working in the lab.
- Do not use the computer, touch your cell phone or other “clean” surfaces with contaminated gloves.
- Wash hands after glove removal and before exiting the laboratory.

Transportation of Biological Materials

Transport procedures for biological agents between locations (i.e. through hallways and other non-laboratory areas) requires transportation of agents inside a sealed, leakproof primary container inside a well-labeled sealed, leakproof, durable secondary container. For regulatory requirements, procedures and training for transport of biological materials via personal vehicle or by shipment, see Chapter 10 for more information.

Training Requirements

The following computer-based training is required for Faculty/Researchers/Laboratory Workers (see Chapter 10 for more information):

- Initial Biosafety and Bloodborne Pathogen Training (required once)
- Refresher Biosafety and Bloodborne Pathogen Training (required annually)
- Shipping Biological Substances and Support Materials (required every 2 years) – only for persons who are responsible for marking, labeling, packaging, shipping, transporting, or receiving biological materials).
- NIH Guidelines 101 (required once) – only for individuals that will be conducting experiments that are subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids*.

The following in-class training is required for all students:

- Instructors must develop general laboratory safety rules and review them with students at the beginning of each semester. A written record of training (i.e. signature log) should be retained for a minimum of one year.
- Students should locate the eye wash station/safety shower and critical event emergency response guide as shown in Figures 11.1 and 11.2.
- Students should be familiar with the hazards present in the laboratory, the minimum PPE requirements and emergency contacts. This information is available on the EH&S placard, shown in Figure 11.3.

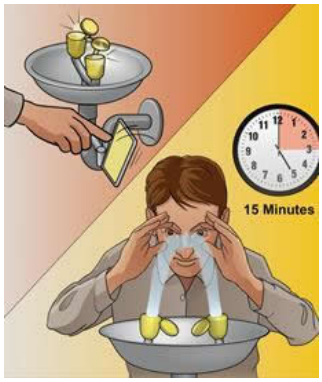


Figure 11.1 – Eye Wash Station

Figure 11.2 – Emergency Response Guide

Figure 11.3 – EH&S Placard

- Students that are engaging in research must adhere to the training requirements for *Faculty/Researchers/Laboratory Workers*. See training requirements above or Chapter 4 for more information.

Decontamination

Laboratory work surfaces and equipment must be decontaminated when work is completed, at the end of each day, and after a possible contamination with biological material. Equipment should also be decontaminated before repair work and before moving from the lab. It is the responsibility of the instructor, with guidance from the Biological Safety Office, to determine the best decontamination method based on biological agents present in the laboratory.

Waste Disposal

Solid Biomedical Waste (i.e. plasticware, tubing, pipette tips, gloves)**:** Solid biomedical waste should be placed in a biohazard, red-bag lined box, provided by Environmental Services, as shown below in Figure 11.4. To request additional biohazardous waste containers, or to request waste pick-ups, please contact 706-721-2434.

Sharps Waste (i.e. needles, glass, scalpels, razor blades): There are two types of sharps containers available upon request from Environmental Services, as shown in Figures 11.5 and 11.6. To request additional sharps waste containers, or to request waste pick-ups, please contact 706-721-2434. These are shown below:

Figure 11.4 – Biohazard Box

Figure 11.5 – Standard/Small Sharps Container

Figure 11.6 – 7.5 Gallon Sharps/Biowaste Bucket

Liquid Biomedical Waste (i.e. cultures, stocks, vaccines): Liquids must be decontaminated with an appropriate method (i.e. bleach, autoclave) prior to disposal in the sanitary sewer. Special procedures may be needed to inactivate toxins prior to disposal.

Pathological Waste (i.e. human cells, tissues, blood and other body fluids): Human cells and fluids must be treated as liquid biomedical waste. Any item which is identifiable as a human body part or tissue must be incinerated. Contact the Biological Safety Office for disposal procedures.

Animal Waste (i.e. carcasses, tissues, bedding): All animal carcasses and tissues must be transferred to an authorized vendor for incineration. Fixed animal tissue should be separated from fixative and stored in the laboratory until waste pick-up is scheduled. Consult with the Chemical Safety Office for guidance on disposal of

fixative. Unfixed animal tissue must be packaged and labeled according to LAS/IACUC compliant procedures and placed in the necropsy freezer located in SH E1000.

Mixed Waste (i.e. contaminated with chemicals or radioactive materials): If your biomedical waste is mixed waste (i.e. contaminated with chemicals or radioactive materials) that waste will need to be disposed of according to the recommendations of those safety offices.

Spills

Spill Kit

A Biological Spill Kit should be maintained in all laboratories where biologicals are handled for research or teaching purposes. The kit should contain the following items:

- Paper towels or other absorbent materials (diapers or disposable shop towels)
- Concentrated Bleach (or other disinfectant per laboratory SOPs) (<1 year old)
- Broom and dustpan (or other device for removing solid objects within a spill)
- Tongs (or other mechanical device for handling sharps)
- Biohazard bags for the collection of contaminated spill clean-up items
- Biological Spill sign for warning others to avoid the area
- Spill clean-up instructions
- PPE
- A spray bottle or other container for making 10% bleach solutions

Restock supplies as they are used. Decontaminate any reusable items before returning them to the kit using a decontamination method suitable for the agents used in your laboratory or involved in the spill.

Spill Clean-up Procedure

The risks posed by a spill of biological material may depend on the risks posed by the agents themselves, where in the laboratory the spill occurs (e.g. inside a biosafety cabinet, inside a centrifuge), and its volume. Consideration must be given to the aerosols that biological spills may generate, particularly with infectious agents which have a higher potential to be transmitted via aerosols.

The following spills should be reported immediately to the Laboratory Supervisor, Principal Investigator or Instructor and the Biosafety Office (during work hours) or Public Safety (after work hours):

- Large/high risk spill (>10 milliliters of agents requiring BSL1 or BSL2 containment or any volume of a Select Agent/Toxin).
- Any spill outside of an authorized laboratory area (e.g. during intra-campus transport).
- Any spill in which injury or overt exposure has occurred.

Large/high risk agent spills(>10 milliliters of agents requiring BSL1 or BSL2 containment or any volume of a Select Agent/Toxin):

- If risk of aerosol transmission exists, avoid inhaling material and quickly leave the laboratory, while notifying others to leave immediately.
- Remove any contaminated clothing or Personal Protective Equipment and place in biohazard bag for autoclaving and/or disposal as biohazardous waste. Wash your hands!
- After clearing the area, post warning signs to alert others to the danger and immediately notify the laboratory supervisor and the Biosafety Office: 706-721-2663. Do not attempt to clean spill until further instructed by the Biosafety Office.

Small/lower risk spills (<10 milliters of agents requiring BSL1 or BSL2 containment) within a laboratory:

- Remove suspected contaminated PPE. Wash any suspected contaminated body parts appropriately.
- Clear the area of all personnel. Post warning signs to keep other personnel away from the spill area. If injury or overt exposure has occurred, immediately notify the Laboratory Supervisor, Principal Investigator or Instructor and the Biosafety Office 706-721-2663 (during work hours) or Public Safety 706-721-2911 (after work hours):
- Put on appropriate Personal Protective Equipment (PPE, e.g. gloves, lab coat, eye protection).
- If spill has occurred inside of a biosafety cabinet (BSC), leave the BSC ON at all times while cleaning the spill.
- Remove any debris (broken tubes, etc.) using mechanical means (forceps, disposable dustpan/broom). Items which need to be retained (e.g. undamaged centrifuge tubes) should be removed to a secondary containment for immediate transfer to a biosafety cabinet and subsequent decontamination.

- Decontaminate spill:
  - ✓ Cover and contain spill with disinfectant-soaked paper towels. Use appropriate disinfectant. Appropriate disinfectants may include freshly prepared 10% household bleach solution or other hospital approved disinfectant appropriate to decontaminate the spilled agents.
  - ✓ Thoroughly wipe down any potentially contaminated vertical surfaces (e.g. Biosafety cabinet walls, centrifuge walls) with disinfectant soaked paper towels.
  - ✓ Flood any surfaces in which liquids can be contained (BSC work surfaces, drain pans, catch basins or centrifuge bowls) with disinfectant.
- Allow at least 30 minutes exposure time for decontamination of any surface.
- Clean area again with disinfectant-soaked paper towels. In Biosafety cabinets, remove exhaust grills and trays and clean top and bottom surfaces with disinfectant-soaked paper towels before replacing.
- Dispose all paper towels and gloves or disposable PPE as biohazardous waste. Autoclave any other potentially exposed material for disinfection.
- Wash your hands**!**

Accidents/Incidents

Refer to the flip chart “Critical Event and Emergency Response Guide” located on the wall in your lab for medical emergency guidance.

- Alert others to avoid the area if hazards are present (post spill sign, secure sharps).
- For inhalation hazards, leave the room, alert others to avoid the area (post spill sign, close door and wait 30 minutes if aerosol involved).
- Report the incident to your Supervisor/instructor.
- Seek medical attention.
- Notify the Biological Safety Office as soon as possible to assure that the appropriate treatment and post-exposure follow-up measures are implemented.

Subcutaneous exposure: If injected, remove gloves. Wash with soap for 15 minutes and express the wound under running water.

Oral exposure: If swallowed, wash out mouth with water, provided person is conscious. Seek medical attention as soon as possible.

Inhalation exposure: If inhaled, remove to fresh air. If breathing becomes difficult call 911.

Dermal exposure: In case of skin contact, wash the skin thoroughly with soap and water for 15 minutes. Rinse with copious amounts of water. Remove contaminated clothing and shoes. If symptoms persist after washing, seek medical attention (see instructions below).

Eye exposure: In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers as shown in Figure 11.1.

APPENDIX A
BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN (ECP)

The mission of the Occupational Health and Safety Administration (OSHA) is to save lives, prevent injuries, and protect the health of America's workers. OSHA'S bloodborne pathogens (BBP) standard protects employees who work in occupations where they are at risk of exposure to blood or other potentially infectious materials (OPIMs). It requires employers to develop written documents to explain how they will implement each standard, provide training to employees, and protect the health and safety of their workers.

The full text of OSHA's bloodborne pathogen standard is found in 29 CFR 1910.1030. A link to the standard is provided on the Biological Safety Office webpage.

Policy

Augusta University is committed to providing a safe and healthful work environment for all faculty, staff, and students. In pursuit of this goal, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens." The ECP is a key document to assist our organization in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes:

- Determination of employee exposure
- Implementation of exposure control methods
- Hepatitis B vaccination
- Post-exposure evaluation and follow-up
- Training and communication of hazards to employees
- Recordkeeping
- Procedures for evaluating circumstance surrounding exposure incidents

Implementation methods for these elements of the standard are discussed in the subsequent pages of this ECP. Contact information for responsible parties is provided at the end of this document.

Program Administration

The Biological Safety Office is responsible for implementation of the ECP. The Biological Safety Office will maintain, review, and update the ECP at least annually, and whenever necessary to include new or modified tasks and procedures.

Those employees who are determined to have occupational exposure to blood or OPIMs must comply with the procedures and work practices outlined in this ECP.

Principal Investigators (PIs)/supervisors and/or their respective departments will provide and maintain all necessary personal protective equipment (PPE). The PI/supervisor or department manager will ensure that adequate supplies of the aforementioned equipment are available in the appropriate sizes.

Environmental Services will provide sharps containers and red biohazard buckets and will ensure that adequate supplies are available.

The School of Medicine's Office of Operations will provide biohazard boxes and red carts and will ensure that adequate supplies are available.

Employee Health and Wellness and Student Health Services will be responsible for ensuring that all medical actions required by the standard are performed and that appropriate employee/student health and OSHA records are maintained.

The Biological Safety Office will be responsible for training, documentation of training, and making the written ECP available to employees/students, OSHA, and NIOSH representatives.

Employee Exposure Determination

Augusta University's Employee Health and Wellness and Student Health Services identifies personnel exposure determination, i.e. risk of exposure to blood and/or OPIM, based on job classification, tasks or procedures performed, without regard to the use of personal protective equipment (PPE) and regardless of employment status (i.e. full-time, part-time, temporary, per diem, student, volunteer). Employee Health and Wellness and Student Health Services screens on hire/matriculation for bloodborne pathogen risk.

The exposure control measures described in this plan will be extended to full time, part-time, temporary, and per diem employees. Measures will be extended to contract employees through the contracting employer.

Methods of Implementation and Control

Universal Precautions: All employees/students will utilize universal precautions, which are intended to prevent exposure to bloodborne pathogens. Under universal precautions, the blood and other potential infectious materials of all patients are considered potentially infectious for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens.

Exposure Control Plan: Employees/students covered by the bloodborne pathogens standard receive an explanation of this ECP during their initial training and a review during annual refresher training. The *Initial Biosafety and Bloodborne Pathogen Training* and *Annual Biosafety and Bloodborne Pathogen Refresher Training* modules are available through Workforce Learn Online. Augusta University's ECP is available for review on the Biological Safety Office's webpage. Employees/students can request an electronic or paper copy of the ECP by contacting the Biological Safety Office. Contact location/phone number/email: CI building/706-721-2663/biosafety@augusta.edu.

Engineering Controls and Work Practices: Engineering controls and work practice controls will be used to prevent or minimize exposure to bloodborne pathogens. The specific engineering controls and work practice controls used are listed below:

- Eating, drinking, smoking, handling contact lenses, or applying cosmetics are not permitted in the laboratory
- Food and beverages should be stored outside of the laboratory in cabinets or refrigerators designated and used for this purpose.
- Mechanical pipetting devices should be used (e.g., mouth pipetting is not permitted).
- Procedures should be done in a way to minimize aerosols, splashes are sprays (i.e. pipetting along the wall of a container, homogenizing/sonicating using a containment device, opening vacutainer tubes with gauze pad or decapper).
- Contaminated solid waste (i.e. gloves, tissue culture flasks, etc.) should be placed in biohazard waste containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded (see the following section "Labels")
- Sharps should not be bent, sheared, broken, recapped, removed from disposable syringes, or manipulated by hand.
- Used disposable sharps should be discarded immediately in puncture-resistant containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled (see the following section "Labels") or color- coded.
- Puncture-resistant containers used for sharps disposal should be placed near the areas where sharps are used.
- Non-disposable sharps should be placed in a hard-walled container for storage and transport (not left unprotected and/or exposed on bench tops or shelves).
- Sharps safety device are discussed during initial training and during laboratory assistance visits; the use of sharps safety devices is determined at the individual research group level.
- Equipment should be made available for handling of broken glassware (forceps, broom and dustpan, tongs, etc.).
- Equipment should be decontaminated prior to removal from the lab for repair, maintenance, or disposal.
- If the laboratory procedures involve intramural transport of biological materials outside of the laboratory, appropriate containment device(s) should be available (e.g., a sealed, leak-proof primary container inside a well-labeled, sealed, leak-proof durable secondary container).
- A sink and handwashing supplies (i.e. soap, paper towels) must be available in the laboratory.
- Laboratory staff must wash their hands after handling viable materials, after removing gloves, and before leaving laboratory.
- Laboratories must be designed so they can be easily cleaned (carpets and rugs are not allowed in laboratory work areas and all furniture must be non-porous; no cloth chairs, curtains, wall covers, or bulletin boards).
- Laboratory surfaces and equipment must be cleaned at the end of each day, after a spill, or when contaminated.

The Biological Safety Office identifies the need for changes in engineering controls and work practices during regular laboratory assistance visits, through review of reported incidents and when indicated by the Institutional Biosafety Committee.

Sharps safety devices are evaluated regularly by Augusta University Health System. This information is available to Augusta University Employees upon request.

Principal Investigators, area supervisors/managers and their staff develop standard operating procedures with assistance from the Biological Safety Office.

Principal Investigators, area supervisors/managers are responsible for ensuring that these recommendations are implemented. The Biological Safety Office conducts follow-up laboratory assistance visits if needed to verify.

Personal Protective Equipment (PPE): PPE is provided to our employees at no cost to the employee. Training in the use of the appropriate PPE for specific tasks or procedures is provided by the Biological Safety Office. The types of PPE available to employees are as follows:

- Lab coats, gloves and protective eyewear (i.e. safety glasses, goggles) should be worn when working in the laboratory.
- Additional protection (i.e. face shield) is required when splashes, sprays, spatters, or droplets of blood or other potential infectious materials pose a hazard to the eye, nose, or mouth.

Principal Investigators, area supervisors/managers are responsible for establishing a location for PPE, for ensuring that adequate PPE is available for all employees/students, and for familiarizing new employees/students with the procedures for obtaining PPE.

All employees using PPE must observe the following precautions:

- Wash hands immediately or as soon as feasible after removing gloves or other PPE.
- PPE should be changed frequently, when contaminated or damaged, and before leaving the work area.

The procedure for handling used PPE is as follows:

- Used gloves should be placed in a biohazard waste container after use; gloves should NOT be reused.
- Protective clothing should be decontaminated on site and laundered onsite or with a commercial laundering facility; specific laundering arrangements are made on a departmental basis.
- The Biological Safety Office should be contacted for assistance with grossly contaminated PPE.
- Protective clothing should NOT be taken home.

Housekeeping:

- Biohazard waste containers should be disposed of periodically and not allowed to overfill (not more than approximately 2/3 full).
- Biohazard waste containers must be closed prior to removal to prevent spillage or protrusion of contents during handling.
- Sharps containers should be disposed of periodically and not allowed to overfill (not more than approximately 2/3 full).

Labels:

- Areas where human materials are processed or stored with be placarded (i.e. laboratories, soiled laundry, cryostorage areas)
- Equipment used for human materials processing, incubation or storage will be labelled with a biohazard sticker (centrifuges, incubators, cryotanks, freezers, etc.)
- Contaminated solid waste will be placed in a red bag or in a container labelled with a biohazard sticker.
- Soiled laundry will be placed in a red bag.

PIs/supervisors are responsible for ensuring that warning labels are affixed or red bags are used as required. Employees are to notify the Biological Safety Office if they discover regulated waste containers, refrigerators containing blood or other potentially infectious material, contaminated equipment, etc., without proper labels.

Hepatitis B Vaccination

The Biological Safety Office will provide training to employees on hepatitis B vaccinations. Training will address safety, benefits, efficacy, methods of administration, and availability.

The hepatitis B vaccination series is available at no cost after initial employee training and within 10 days of initial assignment to all employees identified in the exposure determination section of this plan. Vaccination is encouraged unless: 1) documentation exists that the employee has previously received the series; 2) antibody testing reveals that the employee is immune; or 3) medical evaluation shows that vaccination is contraindicated. However, if an employee declines the vaccination, the employee must sign a declination form. Employees who decline may request and obtain the vaccination at a later date at no cost. Documentation of refusal of the vaccination is kept at Employee Health and Wellness or Student Health Services.

Vaccinations will be provided by Employee Health and Wellness or Student Health Services.

Post-Exposure Evaluation and Follow-Up

Should an exposure incident occur, contact PI/supervisor and the Biological Safety Office (during normal business hours) or Public Safety (after hours, weekend or holidays). An immediately available confidential medical evaluation will be conducted by Employee Health and Wellness or Student Health Services. After hours, weekends and on holidays the initial evaluation will be conducted by the Augusta University Medical Center emergency room. Follow up will be conducted by Employee Health and Wellness or Student Health Services. Following initial first aid (clean the wound, flush eyes or other mucous membrane, etc.), the following activities will be performed:

- Document the routes of exposure and how the exposure occurred.
- Identify and document the source individual (unless the employer can establish that identification is infeasible or prohibited by state or local law).
- Obtain consent and make arrangements to have the source individual tested as soon as possible to determine HIV, HCV, and HBV infectivity; document that the source individual's test results were conveyed to the employee's health care provider.
- If the source individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed.
- Assure that the exposed employee is provided with the source individual's test results and with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).
- After obtaining consent, collect exposed employee's blood as soon as feasible after exposure incident, and test blood for HBV and HIV serological status
- If the employee does not give consent for HIV serological testing during collection of blood for baseline testing, preserve the baseline blood sample for at least 90 days; if the exposed employee elects to have the baseline sample tested during this waiting period, perform testing as soon as feasible.

Administration of Post-Exposure Evaluation and Follow-up

The Biological Safety Office ensures that health care professional(s) responsible for employee's hepatitis B vaccination and post-exposure evaluation and follow-up are given a copy of OSHA's bloodborne pathogens standard.

PI/supervisor ensures that the health care professional evaluating an employee after an exposure incident receives the following:

- A description of the employee's job duties relevant to the exposure incident
- Route(s) of exposure
- Circumstances of exposure

Procedures for Evaluating the Circumstances Surrounding an Exposure Incident

The Biological Safety Office will review the circumstances of all exposure incidents to determine:

- Engineering controls in use at the time
- Work practices followed
- A description of the device being used (including type and brand)
- Protective equipment or clothing that was used at the time of the exposure incident (gloves, eye shields, etc.)
- Location of the incident
- Procedure being performed when the incident occurred
- Employee's training

Employee Health and Wellness and Student Health Services will record all percutaneous injuries from contaminated sharps in a Sharps Injury Log, if required.

If revisions to this ECP are necessary, the Biological Safety Office will ensure that appropriate changes are made.

Employee Training

All employees who have occupational exposure to bloodborne pathogens receive initial and annual training designed by the Biological Safety Officer. Training includes epidemiology, symptoms, and transmission of bloodborne pathogen diseases. In addition, the training program covers, at a minimum, the following elements:

- A copy and explanation of the OSHA bloodborne pathogen standard
- An explanation of our ECP and how to obtain a copy
- An explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident

- An explanation of the use and limitations of engineering controls, work practices, and PPE
- An explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE
- An explanation of the basis for PPE selection
- Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be offered free of charge
- Information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM
- An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available
- Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
- An explanation of the signs and labels and/or color coding required by the standard and used at this facility
- An opportunity for interactive questions and answers with the person conducting the training session.

Training materials for this facility are available on Workforce Learn Online (train.augusta.edu).

Record Keeping

Training Records: Training records are completed for each employee upon completion of training. These documents will be kept for at least three years in the Biological Safety Office.
The training records include:

- The dates of the training sessions
- The contents or a summary of the training sessions
- The names and qualifications of persons conducting the training
- The names and job titles of all persons attending the training sessions

Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days. Such requests should be addressed to the Biological Safety Offic

Medical Records: Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.1020, "Access to Employee Exposure and Medical Records." Employee Health and Wellness or Student Health Services is responsible for maintenance of the required medical records. These confidential records are kept for at least the duration of employment plus 30 years. Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be submitted to Employee Health and Wellness or Student Health Services.

OSHA Recordkeeping: An exposure incident is evaluated to determine if the case meets OSHA's Recordkeeping Requirements (29 CFR 1904). This determination and the recording activities are done by Employee Health and Wellness or Student Health Services, if required.

Sharps Injury Log: In addition to the 1904 Recordkeeping Requirements, all percutaneous injuries from contaminated sharps are also recorded in a Sharps Injury Log. All incidences must include at least:

- Date of the injury
- Type and brand of the device involved (syringe, suture needle)
- Department or work area where the incident occurred
- Explanation of how the incident occurred.

This log is reviewed as part of the annual program evaluation and maintained for at least five years following the end of the calendar year covered. If a copy is requested by anyone, it must have any personal identifiers removed from the report.

Important Contacts

Department/Division	Office phone	After hours phone	Location	Email address
Biological Safety Office	706-721-2663	706-721-2911	CI-1001	biosafety@augusta.edu
Employee Health and Wellness	706-721-3418	N/A	FG-1174	
Environmental Services	706-721-2434	706-721-2434	RA-102	
SOM Office of Operations	706-721-2314	N/A	AA-1015	jcovar@augusta.edu
Student Health Services	706-721-3448	N/A	AF-1040	studenthealth@augusta.edu

APPENDIX B
TUBERCULOSIS EXPOSURE CONTROL PLAN

Personnel who face occupational exposure to Tuberculosis (TB) should be enrolled in the University's Tuberculosis Exposure Control Plan. The Occupational Safety and Health Administration has identified workers from the following areas as potentially exposed:

- Laboratories that may handle *M. tuberculosis* or be exposed to patients or specimens from patients with tuberculosis
- Healthcare facilities
- Long term care facilities
- Correctional facilities
- Homeless shelters
- Substance abuse treatment facilities

The purpose of this policy is to enhance and promote education and research activities while simultaneously preventing the transmission of TB to students, employees, and visitors.

Tuberculosis (TB) is a disease caused by the bacteria *Mycobacterium tuberculosis* which is spread by people who have active pulmonary or laryngeal TB. The microorganism is carried in airborne particles that are generated when people with active pulmonary or laryngeal TB cough, sneeze, talk, shout, or sing. The particles are small enough that air currents can keep them airborne for hours and quickly spread them throughout a room or building. Infection occurs when a susceptible host breathes in the air particles containing the bacteria. To minimize the risk of transmission of the disease, the Centers for Disease Control (CDC) recommend a written exposure control plan that covers the facilities' policies and procedures for prevention of transmission of tuberculosis in the workplace.

Signs and Symptoms of Active TB

- Coughing that lasts three or more weeks
- Coughing up blood
- Chest pain, or pain with breathing or coughing
- Unintentional weight loss
- Fatigue
- Fever
- Night sweats
- Chills
- Loss of appetite

Employees, students or volunteers with any of the signs or symptoms above should request a TB test from Employee Health and Wellness, Student Health Services, their personal physician, or the health department. It is recommended that the Biological Safety Office be notified of any cases of active TB infection. The Biological Safety Office will then work with Hospital Epidemiology to develop a course of action to limit the spread of infection.

APPENDIX C
HUMAN GENE TRANSFER CLINICAL TRIALS

Proposed clinical trials involving human gene transfer require registration and approval from both campus and federal agencies before initiation. NIH defines human gene transfer as the "the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human subjects." The Augusta University Institutional Biological Safety Committee requirements for human gene therapy protocols are detailed below. Federal requirements (NIH and FDA) for these experiments are described in significant detail in Appendix M of the NIH Guidelines for Research Involving Recombinant DNA, and in the Code of Federal Regulations, 21 CFR, Part 312 (FDA Points to Consider).

Application for Human Gene Transfer Clinical Trials at AU

To initiate the review of a proposed human gene transfer clinical trial, please submit a description of your protocol in the format described in Appendix M of the NIH Guidelines for Research involving recombinant or synthetic nucleic acids. To obtain a copy of the NIH Guidelines, access the NIH Office of Science Policy web site or contact the Biosafety Office.

Only complete protocols will be sent to Committee members for review. Specifically, we'll need:

- Your responses to NIH Guidelines Appendix M-II through M-V
- Your response to Adverse Event reporting requirements detailed in Appendix M-VII
- A copy of your clinical protocol (your IND Submission)
- A copy of the Investigator's Brochure
- A copy of the Informed Consent Document
- Curricula vitae (2 pages) for each key professional in biographical sketch format
- The proposed location for vector production and description of the Good Manufacturing or Good Clinical Practices that will be utilized to prepare the vector
- A copy of the Certificate of Analysis (CoA) for sterility for each lot of vector made at Augusta or sent to the University for this experiment

Additional responsibilities of the Principal Investigator conducting a recombinant or synthetic nucleic acid experiment are detailed in Section IV-B-7, Roles and Responsibilities of the NIH Guidelines.

Adverse Events

All adverse events must be reported in an annual data summary that is prepared for the IRB and the IBC, the FDA, the NIH Office of Science Policy, and your sponsor. Any Serious Adverse Events (SAE's) must be reported by telephone within 24 hours followed by a written report within 10 days. This report must be on file with the IRB and IBC, the NIH OSP, the FDA, and NIH Office for Protection from Research Risks if applicable within 15 days. Please note that SAE's must be reported whether related to the protocol or not. SAE's shall not be designated as confidential, either in whole or in part, and the SAE reports shall be stripped of patient identifiers, such as name, address, contact information, social security numbers, and date of birth. If the SAE occurs after the trial and deemed related to the HGT trial, it must be reported within 15 days of the date of determination.

APPENDIX D
GUIDE TO SHIPPING BIOLOGICAL SUBSTANCES AND SUPPORT MATERIALS

The following Section is an adapted version of materials originally developed by Andy Glode and David R. Gillum at the University of New Hampshire. The Augusta University Biosafety Office wishes to thank Mr. Glode and Mr. Gillum for their work in producing the original document and their generosity in sharing their document with Augusta University.

This guide includes information about how to properly classify, package, mark and label your biological materials for shipment or extramural transport. This Section also describes the training requirements necessary to ship biological materials and support materials (e.g., dry ice, liquid nitrogen, small amounts of fixative). Requirements for ***intramural*** transport are discussed in the AU Biosafety Guide, Chapter 5. VIII – Transport of Biological Materials. Information on the regulations and procedures for transport/shipping of **live animals** can be found through the Division of Laboratory Animal Services.

Shipped/transported biological specimens, infectious agents and other biological materials are regulated by governmental and non-governmental, consensus development organizations. Penalties for non-compliance with the rules are significant and could result in the following fines:

- Up to $250,000 and up to a year jail sentence for individuals.
- Up to $500,000 per incident for organizations.

Several agencies regulate the shipment and transport of biological materials including:

- International Air Transport Association (IATA).
- US Department of Transportation (DOT).
- US Public Health Service (PHS).
- Occupational Health and Safety Administration (OSHA).
- United States Postal Service (USPS).

Infectious substances and other dangerous goods must always be transported according to the appropriate regulations. Carrying dangerous goods by hand, for example in a vial in your pocket or in luggage, is strictly prohibited. IATA and DOT regulations cover your checked luggage, materials you carry on, or materials you carry in your pockets when you board an airplane. Persons who violate regulations are subject to fines and criminal prosecution.
IATA regulations are commonly encountered since they regulate materials transported by air and are generally the most restrictive. For these reasons, this guide pays special attention to IATA protocols; however the DOT standards often reflect those of IATA and also pertain to ground transportation of your materials.

10.1 TRAINING REQUIREMENTS

Federal rules require that anyone wishing to ship biological materials or dry ice must first have shipping training. If you intend to package biological materials or dry ice for shipment, you must complete a special training module, and provide documentation for training to the AU Biosafety Office. AU must be able to document training certification for anyone shipping dangerous goods during regulatory audits. Training consists of:

1. ***Read this section of the Biosafety Guide.*** This document will provide familiarity with the general provisions relating to the regulations and will direct you to obtain more detailed training in the requirements applicable to shipping biological materials and/or dry ice.

2. ***Have a current Biosafety training and Bloodborne Pathogen training.*** This training ensures that you are familiar with hazards presented by infectious materials, proper handling and emergency response procedures.

3. ***Complete an DOT/IATA-compliant shipping training module.*** This must provide you with a certificate of completion and a copy of this certificate must be submitted to the Biosafety Office. This training is required once every two years. Currently, the Biosafety Office has created online shipping training module that can be accessed through the Workforce learn online training system. However, the Biosafety Office may accept alternate forms of training, as long as the content of the class can be documented and complies with the DOT/IATA requirements.

4. ***Document your intent to ship or transport biological materials.*** The IBC will ask that you document your intent to ship or transport biological materials in your Biosafety Protocol or by generating a shipping Standard Operating Procedure. For shipment of certain High Consequence Dangerous Goods, development of safety and security plans are required by law.

Shipping regulations change frequently so it is necessary to repeat training certification every two years.

10.2 Shipping Overview

Follow these steps when shipping biological materials and support materials.

1. Classify your materials for shipment/transport. See Section 10.3.
2. Package, mark, and label your material(s) appropriately. See Section 10.4.
3. Fill out the Shipper's Declaration for Dangerous Goods form. See Section 10.5.
4. If you are shipping any federally regulated materials, including Select Agents, special regulations may apply and/or permits may be required. Consult Section 10.6.
5. If you plan on importing or exporting biological materials, permits may be required. Consult Section 10.7.

10.3 Shipment Type

For shipment purposes, biological material will fit into one of the following categories:

- Unregulated biological material;
- Category A infectious substances;
- Category B infectious substances;
- Patient specimens;
- Genetically modified organisms and microorganisms; or
- Regulated Medical/Clinical Waste

Read each material section carefully to determine how to classify a material. If you are shipping a biological material that *cannot cause disease*, infectious substance regulations do not apply, unless sent by mail (see Section 10.9). Refer to the classification guide to assist with classification of materials (Figure 10.3). **Note:** All specimens or packaging containing dry ice or liquid nitrogen must be shipped properly (see Other Packaging Requirements, Section 10.4.2). All samples preserved with flammable or corrosive materials, such as ethanol or formalin, must receive consultation and pre-authorization from the Augusta University Chemical Safety Office and be shipped appropriately (also please see Section 10.4.2). Materials which are both biological and radioactive require consultation with and pre-authorization from the Radiation Safety Office.

10.3.1 Unregulated Biological Material

The materials listed below are technically not subject to IATA or DOT infectious substance shipping regulations. However, guidance for shipping these materials (*e.g.,* patient specimens, biological products) are found in subsequent sections and these may require a permit for shipment abroad. Please check with the Biosafety Office if you have any questions about these materials. All shipments of blood and blood products must be labeled with a biohazard symbol.

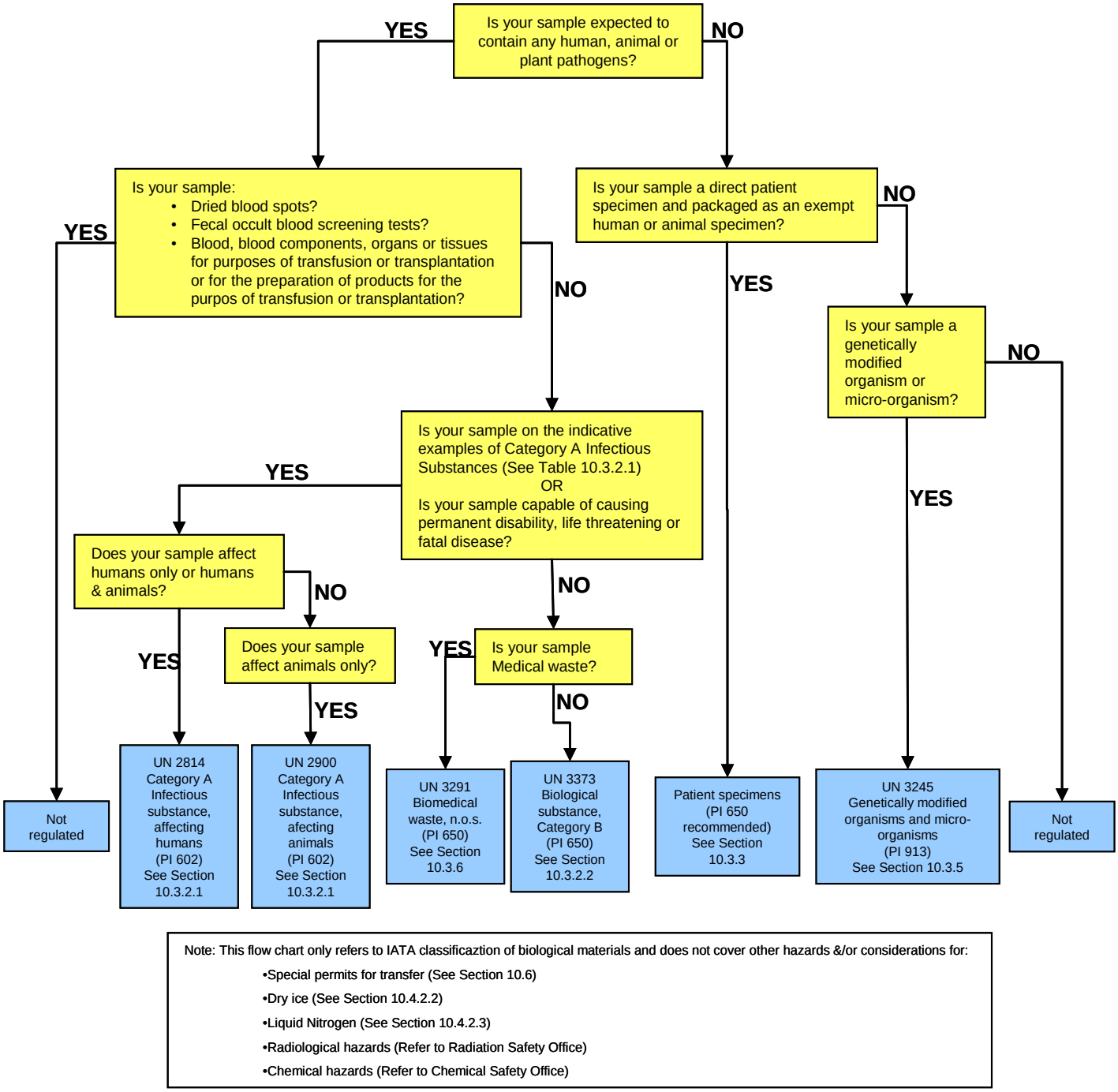
- Substances which do not contain infectious substances or which are unlikely to cause disease in humans or animals;
- Non-infectious biological materials from humans, animals or plants. Examples include non-infectious cells, tissue cultures, blood or plasma from individuals not suspected of having an infectious disease, DNA, RNA, or other genetic elements;
- Substances containing microorganisms, which are non-pathogenic to humans or animals;
- Substances that have been neutralized or inactivated such that they no longer pose a health risk;
- Environmental samples which are not considered to pose a significant risk of infection;
- Dried blood spots*;
- Fecal occult blood screening tests*;
- An infectious substance, other than a Category A infectious substance (See Section 10.3.2.1), contained in a patient sample being transported for research, diagnosis, investigational activities, or disease treatment and prevention, or a biological product, when

such materials are being transported by a private or contract carrier in a motor vehicle used exclusively to transport such materials;

- Blood or blood components which have been collected for the purpose of transfusion or the preparation of blood products to be used for transfusion or transplantation*;
- Tissues or organs intended for use in transplantation*;
- A material with a low probability of containing an infectious disease or where the concentration of the infectious substance is at a level naturally occurring in the environment so it cannot cause disease when exposure to it occurs. Examples of these materials include foodstuffs and environmental samples (such as water or a sample of dust or mold); or
- A 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 Food and Drug Administration (see, *e.g.,* http://www.fda.gov/importeddrugs/ or http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm), or the US Department of Agriculture* (see, *e.g.,* http://www.aphis.usda.gov/import_export/index.shtml and http://www.aphis.usda.gov/vs/ncie/fac_imp.html for guidance).

* When mailing these items with the USPS, follow packaging guidelines for non-regulated items. See Section 10.9.

Figure 10.3 The Classification Guide



10.3.2 Infectious Substances

Infectious substances are materials known to be, or are reasonably suspected to contain, an animal or human pathogen. A pathogen is a virus, microorganism (including bacteria, plasmids, or other genetic elements), proteinaceous infectious particle (prion) or recombinant microorganism (hybrid or mutant) that is known or reasonably expected to cause disease in humans or animals. Microorganisms that are unlikely to cause human or animal disease are not subject to biological shipping regulations.

10.3.2.1 Category A Infectious Substances

Category A infectious substances are capable of causing permanent disability, life threatening or fatal disease in humans or animals when exposure to them occurs. Category A infectious substances are shipped as infectious substances, affecting humans (UN2814), or infectious substances affecting animals (UN2900). Indicative examples of Category A infectious substances are listed in Table 10.3.2.1.

10.3.2.1.1 Packaging

The triple packaging concept (explained in Section 10.4) applies to Category A infectious substances. Purchase packaging compliant with IATA Packing Instruction 602 as detailed in the IATA Dangerous Goods Regulations (DGR), which is available in the Biosafety Office. See Table 10.3.2.1.1 for a list of packaging suppliers. Make sure to specify if you are shipping a refrigerated sample (ice packs or dry ice). The maximum quantity of infectious substance that can be shipped by air in one package is 4 L or 4 kg. The maximum quantity that may be shipped via passenger aircraft is 50 mL or 50 g.

Table 10.3.2.1. Indicative Examples of Category A Infectious Substances

UN # and Proper Shipping Name	Microorganism	
UN 2814 Infectious substance affecting humans	- *Bacillus anthracis* cultures - *Brucella abortus* cultures - *Brucella melitensis* cultures - *Brucella suis* cultures - *Burkholderia mallei - Pseudomonas mallei* - Glanders cultures - *Burkholderia pseudomallei - Pseudomonas pseudomallei* cultures - *Chlamydia psittaci* - avian strains cultures - *Clostridium botulinum* cultures - *Coccidioides immitis* cultures - *Coxiella burnetii* cultures - Crimean-Congo hemorrhagic fever virus - Dengue virus cultures - Eastern equine encephalitis virus cultures - *Escherichia coli*, verotoxigenic cultures - Ebola virus - Flexal virus - *Francisella tularensis* cultures - Guanarito virus - Hantaan virus - Hantavirus causing hemorrhagic fever with renal syndrome - Hendra virus - Hepatitis B virus cultures - Herpes B virus cultures - Human immunodeficiency virus cultures - Highly pathogenic avian influenza virus cultures	- Japanese Encephalitis virus cultures - Junin virus - Kyasanur Forest disease virus - Lassa virus - Machupo virus - Marburg virus - Monkeypox virus - *Mycobacterium tuberculosis* cultures - Nipah virus - Omsk hemorrhagic fever virus - Poliovirus cultures - Rabies virus cultures - *Rickettsia prowazekii* cultures - *Rickettsia rickettsia* cultures - Rift Valley fever virus - Russian spring-summer encephalitis virus cultures - Sabia virus - *Shigella dysenteriae* type 1 cultures - Tick-borne encephalitis virus cultures - Variola virus - Venezuelan equine encephalitis virus - West Nile virus cultures - Yellow fever virus cultures - *Yersinia pestis* cultures

UN 2900 Infectious substance affecting animals	- African swine fever virus cultures - Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus cultures - Classical swine fever virus cultures - Foot and mouth disease virus cultures - Lumpy skin disease virus cultures - *Mycoplasma mycoides* - Contagious bovine pleuropneumonia cultures - Peste des petits ruminants virus cultures - Rinderpest virus cultures - Sheep pox virus cultures - Goatpox virus cultures - Swine vesicular disease virus cultures - Vesicular stomatitis virus cultures

* This list is not exhaustive. New or emerging pathogens not on the list may meet the criteria to be included in Category A.

Table 10.3.2.1.1. Manufacturers of Shipping Containers for Infectious Substances and Dry Ice

Air Sea Atlanta
1234 Logan Circle
Atlanta GA 30318
Phone: 404-351-8600
http://www.airseaatlanta.com

All-Pak, Inc.
Corporate One West
1195 Washington Pike
Bridgeville, PA 15017
Phone: 800-245-2283
http://www.all-pak.com

CARGOpak Corporation
3215-A Wellington Court
Raleigh, NC 27615
Phone: 800-266-0652
http://www.cargopak.com

DG Supplies, Inc.
5 Boxal Drive
Cranbury, NJ 08512
Phone: 800-347-7879
http://www.dgsupplies.com

EXAKT Technologies, Inc.
7416 N Broadway Ext., Suite E
Oklahoma City, OK 73116
Phone: 800-923-9123
http://www.exaktpak.com

HAZMATPAC, Inc
5301 Polk St., Bldg 18
Houston, TX 77023
Phone: 800-347-7879
http://www.hazmatpac.com

Inmark, Inc.
220 Fisk Drive S.W.
Atlanta, GA 30336-0309
Phone: 800-646-6275
http://www.inmarkinc.com

JIT Certified, Inc.
1740 Fenpark Drive
Fenton, MO 63026
Phone: 800-962-8636
http://www.jitcertifed.com

Polyfoam Packers Corporation
2320 S. Foster Avenue
Wheeling, IL 60090
Phone: 888-765-9362
http://www.polyfoam.com

SAF-T-PAK, Inc.
10807 - 182 Street Edmonton,
Alberta, Canada, T5S 1J5
Phone: 800-814-7484
http://www.saftpak.com

Source Packaging of New England, Inc.
405 Kilvert St.
Warwick, RI 02886
Phone: 800-200-0366
http://www.sourcepak.com

Therapak Corporation
1440 Arrow Highway, Unit A
Irwindale, California 91706
Phone: 888-505-7377
http://www.therapak.com

10.3.2.1.2 Labeling

The outer container of a Category A infectious substance shipment must display the following information:

- Sender and recipient's full name and address;
- Infectious substance label (see below);
- "UN2814, Infectious substance, affecting humans" and net quantity or "UN2900, Infectious substance, affecting animals" and net quantity;
- The text "Person responsible: [*name, phone number*]" You must provide a 24 hr/day, 7 days/week contact for a person who knows what material has been shipped and emergency response information. This should be documented in your shipping/transport SOP;
- Class 9 label (see below), including UN1845 and net weight, if packaged with dry ice; and

- Cargo Aircraft Label (see below), when shipping over 50 mL or 50 g.

Infectious Substance Label

Class 9 Label

Cargo Aircraft Label

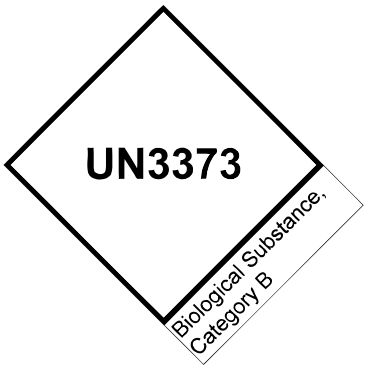
10.3.2.2 Category B Infectious Substances

Category B infectious substances are materials that are infectious, but do not meet the standard for inclusion in Category A. Category B infectious substances are assigned to UN3373.

10.3.2.2.1 Packaging

The basic triple packaging concept applies to Category B infectious substances. Purchase packaging that complies with IATA Packing Instruction 650. See Table 10.3.2.1.1 for a list of some packaging suppliers. Be sure to specify if the shipment is a refrigerated sample (*e.g.,* ice packs or dry ice) or will be sent at ambient (room) temperature.

For Category B infectious substances, the maximum quantity of liquid per primary receptacle is 1 liter and outer packaging must not contain more than 4 L or 4 kg.



UN3373 Label

10.3.2.2.2 Labeling

The outer container of a Category B infectious substance shipment must display the following information:

- The sender and recipient's full name and address;
- The words "Biological Substance, Category B";
- UN3373 label (see right);
- The text "Person responsible: [*name, phone number*]" You must provide a 24 hr/day, 7 days/week contact for a person who knows what material has been shipped and emergency response information. This should be documented in your shipping/transport SOP; and
- Class 9 label (see Section 10.2.2.1.2), if packaged with dry ice.

10.3.3 Patient Specimens

Patient specimens that have a minimal likelihood of containing pathogens are exempt from many shipping requirements. Professional judgment is used to determine if a specimen contains pathogens and should be based on the patient's medical history, symptoms, local conditions and individual circumstances.

If there is more than a "minimal likelihood" that a patient specimen contains pathogens, it must be shipped as a Category A infectious substance (UN2814 or UN2900) or a Category B infectious substance (UN3373).

Patient specimens unlikely to contain pathogens must be prepared for shipment as follows:

10.3.3.1 Packaging

- Leak-proof primary container;
- Leak-proof secondary packaging;
- Fragile primary containers must be wrapped or separated to prevent breakage;
- Absorbent material must be placed between the primary and secondary containers to absorb entire contents so that no liquid release will reach the outer packaging; and
- Outer packaging must be durable enough for its intended use with at least one side 100 mm x 100 mm or larger.

10.3.3.2 Labeling

The outer package must be marked with “Exempt human specimen,” or “Exempt animal specimen.”

10.3.3.3 Dried blood

Special guidance has been provided by the CDC for shipment of dried blood spot specimens which vary from those above. In particular, these should not be packaged in airtight, leak-proof plastic bags because the lack of air exchange in the inner environment of a sealed plastic bag causes heat buildup and moisture accumulation that can damage the dried blood spot test substances. In addition, various chemicals that can adversely affect the test substances in the dried blood spots could leach from these plastics and thus cause incorrect analytical test results. See: http://www.cdc.gov/od/ohs/biosfty/driblood.htm for further information.

10.3.4 Biological Products

Biological products are derived from living organisms and manufactured for use in the prevention, diagnosis, treatment or cure of diseases in humans or animals and are certified by the USDA, FDA or other national authority.

Examples of biological products include certain viruses, therapeutic serums, toxins, antitoxins, vaccines, blood, and blood products. Materials which contain incidental blood products, such as fetal calf serum, may also be regulated, particularly internationally. For further information and guidance for shipping biological materials, see:

- Food and Drug Administration Guidelines
  - Importation: http://www.fda.gov/ora/import/
  - Exportation: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm
- US Department of Agriculture
  - Importation/exportation URL: http://www.aphis.usda.gov/import_export/index.shtml
  - Materials which do not require permits: http://www.aphis.usda.gov/biotechnology/submissions.shtml

Biological products transported for final packaging, distribution, or use by medical professionals are not subject to biological shipping regulations (although international shipments may have importation or exportation standards, See Section 10.7). Biological products that do not meet these criteria must be assigned to UN2814, UN2900 or UN3373, as appropriate.

10.3.5 Genetically Modified Organisms or Microorganisms

Genetically modified organisms (GMO) or microorganisms (GMMO) are organisms and microorganisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. GMOs and GMMOs that are not infectious but that can alter animals, plants or microorganisms in a way that is not normally the result of natural reproduction are considered a miscellaneous hazard (Class 9) and are assigned to UN3245. GMOs and GMMOs that are infectious must be assigned to UN2814, UN2900 or UN3373.

10.3.5.1 Packaging

These materials are packed for shipment in the same way as Category A infectious substances, except there are no testing requirements for the packaging; this packaging variation is IATA Packing Instruction 913. Packages designed for Packing Instruction 913 may not be available from most vendors. In this case, use packages compliant with Packing Instruction 602.

The maximum allowable quantity per primary receptacle is 100 mL or 100 g. There is no maximum net quantity per package.

10.3.5.2 Labeling

The outer container of a GMO or GMMO assigned to UN3245 must display the following information:

- The sender and recipient's full name and address;
- Class 9 label (See Section 10.3.2.1.2); and
- Genetically modified microorganisms, UN3245, and net quantity.

10.3.6 Regulated Medical Waste

Regulated Medical Waste (also sometimes referred to as Regulated Biomedical Waste or Clinical Waste) is defined differently by many state and federal agencies. Under DOT rules, regulated medical waste (RMW) is a waste or reusable material suspected or known to contain an infectious substance, and is generated in the diagnosis, treatment, immunization, or biomedical research of humans or animals. Regulated Medical Waste (RMW) is assigned UN 3291 and is generally packaged consistently with IATA packing instruction 650 (See Section 10.3.2.2, Category B Infectious Substances for further information about packing instruction 650), although some special exceptions exist in the DOT regulations (49 CFR 173.137 (c) and (d) and 179.197).

AU currently packages all RMW in boxes and carts provided by Stericycle® (See Chapter 9, Waste Management); which comply with the regulations for packaging and labeling of RMW. Typically, these are transported from AU campus by Stericycle® personnel who have to adhere to the requirements for transport of these materials, and are generally not transported by most AU personnel in vehicles on public roads. However, special considerations should be made should occasion arise that any regulated medical wastes are to be transported, offered for transport or shipped if these wastes are to be:

- Transported via vehicles traveling on public thoroughfares (*e.g.,* to AU or to the Stericycle® truck from remote campus locations)
  Any material transported under the Regulated Medical Wastes must be in a vehicle dedicated for RMW transport if it may contain agents of Risk Group 2 or higher.

- Transported outside of campus in containers other than the large Stericycle® boxes or carts (e.g., in sharps containers), which may not have the required markings. These should be appropriately packaged and labeled prior to transport.

Please contact the Biosafety Office to declare your intention to transport RMW and for further guidance prior to transport.

10.4 PACKAGING BIOLOGICAL MATERIALS

Potentially hazardous biological materials must be packaged to withstand leakage of contents, shocks, temperature, pressure changes and other conditions that can occur during ordinary handling in transportation. Packaging your material(s) appropriately is accomplished by purchasing certified packaging. Refer to Table 10.3.2.1.1 for vendors that can supply certified packaging for biological materials. When ordering, specify what type of material(s) you will be shipping: Category A infectious substances, Category B infectious substances, etc. Different categories have slightly different packaging needs, but all follow the basic triple packaging requirements described below.

10.4.1 Triple Packaging

Biological materials must be packaged according to the triple packaging principle. The three elements of triple packaging include: primary receptacle, leak-proof secondary container, and durable outer container. Infectious substances in Category A and B, patient specimens and genetically modified microorganisms must be packaged in this way, with slight variations. An example of triple packaging is illustrated in Figure 10.4.1.

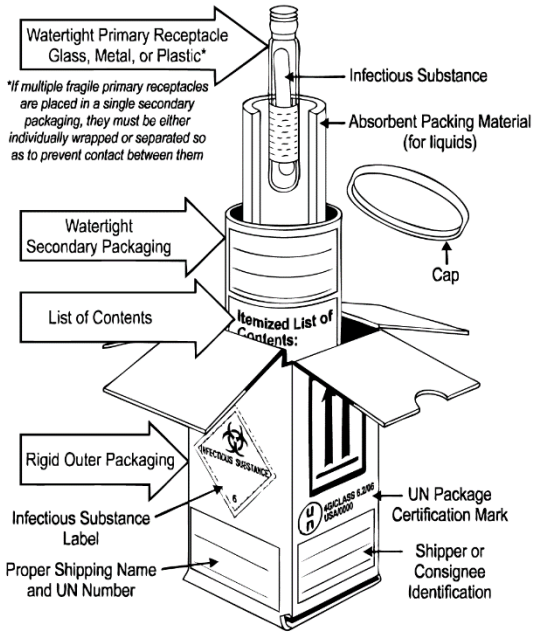
The ***primary container*** holds the biological material; it must be leak-proof. It must be labeled with the name of the contents. A leak-proof seal, such as a heat seal, skirted stopper or metal crimp, is required. If the container has a threaded lid, it must be secured with waterproof tape (e.g., Parafilm, etc.). Petri

plates cannot be used as primary receptacles. Lyophilized substances can only be shipped in flame sealed glass ampoules or rubber stopped glass vials with metal seals. Packaging purchased for shipping infectious substances usually does not include the primary container.

The ***secondary container*** holds one or more primary containers, and must also be leak-proof. Secondary containers for all Category A and liquid Category B infectious substances must meet specific pressure test standards when shipping liquids. Containers purchased from commercial vendors are designed to meet the necessary standards. If you are shipping any liquid, there must be enough absorbent material in the secondary container to absorb all of the liquid in the primary receptacle(s). If multiple primary containers are used, they must be wrapped to prevent contact between them so they do not break during transport.

The ***outer container*** must be rigid and have one side that is at least 100 mm X 100 mm, in order for required markings and labels to fit. The outer package must be of adequate strength for its capacity, mass, and intended use. An **itemized list** of package contents must be included between the outer and secondary container. The outer package should be marked to identify hazardous contents, including the proper shipping name, UN number and net quantity for each substance, if required.

Figure 10.4.1



Source: Transporting Infectious Substances Safely, US DOT Document PHH50-0079-0706.

10.4.2 Other Packaging Requirements

10.4.2.1 Overpacks

An overpack can be used to combine several triple packages into one large package. This may be done to save on shipping charges when shipping multiple samples. Each triple package inside the overpack must be properly marked and labeled. The outside of the overpack must bear the same markings and labels as the triple packages within including hazard labels and proper shipping names. The outer container of the overpack must also be marked with the word, "Overpack."

10.4.2.2 Dry Ice

10.4.2.2.1 Hazard Identification

Dry ice is classified by DOT and IATA as a "miscellaneous" hazard, class 9. Dry ice is considered hazardous during transportation for three reasons:

Explosion hazard: Dry ice releases a large volume of carbon dioxide gas as it sublimates. If packaged in a container which does not allow for release of the gas, it may explode, causing potential injury and/or property damage.

Suffocation hazard: a large volume of carbon dioxide gas emitted in a confined space may create an oxygen-deficient atmosphere.

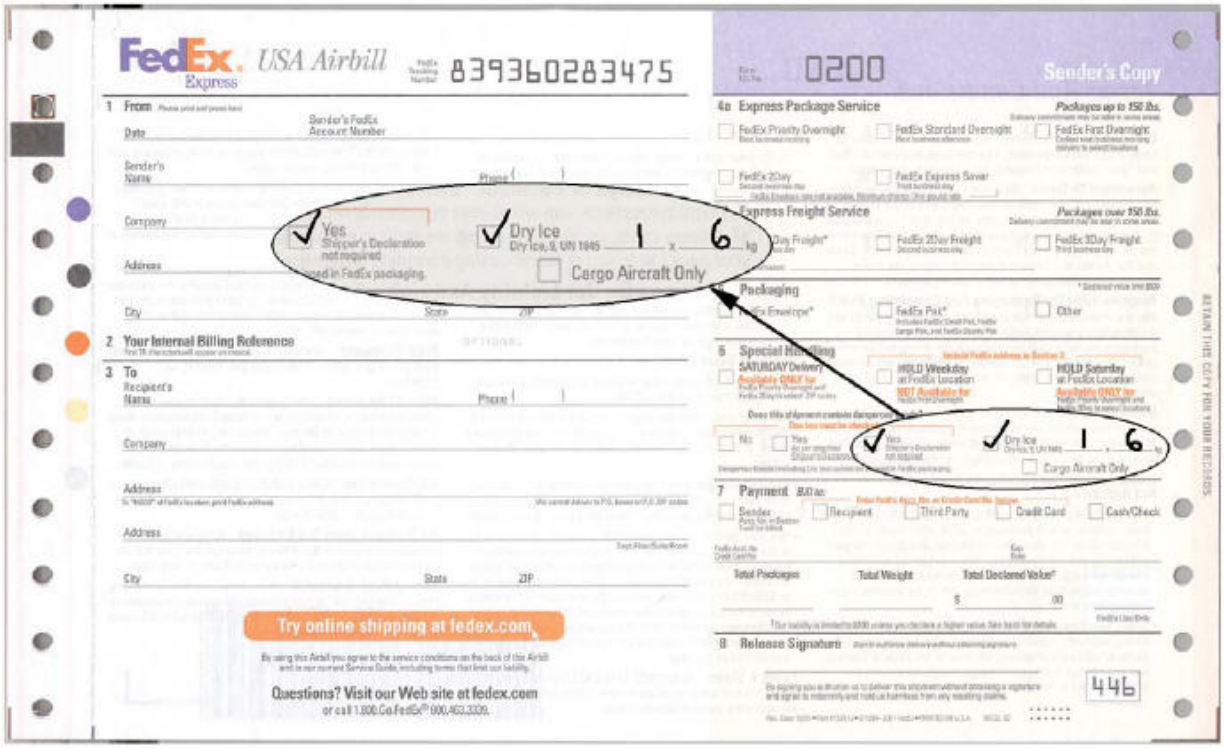
Contact hazard: Dry ice is a cryogenic material that causes severe frostbite upon contact with skin..

Packaging dry ice properly will minimize the risk to personnel transporting the material. The explosion hazard will be eliminated with a package designed to vent gaseous carbon dioxide. Suffocation and contact hazards will be greatly reduced by labeling the package correctly, so those who come in contact with it will be aware of the contents.

10.4.2.2.2 Packaging Dry Ice

There are five basic requirements for all shipments of dry ice:

a. **Gas venting**: packages must allow for release of carbon dioxide gas. Dry ice must never be sealed in a container with an airtight seal such as a jar with a threaded lid or a plastic cooler. When transporting in a vehicle, the box should not be placed inside the passenger compartment to prevent carbon dioxide accumulation within the vehicle.
b. **Package integrity**: a package containing dry ice must be of adequate strength for intended use. It must be strong enough to withstand the loading and unloading normally encountered in transport. It must also be constructed and closed in order to prevent any loss of contents that might be caused by vibration of by changes in temperature, humidity, or altitude.
c. **Package materials**: do not use plastics that can be rendered brittle or permeable by the temperature of dry ice. This problem can be avoided by using commercially available packages intended to contain dry ice (see Table 10.3.2.1.1).
d. **Waybill**: the waybill (also referred to as the airbill) must include the statement “Dry ice, 9, UN1845, [*number of packages*] X [*net weight in kilograms*]” FedEx has a check box on their waybill to satisfy this requirement (see Figure 10.4.2.2.2A). Airborne Express requires a slightly different format (see Figure 10.4.2.2.2B). Check with your courier to make sure you have made the proper notation on their paperwork.
e. **Labeling**: the outermost container must be labeled with a hazard class 9 label, UN1845m and net weight of dry ice in kilograms. See Figure 10.4.2.2.2C, below. This must be a specific size (5” x 5”).



f.

Figure 10.4.2.2.2A. FedEx Waybill which properly documents 1 box containing 6 kg of dry ice.

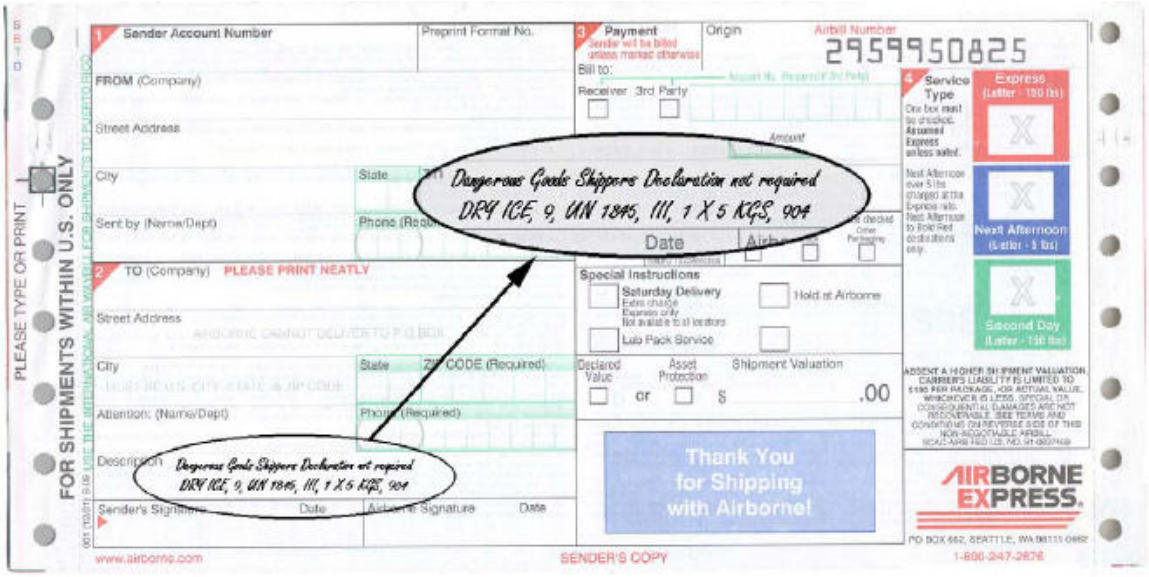


Figure 10.4.2.2.2B. AirBorne Express waybill which properly documents 1 box containing 5 kg of dry ice.

If shipping biological materials with your dry ice, you must comply with the requirements for **both** shipping of biological materials **and** dry ice.

When shipping biological materials and dry ice together:

a. Dry ice must be placed **outside** the secondary packaging (See Figure 10.4.2.2D)

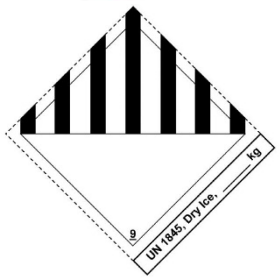


Figure 10.2.2.2C Dry ice label (not to size)

b. Secure your samples in such a way that when the dry ice sublimates, they will not move freely inside the insulated box. This can be accomplished by wedging your samples in place with cardboard or Styrofoam. Fragile containers such as glass tubes or vials should be wrapped in cushioning material.
c. A Shipper's Declaration for Dangerous Goods is not required for shipments in which dry ice is the only hazardous material; however, dry ice is included on declarations for shipments that include other hazardous materials such as infectious substances.

Other issues that you should consider when shipping with dry ice:

a. Refer to your package manufacturer's recommendations. Make arrangements with your cosignee to make sure your package will be received on its intended delivery date. Take into account local holidays or closings that might delay package receipt.
b. Minimize the volume of air to which the dry ice is exposed in order to slow the rate of sublimation. If there is any air space after you fill the package with dry ice, fill it with packing peanuts or other material to reduce the volume of air space.
c. Shipments are generally recommended to contain 5-10 pounds (2.27-4.54 kg) of dry ice per 24 hours.
d. Dry ice shipments can be made with FedEx and DHL. UPS and the U.S. Postal Service have extremely restrictive policies concerning shipments of hazardous materials. Do not ship dry ice with UPS or with the U.S. Postal Service.

10.4.2.3 Liquid Nitrogen

Biological materials can be shipped refrigerated with liquid nitrogen in cryogenic dry shippers, which are insulated packages containing refrigerated liquid nitrogen fully absorbed in a porous material. The dry shippers, themselves, do not contain hazardous materials, do no allow for the build-up of pressure within the container and will not permit the release of any refrigerated liquid nitrogen regardless of the dry shipper's orientation. Properly used, the dry shippers, alone, do not contain free liquid nitrogen, and are not subject to hazardous material regulations by the DOT or IATA. Dry shippers are capable of maintaining cryogenic temperatures normally associated with liquid nitrogen for approximately 24 hours (depending on the manufacturer) without risk of liquid nitrogen spilling. However, be aware, improperly filled dry shippers present a risk of liquid nitrogen leakage and are subject to regulation should spillage occur.

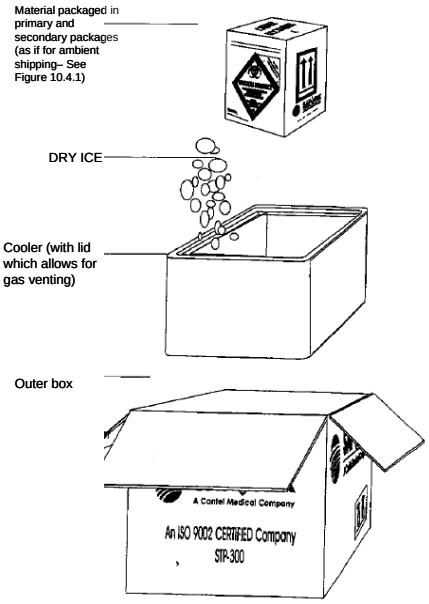


Figure 10.2.2.2D Packaging for Dry Ice

Follow the manufacturer's instructions for filling the dry shipper. Some general practices when filling the dry shipper are:

a. Wear insulated gloves made for handling liquid nitrogen and a face shield.
b. Add the liquid nitrogen slowly since a significant volume of nitrogen gas will form as the cold liquid contacts the warm surfaces.
c. When the liquid level reaches the neck of the dry shipper, stop filling. Replace the cap and set the dry shipper aside for the period specified by the manufacturer to allow the liquid nitrogen to saturate the absorbent.
d. Repeat steps a-c until the liquid level no longer drops on standing. Special packing regulations apply to shipments containing nitrogen. Contact the Biosafety Office if you need to ship materials with liquid nitrogen.

Some manufacturers have empty and full weights for their dry shippers. Dry shippers that will not achieve their full weight may indicate a problem with the absorbent's ability to hold the nitrogen. This may prevent the dry shipper from maintaining the proper cryogenic temperatures during shipment and may damage your samples. Contact the manufacturer to determine if the dry shipper is safe to use.

When you are ready to ship, follow the following steps:

a. Remove all free liquid nitrogen from the dry shipper before transport.
b. Wear insulated gloves and a face shield when emptying the dry shipper.

c. Do not pour liquid nitrogen on to the floor since it could splash on your shoes or legs and cause severe burns. It is recommended to pour the excess liquid nitrogen back into a large liquid nitrogen dewar.
d. Hold the dry shipper upside down until the liquid stops flowing.
e. Stand the dry shipper upright for the period specified by the manufacturer.
f. Repeat steps a-e, above as many times as necessary to remove remaining liquid nitrogen.
g. Place your canes of material into the dry shipper and replace the cap.
h. Place the dry shipper into the case supplied by the manufacturer.

Make sure that the materials you are transporting are not hazardous chemicals such as samples frozen in propane, ethane, halocarbon or other hazardous gas. If you are shipping biological materials, your specimens will still have to comply with the IATA/DOT standards for biologicals, as described above.

Special packing regulations apply to shipments containing liquid nitrogen. Contact the Chemical Safety Office at x1-2663 if you need ship or transport materials with liquid nitrogen.

10.4.2.4 Samples Preserved in Fixative

Special consultation with both the Biosafety and Chemical Safety Offices are required before shipping materials which may be preserved in chemical, such as formalin or ethanol. However, below are reference guidelines for shipping materials preserved in aqueous solutions of formalin or ethanol. Packages prepared according to these guidelines must not contain any materials other than those described (i.e. containers holding formalin- or ethanol-preserved specimens and related absorbent or packaging materials). Laboratory or sampling equipment, unrelated documents, or other goods must be packaged and shipped in separate boxes.

10.4.2.4.1 In Aqueous Formaldehyde Solutions (Formalin) <25%

Aqueous formaldehyde solutions of less than 25% are considered hazardous materials when shipped by air. This is because formalin can cause eye, skin, and respiratory tract irritation. Formaldehyde is regulated by OSHA as a carcinogen. Additionally, exposure to formaldehyde solutions may cause an allergic respiratory reaction. Be sure to review the MSDS before handling or shipping any hazardous material.

Proper packaging shipments of formalin will minimize the chance of leakage during transportation. Properly labeling and documenting these shipments will communicate the hazard to transport workers who may be exposed to the formaldehyde in the event of a leak.

Formaldehyde solutions are assigned to hazard class 9, packing group II. As such, each inner packaging may not contain more than 30 ml. Each outer package may contain not more than 500 ml. At this amount, these are considered “excepted quantities”.

Packaging for excepted quantities must have three basic components:

a. **Inner (primary) packaging,** such as a vial, tube, jar, etc. Do not completely fill inner packagings; allow 10% head-space for liquid expansion. Liquids must not completely fill inner packagings at a temperature of 55°C (130°F). Closures of inner packagings must be held securely in place with tape, wire, metal crimps, or other positive means.
b. **Intermediate (secondary) packaging**, such as a ziplock or other plastic bag. Use good quality bags that are well sealed. Intermediate packaging must contain enough absorbent material to absorb all contents and must not react with formaldehyde. Use two plastic bags: put the absorbent and the inner container(s) in the first bag and seal it well with tape. Then seal this bag in another bag for added protection.
c. **Outer packaging,** such as a cardboard box. Formaldehyde solutions may not be shipped in envelopes, Tyvek sleeves, or other non-rigid mailers. The dimensions of the outer box must be at least 100 m (~4 inches) on two sides.

Labels and Marks on the outer packaging must include the following:

a. Dangerous Goods in Excepted Quantities Label, See Figure 10.4.2.4A. This label must be filled out with the signature, title, name and address of the shipper and the date. It must be affixed to the outer container on a vertical side. For formaldehyde solutions of less than 25%, check the box for Class 9 material and enter “UN 3334” as the

applicable UN number. The printable label may be found in Appendix K and must be printed in color. Its overall dimensions must be at least 100 mm x 100 mm (~4 in. x 4 in).

b. Name and Address: The outer container must display the name and address of the shipper and consignee.

Many printer inks run when exposed to small amounts of water, such as rain or snow. Therefore, it may be necessary to fully cover each label you have affixed to the box with clear plastic tape. Also, when re-using shipping boxes, completely obliterate all unnecessary labels and marks.

Figure 10.4.2.4A. Dangerous Goods in Excepted Quantities Label (not to scale)

Package Tests must be performed and documented to ensure package compliance. A representative example of packaging used for excepted quantities of formaldehyde solutions must pass a drop test and compressive load test without any breakage or leakage of any inner packaging and without any significant reduction in package effectiveness. Perform the following tests on representative example of your packaging and keep a record of the results.

Drop Test. Drop a representative package from a height of 1.8 m (5.9 feet) directly on to a solid unyielding surface:

- One drop flat on bottom;
- One drop flat on top
- One drop flat on the long side;
- One drop flat on the short side; and
- One drop on a corner at the junction of three intersecting edges.

Compressive Load Test. Apply a force to the top surface of a representative package for a duration of 24 hours, equivalent to the total weight of identical packages if stacked to a height of 3 meters.

Proper documentation is required for all shipments of hazardous materials. Incorrect documentation is the most common cause of package refusal. If using documentation for couriers other than FedEx and DHL, contact EHS for assistance.

For domestic shipments with FedEx Express, fill out the standard US waybill. Fill out the form completely and be sure to include the following information:
In section 6, Special Handling, check the box “Yes, Shipper’s Declaration not required.”
On the top of the form above the FedEx tracking number, include the statement, “Dangerous Goods in Excepted Quantities”. See example in Figure 10.4.2.4B.

For DHL shipments, under the “Nature and Quantity of Goods” box on the air waybill, include the words “Dangerous Goods in Excepted Quantities”.

10.4.2.4.2 In Aqueous Ethanol Solutions of 55-100%

Ethanol solutions of 55-100% are considered hazardous materials when shipped by air. This is because ethanol is a flammable liquid (NFPA rating = 3), and its vapor can travel a considerable distance to an ignition source and "flash back". Contact of ethanol with strong oxidizers, peroxides, strong alkalis, and strong acids may cause fires and explosions. Be sure to review the manufacturer MSDS before handling or shipping any hazardous material.

Ethanol solutions are assigned to hazard class 3, packing group II. As such, each inner packaging may not contain more than 30 ml. Each outer package may contain no more than 500 ml.

Figure 10.4.2.4B Example of FedEx waybill for excepted quantity shipment

Packaging, labeling requirements, package tests and documentation are similar to those indicated above for formaldehyde solutions (See Section 10.4.2.4.1) *with the exception* that for ethanol solutions of 55-100%, the Dangerous Goods in Excepted Quantities Label (as seen in Figure 10.4.2.4A for formaldehyde solutions) should have the Class 3 material box checked and "**UN 1170**" as the applicable UN number.

10.5 SHIPPER'S DECLARATION FOR DANGEROUS GOODS

A Shipper's Declaration for Dangerous Goods must be completed when shipping a Category A infectious substance assigned to UN2814 or UN2900or a GMO or GMMO assigned to UN3245. A declaration is not required for shipments in which dry ice is the only hazardous material. A declaration is not required for shipments

of Category B infectious substances assigned to UN3373. Improperly completed declarations are the most common cause of package refusal.

Refer to the Shipper's Declaration for Dangerous Goods (Figure 10.5) for an explanation of each section:

A. Shipper: Enter your full name, address and telephone number.
B. Consignee: Enter full name and address of recipient. When shipping infectious substances, include the text, "Person responsible:" [***then you must provide a 24 hr/day, 7 days/week contact for a person who knows what material has been shipped and emergency response information. This should be documented in your shipping/transport SOP***].
C. Transport Details: Indicate here if your shipment is restricted to cargo aircraft only (if it is more than 50 ml or 50 g of an infectious substance). Airport of departure and airport of destination will be filled out by the carrier, leave blank.
D. Shipment Type: Cross out "radioactive" to indicate you are shipping a non-radioactive substance.
E. UN or ID Number: Enter appropriate UN number as found in Table 10.5.
F. Proper Shipping Name: Enter the proper shipping name exactly as it appears in Table 10.5.
G. Class or Division: Enter appropriate hazard class as found in Table 10.5.
H. Packing Group: For dry ice, enter "III" in this column. Biological materials are not assigned packing groups.
I. Quantity and Type of Packaging: Enter the net quantity for each material here. Use only metric units. At the bottom of this column, indicate the number and type of packages used (usually, "All packed in one fibreboard box."). If using an overpack, indicate here with "Overpack Used."
J. Packing Instructions: Enter appropriate packing instruction number. Refer to Table 10.5.
K. Authorization: Leave this column blank.
L. Additional Handling Instructions: You must provide an emergency contact name and phone number which can be reached 24 hours per day, 7 days per week to provide emergency response information should a question develop about your package during transport. The statement "Emergency Contact: [fill in contact name; phone number]" must be provided.
M. This section is self-explanatory. Sign and date each copy of your Shipper's Declaration.

A blank Shipper's Declaration for Dangerous Goods is available in Adobe PDF format at http://www.unh.edu/ehs/shipping. Please note the following:

- Declarations must be typewritten or computer-generated; handwritten declarations will not be accepted.
- Declarations must be printed in color to display the red-striped border.
- Always print at least four copies: provide three to the carrier and keep one for your records.
- Remember to sign and date each copy.
- Regulations require that you must retain your copy for ***2 years***.

A completed sample declaration can be found in Figure 10.5B. Contact the Biosafety Office with any questions regarding the Shipper's Declaration.

Table 10.5. Summary of Shipping Information.

Shipment Type	Proper Shipping Name	UN Number	Hazard Class	Packing Group (PG)	Packing Instruction (PI)	Max. qty. per primary receptacle	Max. Net qty./pkg. for Passenger Aircraft	Max. Net qty./pkg. for Cargo Aircraft
Category A infectious substance, affecting humans and possibly animals	Infectious substance, affecting humans	UN2814	6.2	-	602	Liquids: 4 L Solids: 4 kg	50 ml or 50 g	4 L or 4 kg

Category A infectious substance, affecting only animals (not humans)	Infectious substance, affecting animals	UN2900	6.2	-	602	Liquids: 4 L Solids: 4 kg	50 ml or 50 g	4 L or 4 kg
Category B infectious substance	Biological substance, Category B	UN3373	6.2	-	650	Liquids: 1 L Solids: 4 kg	4 L or 4 kg	4 L or 4 kg
Dry Ice	Dry Ice or Carbon Dioxide, solid	UN1845	9	III	904	N/A	200 kg	200 kg
Non-infectious, transducing genetically modified organism or microorganism	Genetically modified microorganisms	UN3245	9	-	913	No limit	No limit	No limit
Clinical waste, Biomedical waste Regulated medical waste	Regulated medical waste, n.o.s.	UN3291	6.2	II	650	No limit	No limit	No limit
Aqueous formaldehyde solutions of less than 25%	Aviation regulated liquid, n.o.s.	UN3334	9	II	Dangerous Goods in Excepted Quantities instructions (IATA 2.7)	30 ml	-	500 ml
Aqueous ethanol solutions (55-100%)	Ethanol solution	UN1170	3	II	Dangerous Goods in Excepted Quantities (IATA 2.7)	30 ml	-	500 ml

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper

A

Air Waybill No.

Page of Pages

Shipper's Reference Number (optional)

Consignee

B

Two completed and signed copies of this Declaration must be handed to the operator.

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for: *(delete non-applicable)*

PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY

C

Airport of Departure

Airport of Destination

D

Shipment Type *(delete non-applicable)*

NON-RADIOACTIVE	RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Instructions	Authorization
E	**F**	**G**	**H**	**I**	**J**	**K**

Additional Handling Information

L

Emergency Telephone Number

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to the applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.

Name/Title of Signatory

Place and Date

M

Signature

(see warning above)

Figure 10.5B. Example of Completed Shippers Declaration

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper Ben Thompson
Georgia Regents University
1120 15th St., CB-4100

Air Waybill No.
Page 1 of 1 Pages
Shipper's Reference Number (optional)

Consignee Sam Research
2 Langley Road
Boston, MA 11111

Person Responsible: Ben Thompson (706)555-1212

Two completed and signed copies of this Declaration must be handed to the operator.

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for: *(delete non-applicable)*
PASSENGER AND CARGO AIRCRAFT / CARGO AIRCRAFT ONLY XXXX

Airport of Departure

Airport of Destination

Shipment Type *(delete non-applicable)*
NON-RADIOACTIVE / RADIOACTIVE XXXXX

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification				Quantity and Type of Packing	Packing Instructions	Authorization
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group			
UN2814	Infectious substance, affecting humans (Mycobacterium tuberculosis)	6.2		25 mg	602	
UN1845	Dry ice	9	III	5 kg All packed in one fibreboard box	904	

Additional Handling Information

Emergency Telephone Number Ben Thompson (706)555-1212

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to the applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.

Name/Title of Signatory Ben Thompson/professor

Place and Date Augusta, GA, March 30, 2008

Signature *(see warning above)* Ben Thompson

10.6 Regulated Agents Which May Require Special Permits for Transfer

10.6.1 CDC/USDA Select Agents and Toxins

The U.S. Department of Health and Human Services has developed a list of biological agents (see Section 2.6.2.2) that have the potential to pose a severe threat to public health. Special regulations apply to the use and transfer of these materials, including registration with the AU Institutional Biosafety Committee and the Centers for Disease Control and Prevention (CDC) or United States Department of Agriculture (USDA). If you are planning to, or currently possess, use or transfer any of the select agents and have not registered, contact the Biosafety Officer. Specific shipping restrictions apply to these agents which are not discussed in this document.

10.6.2 Agricultural Pests, Pathogens and Biological Agents

The USDA/APHIS requires permits to transfer any **plant or agricultural animal pest or pathogens**. In addition, permits may be required to export or import the agents shown below. Further information can be obtained from the URL and phone number shown below:

APHIS Agricultural Permits
http://aphisweb.aphis.usda.gov/ppq/permits/
http://www.aphis.usda.gov/import_export/index.shtml
Material which do not require permits instruction: http://www.aphis.usda.gov/vs/ncie/fac_imp.html
Telephone: 1-877-770-5990

EXPORT/IMPORT

- Arthropods (insects and mites)
- Arthropods inhabiting dung or of medical/veterinary significance
- Bees and bee related articles
- Biological materials containing animal material
- Butterflies
- Cell cultures of bovine or other livestock origins
- Cut flowers
- Earthworms
- Endangered species
- Endangered species of wild fauna and flora
- Entomopathogens
- Farm animals
- Foreign cotton and covers
- Fruits and vegetables
- High consequence livestock pathogens and toxins
- Indian corn or maize, broomcorn and related plants
- Infectious agents of livestock
- Khapra beetle products
- Live arthropods for display or educational purpose
- Livestock
- Moths
- Noxious weeds
- Nursery stocks (including seeds)
- Parasitic plants
- Plant pathogens
- Predators and parasitoids of arthropods
- Prohibited material for research purposes
- Rice and rice related articles
- Seeds
- Snails and slugs
- Soil
- Sugarcane products and by-products (including parts of the sugarcane plant)
- Tissue culture materials of bovine or other livestock origins
- Weed biocontrol
- Wildlife
- Wood products

10.6.3 Agents of Vectors of Human Disease

CDC permits are required when shipping any infectious agent known or suspected to cause disease in humans, unsterilized specimens of human or animal tissues (including blood and other fluids), or biological vectors of infectious animals, bats, insects, arthropods and snails. This includes the materials in the table below; further information can be obtained at the URL and phone numbers below.

CDC Permit to Import or Transport Agents or Vectors of Human Disease
[http://www.cdc.gov/od/ohs/biosfty/imprtper.htm]
Telephone: 1-404-498-2260

INFECTIOUS SUBSTANCES

- It is impractical to list all of the several hundred species of infectious substances. In general, an import permit is needed for any infectious substance known or suspected to cause disease in man.

BIOLOGICAL MATERIALS

- Unsterilized specimens of human and animal tissues (such as blood, body discharges, fluids, excretions or similar material) containing an infectious agent requires a permit in order to be imported.

VECTORS

- ***Animals***: Any animal known or suspected of being infected with an organism capable of causing disease transmissible to man may require a CDC permit. Importation of live turtles of less than 4 inches in shell length and all nonhuman primates requires an importation permit issued by the Division of Quarantine.
- ***Bats:*** All live bats require an import permit from the CDC and the U.S. Department of Interior, Fish and Wildlife Services.
- ***Insects or Arthropods:*** All live fleas, flies, lice, mites, mosquitoes, or ticks require a CDC import permit, regardless of infection status. Permits are required for adult forms, as well as eggs, larvae, pupae, and nymph stages. Any other living insect or arthropod, known or suspected of being infected with any disease transmissible to man requires a CDC import permit.
- ***Snails:*** Any snail species capable of transmitting a human pathogen require a permit from the Centers for Disease Control.

10.6.4 Department of Commerce- Bureau of Industry and Security (BIS) Regulated Agents

A permit may be required from the Commerce Department, when exporting infectious agents of human, plant, and animal diseases, including genetic material, and products which might be used for culture of large amounts of agents (Commerce Control List Supplement No. 1 to Part 774 Category 1, pages 54 - 59). In fact, in some instances, permits may be required to domestically ship commerce-controlled materials to certain foreign nationals or U.S. nationals who may fall on U.S. Governmental prohibition lists. In fact, these same individuals may even require a permit in order to access to these materials or their information while at AU (known as “deemed exports”). See the list below for the biological agents which fall on the Commerce Control List. For further information on export compliance, view the URL below and contact the AU Legal Office for further guidance.

HUMAN PATHOGENS and TOXINS

Bacteria

- *Bacillus anthracis*
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*
- *Burkholderia mallei* (*Pseudomonas mallei*)
- *Burkholderia pseudomallei* (*Pseudomonas pseudomallei*)
- *Chlamydia psittaci*
- *Clostridium botulinum*
- *Clostridium perfringens,* epsilon toxin producing types
- Enterohaemorrhagic *Escherichia coli,* serotype O157 and other verotoxin producing serotypes
- *Francisella tularensis*
- *Salmonella typhi*
- *Shigella dysenteriae*
- *Vibrio cholerae*
- *Yersinia pestis*

Toxins

- Abrin
- Aflatoxins
- Botulinum toxins
- Cholera toxin
- *Clostridium perfringens* toxins
- Conotoxin
- Diacetoxyscirpenol toxin
- HT-2 toxin
- Microcystin (Cyanginosin)
- Modeccin toxin
- Ricin
- Saxitoxin
- Shiga toxin
- *Staphylococcal aureus* toxins
- T-2 toxin
- Tetrodotoxin
- Verotoxin
- Volkensin toxin
- Viscum Album Lectin 1 (Viscumin)

Viruses

- Chikungunya virus
- Congo-Crimean haemorrhagic fever virus
- Dengue fever virus
- Eastern equine encephalitis virus
- Ebola virus
- Hantaan virus
- Hendra virus (Equine morbillivirus)
- Japanese encephalitis virus
- Junin virus
- Kyasanur Forest virus
- Lassa fever virus
- Louping ill virus
- Lymphocytic choriomeningitis virus
- Machupo virus
- Marburg virus
- Monkey pox virus
- Murray Valley encephalitis virus
- Nipah Virus
- Omsk haemorrhagic fever virus
- Oropouche virus
- Powassan virus
- Pulmonary and renal syndrome-haemorrhagic fever viruses (Seoul, Dobrava, Puumala, Sin Nombre)
- Rabies virus cultures
- Rift Valley fever virus cultures
- Rocio virus
- South American haemorrhagic fever virus (Sabia, Flexal, Guanarito)
- St. Louis encephalitis virus
- Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus)
- Variola virus
- Venezuelan equine encephalitis virus cultures
- Western equine encephalitis virus
- White pox
- Yellow fever virus

Rickettsiae

- *Bartonella quintana* (*Rochalimea quintana*, *Rickettsia quintana*)
- *Coxiella burnetii*
- *Rickettsia prowasecki*
- *Rickettsia rickettsii*

ANIMAL PATHOGENS and TOXINS

Bacteria

Mycoplasma mycoides

Viruses

- African horse sickness virus
- African swine fever virus
- Avian influenza virus (certain highly pathogenic strains – see the Export Administration Regulations for more information)
- Bluetongue virus
- Foot and mouth disease virus
- Goat pox virus
- Lumpy skin disease virus
- Lassa virus
- Newcastle disease virus
- Peste des petits ruminants virus
- Porcine enterovirus type 9 (swine vesicular disease virus)
- Porcine herpes virus (Aujeszky's disease)
- Rinderpest virus
- Sheep pox virus
- Swine fever virus (Hog cholera virus)
- Teschen disease virus
- Vesicular stomatitis virus

GENETIC ELEMENTS/GENETICALLY MODIFIED ORGANISMS

- Genetic elements that contain nucleic acid sequences associated with the pathogenicity of controlled microorganisms.
- Genetic elements that contain nucleic acid sequences coding for any controlled "toxins" or "sub-units of toxins."
- **Technical Note:** Genetic elements include, inter alia, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified.
- Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of controlled microorganisms.
- Genetically modified organisms that contain nucleic acid sequences coding for any controlled "toxins" or "sub-units of toxins."

PLANT PATHOGENS

Bacteria

- *Xanthomonas albilineans*
- *Xanthomonas campestris* pv. citri including strains referred to as *Xanthomonas campestris* pv. *citri* types A,B,C,D,E or otherwise classified as *Xanthomonas citri*, *Xanthomonas campestris* pv. *aurantifolia* or *Xanthomonas campestris* pv. *Citrumelo.*

Fungi

- *Colletotrichum coffeanum* var. *virulans* (*Colletotrichum kahawae*)
- *Cochliobolus miyabeanus* (*Helminthosporium oryzae*)
- *Magnaporthe grisea* (*pyricularia grisea/pyricularia oryzae*)
- *Microcyclus ulei* (*Dothidella ulei*)
- *Puccinia graminis* (*Puccinia graminis* f. sp. *tritici*)
- *Puccinia striiformis* (*Puccinia glumarum*)

10.6.5 FDA Import Permits

All food (except most meat and poultry), drugs, biologics, cosmetics, medical devices, and electronic products that emit radiation require a permit or registration before importation into the United States. See: http://www.fda.gov/ora/import/ for more information about FDA import permits.

Export permits requirement information can be found at:
http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm

10.6.6 Fish and Wildlife Service Permits

A permit may be required for transporting fish, wildlife, endangered species, or materials found in the list below.

Fish and Wildlife Service Permit Station
[http://www.fws.gov/international/permits/antiques.html]
Telephone: 1-800-770-0150

EXPORT

- African elephant ivory
- Animals
- Artificially propagated plants
- Asian elephant ivory
- Biological samples
- Captive-born export
- Circuses/traveling animal exhibitions
- Goldenseal
- Ginseng
- Marine mammals
- Museum specimens
- Personal pet
- Plants
- Raptors
- Trophies by taxidermist
- Wildlife

IMPORT

- African elephant
- African elephant ivory
- African leopard
- Argali
- Asian elephant ivory
- Biological samples
- Birds
- Bontebok
- Circuses/traveling animal exhibitions
- Marine mammals
- Museum specimens
- Personal pet
- Plants
- Polar bears
- Scientific and zoological breeding or display
- Sport hunted trophy
- White rhinoceros
- Wildlife

10.7 INTERNATIONAL SHIPMENTS

Shipping and receiving animals and animal-derived materials, infectious or biohazardous agents, biological toxins, and genetically modified organisms may require the approval of federal agencies, both domestic and foreign. Regulations that govern the transfer of biological materials help to minimize or eliminate the possible threats to public health and agriculture. In addition, the Departments of Commerce, Treasury and State regulate exportation based on special considerations on the material's economic impact, commercial value, ecological impact and/or military dual-use.

Some countries, couriers and airlines restrict the importation or transportation of some hazardous materials (*e.g.,* dry ice). It is advisable for the shipper to determine these restrictions prior to shipment/transport. Contact the Biosafety Office for assistance.

Packages shipped internationally generally require increased preparation time due to the additional paperwork required for such packages. An import/export permit may be required when shipping biological materials internationally (See Section 10.6). Check the following U.S. governmental agencies for permits and additional information.

10.7.1 Exporting from the United States

Depending on the nature of the shipment, a U.S. export permit may be required when sending your package. Additionally, an import permit may be required in the country where the package is being shipped. If your shipment requires an export permit, it must be completed and approved by the appropriate government agency prior to shipment. Typically, a copy of the import permit of the country of destination is included in the shipping documentation and should be obtained from the consignee prior to shipment. For more information on whether your shipment requires an export permit, please contact the Biosafety Office.

Note: Packages may be opened and inspected when leaving the United States or at any time by any inspection service provided by other countries. In order to assure that your package is safely delivered to its intended destination, always consider the following:

1. If necessary, obtain an export permit from the appropriate governmental organization prior to shipment.
2. Package and label the material according to the guidelines listed in this manual.
3. Include a courtesy letter with the shipment describing the contents in detail including information about whether the material is infectious. Copies of importation paperwork from the consignee should be included, if required.

10.7.2 Importing into the United States

All shipments entering the United States are processed by the U.S. Bureau of Customs and Border Protection. An import permit may be required to deliver the package even if a permit is not required by the originating country. Check with the appropriate governmental organization prior to shipment of the material.

Note: Packages may be opened and inspected upon entry into the United States. In order to assure that your package is safely delivered to its intended destination, always consider the following:

If necessary, obtain an import permit from the appropriate governmental organization prior to shipment.

1. Package and label the material according to the guidelines listed in this manual.
2. Consider including a courtesy letter with the shipment.

The **importer** is legally responsible for assuring that foreign personnel package, label, and ship the infectious materials according to USPHS and IATA regulations. Shipping labels containing the universal biohazard symbol, the address of the importer, the permit number, and the expiration date are also issued to the **importer** with the permit. The **importer** must send the labels and one or more copies of the permit

to the shipper. The permit and labels inform the U.S. Customs and Border Protection and U.S. Division of Quarantine personnel of the package contents.

10.8 SHIPPING COMPANY RESTRICTIONS

Some shipping companies may have requirements that are more restrictive than those discussed in this document. Consider the following information before planning a shipment.

10.8.1 DHL

DHL will accept shipments made according to IATA or DOT regulations. Shipments made according to instructions in this manual will be acceptable to DHL.

10.8.2 FedEx

FedEx Express and FedEx Ground will accept shipments prepared according to instructions in this manual. FedEx will not accept any material considered to be in Risk Group 4. A Risk Group 4 pathogen is one that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available.

10.8.3 United Parcel Service (UPS)

UPS will not accept shipments of Category A materials. UPS will accept shipments of UN3373 and exempt patient specimens.

10.8.4 United States Postal Service (USPS)

The USPS has highly restrictive regulations concerning the shipment of hazardous materials by mail. Category A materials may not be mailed with the USPS. USPS will accept shipments of UN3373 and exempt patient specimens. For more information, refer to Section 10.9.

10.9 UNITED STATES POSTAL SERVICE MAILINGS

The United States Postal Service (USPS) does not allow Category A infectious substances to be mailed. Follow the procedures below when mailing Category B substances, exempt patient specimens and non-regulated items.

10.9.1 Mailing Category B Substances

Follow packaging and labeling requirements listed in Section 10.3.2.2 and note the following variations:

- Shipments of both liquid and solid substances must be packaged in a pressure tested primary or secondary container; and
- Category B substances may be mailed as First-Class, Priority, or Express mail.

10.9.2 Mailing Exempt Human and Animal Specimens

Follow packaging and labeling requirements listed in Section 10.3.3 and note the following variations:

- Inner containers and the total volume per package are limited to 500 mL or 500 g;
- Outer packaging must me rigid; and
- Exempt specimens must be mailed as First-Class, Priority, Express, or Package Services mail.

10.9.3 Mailing Non-Regulated Materials

According to USPS regulations, specific packing instructions apply when mailing non-regulated materials. The following are examples of non-regulated biological materials:

- Biological products not containing Category A or Category B substances;
- Blood or blood products collected for transfusion or preparation of blood products;
- Tissues or organs intended for transplantation;
- Dried blood spots; and
- Dried specimens for fecal occult blood detection.

Quantity limits and form of substance (liquid or solid) determine the packaging requirements for non-regulated materials. Refer to the appropriate category below to determine how to package you material.

10.9.3.1 Non-Regulated Liquid Substance, Not Exceeding 50 ml

Primary container and total package contents may not exceed 50 ml. Primary receptacle must be leak-proof and properly sealed. Include cushioning and enough absorbent to absorb entire contents of liquid. Enclose the primary container(s) in a leak-proof secondary container (e.g. plastic bag). Label primary or secondary container with a biohazard symbol. No other labeling is required. Secondary container may serve as the outer container.

10.9.3.2 Non-Regulated Liquid Substance, Exceeding 50 ml

Primary container must not exceed 50 ml; total package may not exceed 500 ml. Package in triple packaging. Include cushioning and enough absorbent to absorb entire contents of liquid. Label primary or secondary container with a biohazard symbol. No other labeling is required.

10.9.3.3 Non-Regulated Dry Substance

Primary container must be sift-proof and must be enclosed in a sift-proof secondary container. Label primary or secondary container with a biohazard symbol. No other labeling is required. Secondary container may serve as the outer container.

10.10 Transport as Airline Baggage

Hazardous materials should **never** be carried in the passenger compartment of an airplane. Do not even attempt to carry these aboard an airline. Although occasionally, limited *non-infectious* biological materials and small amounts of dry ice may be transported as checked baggage on some passenger flights, these must not only comply with DOT/IATA and other standards as described above, but must adhere to *each airlines policies* and prerogative to carry such materials. Some airlines may refuse to carry these. Because of this, the practice is highly discouraged and it is recommended that AU personnel make arrangements to ship their materials prior to departure rather than attempt to check their baggage. However, in the exceptional situations where shipment is not possible, those wishing to transport non-infectious biological materials and/or dry ice as checked baggage must contact the airline(s) well ahead of time to confirm that the airline's policies will permit this and any special limitations/instructions they may have for preparing such packages. All packages must comply with the IATA/DOT packing, marking and labeling standards, and comply with any special permit standards as described in earlier sections. Those who intend on transporting such materials in this manner must have documented shipping training and declare their intentions to carry these materials on a passenger airline on their IBC-approved Biosafety Protocols and SOPs and fully disclose the nature of these materials to airline and TSA personnel.

10.11 TRANSPORT IN GROUND VEHICLES

USDOT regulations do not apply to private or contract motor carriers used exclusively to transport biological materials, diagnostic specimens or biological products; however, other standards (e.g., permits) may still be required. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle provided they are properly packaged and secured against exposure or contamination. Note, in order for the vehicle to be "dedicated," the vehicle cannot be utilized for other purposes at the same time (e.g., patient or passenger transport, food transport). Although no specific packing instructions are required by law, packages should be prepared in accordance with the packaging guidelines outlined in Section 10.4 and the carrier's specifications, if applicable.

All those transporting materials must be licensed drivers and comply with all applicable driving laws and accepted safety standards (*e.g.,* seat belt use).

Intention to transport biological materials or dry ice via vehicles by AU personnel should be fully disclosed in each IBC-approved Biosafety Protocol and SOPs prior to transport. These SOPs should include a description of the steps which should be taken if one is involved in a motor vehicle accident *en route*. These include:

- Call for emergency assistance, if needed
- Let all emergency response teams know that you are transporting potential biohazards
- Notify your supervisor to contact the shipper and recipient of the sample status
- Arrange for alternate transportation if you are not able to get to your destination

10.11.1 Automobiles

Special considerations should be made for the locations and security of the package in a passenger vehicle. During transport, the vehicle must be dedicated to the purpose. Biological materials should not be transported in any area where food/beverages are transported and these areas should be fully decontaminated prior to transport of food/beverages. Packages with dry ice or liquid nitrogen should never be transported in the passenger compartment of the vehicle due to the suffocation hazards (see Section 10.4.2.2). Materials should be secured from theft. Any material transported in an open truck must be secured to prevent loss via jostling of the vehicle during transport.

Transport via privately-owned vehicle is discouraged as many private insurance companies do not cover this activity. Check with your insurance company to verify the terms of your policy prior to transport.

10.11.2 Public Modes of Transportation (e.g., Shuttles busses)

Transport of biological materials or other hazardous materials is not permitted in passenger compartments of vehicles used for public transportation, such as shuttle busses.

10.11.3 Courier Services

Several commercial courier services are available to transport patient (diagnostic) specimens or biological products. Although USDOT regulations do not apply to private or contract motor carriers used exclusively to transport patient (diagnostic) specimens or biological products, and therefore no specific packing instructions are required by law, those wishing to offer their packages of biological materials to a commercial carrier for transport must prepare shipments in accordance to the courier's standards and must fully declare the nature of the materials which are being offered for transport. Often, these will be similar to that described in Section 10.4.