



Biological Safety Manual

Reviewed: April 2023

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INTRODUCTION

This manual is applicable to all laboratory, research, clinical, and educational services and support activities that may involve exposure to biohazardous agents or materials and that may come under the oversight of the Institutional Biosafety Committee (*IBC*). This manual does not address issues of chemical or radiation safety. Those issues are covered in separate manuals available on the EVMS Environmental Health and Safety (*EH&S*) website: www.evms.edu/ehs.

If you are working with potentially biohazardous materials, it is *your* responsibility to

- Know the hazards that may be associated with your work;
- Follow the best guidelines for safe practice in your work;
- Satisfy the requirements for reporting and registration review that the Federal Government has established.

If you are working with bacteria, fungi, parasites or live viruses, it is your responsibility to understand the appropriate risk groups by consulting the National Institute of Health (*NIH*) and Centers for Disease Control and Prevention (*CDC*) guidelines. The Biological Safety Officer (*BSO*) and IBC can assist you in obtaining this information.

Regulatory Requirements and Guidelines

Guidelines developed by the NIH and CDC form the basis for the biological safety practices in this manual. These guidelines **must** be followed to ensure the continuation of grant support from Federal agencies.

National Institutes of Health (NIH)

The NIH, through the Office of Science Policy (*OSP*), issued *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* to:

- Mandate the establishment of an IBC for the review and oversight of biological research
- Outline roles and responsibility within an institution for biological safety
- Establish the practices, procedures and conditions under which recombinant DNA (rDNA) and synthetic nucleic acid work **must** be conducted.

Centers for Disease Control and Prevention (CDC)

The companion to the NIH Guidelines is the CDC's *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*. This guide addresses the appropriate measures and facilities for work with **all** microbial agents.

Occupational Safety and Health Administration (OSHA)

The requirements of OSHA's *Occupational Exposure to Bloodborne Pathogen* standard apply to anyone who works with blood or other potentially infectious (human) materials. Special training, medical surveillance, procedures and equipment that should be implemented are overseen by [EVMS Occupational Health](#).

Virginia Department of Environmental Quality (DEQ)

The DEQ regulates and monitors the handling and disposal of biohazardous materials under its [Regulated Medical Waste Management Regulations](#) found in Virginia's Environmental Code Section 9 VAC 20-120. The procedures for biohazardous waste handling are outlined in the "Biohazardous Waste" section of this manual and comply with the requirements of these regulations.

Department of Transportation (DOT)

The requirements for packaging and shipment of biological materials are provided in the regulations issued in the DOT final rule "Hazardous Materials: Infectious substances; Harmonization with the United Nations Recommendations" ([71 FR 32244; June 2, 2006](#)) and parts of the Hazardous Materials regulations in [49 CFR, Parts 171-180](#). Information on shipping procedures that comply with these regulations is found in the "Packaging and Shipping Biological Materials" section of this manual.

Training at EVMS also satisfies requirements for the International Air Transport Association ([IATA](#)) for shipping to other countries.

Biological Safety Program at EVMS

The EVMS biological safety program developed from the institution's commitment to address and comply with the *NIH Guidelines* regarding safe research with rDNA and associated infectious materials. The fundamental components of the program are:

- The Institutional Biosafety Committee
- EVMS Environmental Health & Safety
- The Biological Safety Officer
- The Principal Investigator
- Occupational Health Department
- The EVMS Veterinarian / Department of Comparative Medicine
- Other associated committees (IRB, IACUC, etc.)

The roles of each are described below.

Institutional Biosafety Committee (IBC)

IBC members include faculty and administrators, the Biological Safety Officer, an Occupational Health representative, a representative from Comparative Medicine and representatives from the community. The IBC:

- Ensures that research involving human and animal pathogens, tissues and toxins are reviewed and found to comply with all federal, state and local requirements;
- Ensures that all rDNA and synthetic nucleic acid registrations (including human gene therapy/transfer) and research are in compliance with NIH guidelines;
- Establishes policies and procedures ensuring biological materials are handled and disposed of safely and in the proper manner.

The IBC conducts business through BioRAFT, a modular software platform for research management and compliance oversight. IBC members, Principal Investigators (PI), and laboratory personnel can

access BioRAFT at <https://evms.bioraft.com/>. Lab registration submissions, agent forms, biosafety-related training and each laboratory's status are contained in BioRAFT.

Environmental Health & Safety (EH&S)

EH&S is responsible for:

- Addressing biosafety issues related to research, experiments, academic endeavors, and clinical environments;
- Assisting personnel with compliance to regulatory requirements and best management practices pertaining to biological and laboratory safety;
- Laboratory inspections to ensure compliance with all governmental guidelines and institutional policies;
- Training PIs, staff and other personnel on safety issues and regulations.

Biological Safety Officer (BSO)

The BSO is responsible for

- Developing protocols and procedures to address issues of biological safety;
- Providing training in the safe use and general procedures for those working with potentially biohazardous materials and research activities;
- Advises PIs on proper waste disposal methods based on federal, state and local regulations;
- Advises personnel on correct shipping requirements for biological substances;
- Advises the IBC and other committees on issues related to biosafety;
- Inspection of bio laboratories to ensure compliance with accepted biosafety practices and with the IBC approved registrations;
- Assists PIs with laboratory registrations and forms required by the IBC.

Principal Investigator (PI)

The PI is responsible for:

- Completing and submitting an IBC Registration for laboratories conducting work with biological materials and agents;
- Accepting responsibility for the health and safety of their laboratory personnel;
- Completing registrations in a timely and proper manner;
- Ensuring proper training and instruction in safe practices and procedures for laboratory personnel involved with handling potentially biohazardous materials;
- Ensuring compliance by laboratory personnel with all relevant regulations, guidelines and policies;
- Reporting accidents, spills, or contamination to the EH&S and the IBC;
- Ensuring all laboratory personnel are aware of the lab-specific hazards involved in their work as well as ensuring personnel are conducting work as specified in an IBC approved registration.

Occupational Health

EVMS Occupational Health is responsible for:

- Provides medical review and medical surveillance, as appropriate, for infectious agent workers, those exposed to laboratory animals and those in the Bloodborne Pathogens (BBP) program;

- Advises investigators, animal care personnel, clinical staff and institutional committees on potential exposures and risks of personal injury associated with laboratory or clinical procedures;
- Advises PIs and staff on practices and procedures for reducing or eliminating exposure and injury.

Veterinarian

The veterinarian provides training to all animal users in safe animal-handling procedures. Additionally, the veterinarian advises the IBC and IACUC on issues of animal safety and procedures when necessary.

IBC Administrator (IBCA)

The IBCA is a non-voting, support staff from the Office of Research. The IBCA sends all correspondence from the IBC to the PIs. The IBCA is charged with the responsibility of IBC records (meeting minutes, registration and PI files, etc.) and is also responsible for meeting agendas, committee minutes, delegating reviewers for registrations, distributing supplemental information to IBC members and initial reviews of adverse event reports.

All form submissions, attachments and other materials requested by the IBC are to be sent to the IBCA. The PI is to send all training documentation to the IBCA at the time of their laboratory submission. If a PI has a change in laboratory personnel, the PI is to send a letter to the IBCA requesting the change. The IBCA can then administratively approve changes in personnel on the BioRAFT registration

Associated Committees

The Institutional Review Board ([IRB](#)) reviews and oversees research involving human subjects. The Institutional Animal Care and Use Committee ([IACUC](#)) reviews and oversees research involving laboratory animals. Both of these committees consult and coordinate with the IBC on any proposals under their purview that involves the use of potentially biohazardous materials or activities.

WORKING WITH BIOLOGICAL MATERIALS

Exposure Control

Biosafety issues are addressed in terms of physical and biological containment. The necessary containment can be achieved by using the appropriate combination of:

1. Proper practices and techniques
2. Safety equipment
3. Laboratory design

Laboratory Practices

The most crucial component of containment is stringent adherence to standard microbiological practices and techniques. Personnel working with infectious agents or biohazardous materials must be aware of the potential danger, and must be trained and proficient in the practices and techniques required for safely handling such materials.

Each PI should identify specific hazards that will occur in the course of their research project, and consider practices and procedures needed to minimize or eliminate risks. *Personnel should be advised of special hazards and are expected to follow the required practices and procedures.*

When [standard laboratory practices](#) are not sufficient to control the hazards associated with a particular agent or procedure, additional measures may be needed. The PIs, with assistance from the BSO, are responsible for selecting additional safety practices, which must be in keeping with the hazards associated with the agent or procedure. Laboratory personnel, safety practices and techniques must be supplemented by appropriate facility design and engineering features, safety equipment and management practices.

Safety Equipment (Primary Barriers)

Safety equipment includes engineering controls and personal protective equipment (PPE), where both serve as primary barriers against exposure to biohazardous materials.

Biological Safety Cabinet

Biological safety cabinets (BSC), enclosed containers, safety centrifuge cups and other engineering controls are designed to eliminate or minimize the exposure to hazardous biological materials. The BSC is the principle device used to provide containment of infectious splashes or aerosols generated by many microbiological procedures. There are three types of BSCs (Class I, II, III) used in microbiological laboratories. Open-fronted Class I and Class II BSCs are primary barriers that offer significant levels of protection to both laboratory personnel and the environment when used with good microbiological techniques. Class II biological safety cabinets also provide protection from external contamination of the materials being manipulated inside the cabinet. Class III BSCs are enclosed, gas-tight and provide the highest attainable level of protection to personnel and the environment.

Inspection

An inspection/field test and certification of the BSC must take place at the time of installation and at least **annually**. Cabinet inspections must also be conducted when HEPA filters are changed, when maintenance repairs have been made to internal parts, when the BSC has been relocated and when other manufacturer's guidelines apply. (*ANSI Standard 49, Annex F.1*)

The inspection and certification of biological safety cabinets are the responsibility of the PI and must be completed by an accredited and certified vendor.

Cleaning

Semi-annual cleaning of biological safety cabinets is *strongly recommended*. The general guidelines on how to clean a BSC using 10% household bleach are:

1. Raise the front window to its highest level.
2. Remove and clean the removable grille inside the cabinet.
3. Remove and clean the one piece work surface or individual work surfaces. Clean both sides.
4. Open the drain valve in the cabinet pan and place a leak-proof container under the opening.
5. Clean all cabinet surfaces, including the pan, back wall, and side panels. Let disinfectant sit 10 minutes before wiping. Gently wipe pooled disinfectant towards the cabinet drain and into the leak-proof container.
6. Spray and wipe entire cabinet with water to prevent pitting of the metal.
7. Reassemble the cabinet interior. Remember to close drain valve!
8. Clean the front window.
9. Dispose of collected liquid down the drain.

Decontamination

BSCs must be decontaminated before disposal, before moving outside its current space, and whenever the internal HEPA filter(s) are removed. BSC decontamination must be conducted by either EH&S or a certified vendor.

Centrifuge

A centrifuge can be an important tool in a clinical or research laboratory. Most hazards with centrifuges stem from two sources: mechanical conditions and processing hazardous materials. Stress, fatigue and corrosion of mechanical parts on a centrifuge are all serious problems.

- Large, floor-model high speed and ultra-centrifuges **must be inspected annually** by an accredited and certified vendor to ensure these issues do not become serious problems.
- EH&S **recommends** bench-top high-speed and micro centrifuges be inspected **annually**.

Centrifugation of hazardous samples can result in exposures to chemical, biological or even radiological agents. Careful consideration must be given to work practices to avoid hazards. Use the following guidelines when hazardous materials are centrifuged:

- Load and unload hazardous samples in ventilated enclosures (biosafety cabinets);
- When hazardous samples are centrifuged, contain samples in safety cups, sealed tubes, or safety rotors;

- **Wait at least 10 minutes after centrifuge has stopped before opening** – allowing any generated aerosols in the chamber to settle;
- Clean and decontaminate all parts after each use, according to manufacturer’s instructions.

Personal Protective Equipment

Safety equipment also includes PPE. This equipment consists of gloves, lab coats, gowns, shoe covers, boots, respirators, face shields, safety glasses or goggles. Appropriate PPE must be worn whenever work is being conducted. *At a minimum, appropriate PPE includes lab coats, gloves and eye protection (if there is the possibility of splashes).* PPE is to be made available to employees by the PI or the department.

PPE is often used in combination with BSCs and other containment devices. In some situations in which it is impractical to work in BSCs, PPE may form the primary barrier between personnel and the infectious material.

While PPE should be worn while in the lab, it is to be disposed of *before exiting. Do not wear laboratory-used PPE in common areas, such as hallways and offices.*

Facility Design (Secondary Barriers)

The design of a facility is important in providing a barrier to protect those working inside and outside the laboratory and to protect people or animals in the community from infectious agents. Facilities must be commensurate with the laboratory’s function and the recommended biosafety level for the agents being manipulated.

The secondary barrier(s) will depend on the risk of transmission of specific agents. Secondary barriers in these laboratories include separation of the laboratory work area from public access, availability of a decontamination facility (e.g. autoclave) and hand washing facilities.

Vaccinations

Vaccinations can be made available for many etiologic agents used in the laboratory *if* the need is great enough. Occupational Health, in conjunction with the IBC, will make the recommendation for the use of vaccinations on a case-by-case basis.

Training

Responsibility

Those individuals working in an active biological laboratory, or a laboratory with biological hazards present, are required to complete biological safety training. Ensuring the completion of proper training by laboratory staff is the responsibility of the individual PI. All biological laboratory personnel, including the PI, must be trained for the hazards contained in the laboratory, and the training must be up-to-date.

Types of Training

Training on BioRAFT

Training on BioRAFT is located in the Course Directory under the “Training” tab. For each course/training, select “Launch course,” view the presentation, complete the quiz and submit.

Biosafety Training

It is mandatory that all faculty, staff, and students working in a laboratory setting containing biohazardous materials must satisfactorily complete Biosafety Training. Completion of this biosafety course is required **every five (5) years**.

Autoclave Safety Training

It is mandatory that all faculty, staff, and students working in a laboratory setting containing biohazardous materials must satisfactorily complete Autoclave Safety Training. Access to the core autoclave rooms is contingent upon completion of the course. Completion of this autoclave training is required **every five (5) years**.

Shipping Training

It is mandatory that all faculty, staff, and students who are involved in shipping or receiving biological materials must satisfactorily complete Shipping Biological Materials training. Completion of this course satisfies requirements of both the International Air Transport Association (*IATA*) and the Department of Transportation (*DOT*) for infectious substances shipping training. Completion of this shipping training is required **every two (2) years**, as long as the laboratory/person continues to be involved with shipping.

NIH Guidelines Training

NIH Guidelines Training is recommended by NIH for all IBC Members and, at a minimum, faculty involved in recombinant DNA research. The PI must review the training presentation **every five (5) years**, at the time of a new IBC submission (or 5-year resubmission) if not taken within the previous year. PIs are responsible for the training of their laboratory members in the NIH Guidelines.

Bloodborne Pathogen Training

Investigators performing studies utilizing human blood or other potentially infectious materials covered by the OSHA Bloodborne Pathogen Standards are required to complete annual Bloodborne Pathogen Training. Other potentially infectious materials (OPIM) include:

Body Fluids:

Amniotic Fluid	Saliva from dental procedures
Cerebrospinal Fluid	Semen
Joint Fluid	Vaginal Secretions
Pericardial Fluid	Any body fluid visibly contaminated with blood
Peritoneal Fluid	Unidentifiable body fluids
Pleural Fluid	

Other Materials:

Any unfixed tissue or organ of human origin

Investigators are required to use “Standard Precautions” when handling specimens of blood, blood products, or OPIM as stipulated in the OSHA *Bloodborne Pathogen Standard*. Standard Precautions involve treating materials as though infectious no matter the circumstance; this involves always using standard PPE and treating the materials with universal precautions.

Personnel who may qualify to be exempted from the annual Bloodborne Pathogen Training requirement must contact EVMS Occupational Health to complete a waiver form. Questions and concerns about Bloodborne Pathogen Training can be submitted to the Occupational Health Executive Director at (757) 446-5870.

Bloodborne Pathogen Training is provided for EVMS personnel only. For guest/visiting researchers and research staff who will be working with human blood or body fluids, Bloodborne Pathogen Training should be completed annually with their employer or school. These researchers should provide the IBCA with documentation stating the last training completion date.

Live Training

Contact EH&S for scheduling supplemental or additional live trainings.

Chemical Hygiene Plan (CHP)

All permanent faculty and staff working in a laboratory must complete Chemical Hygiene Plan class. CHP training credit is obtained by attendance in EH&S’s CHP course. An online CHP Refresher course must be completed **every five (5)** years.

Radiation Safety Training

Radiation safety training is required when personnel will be working with radioactive materials or products containing radioactive material. If working with radioactive materials, completion of the “Radiation Safety in the Laboratory” coursework is mandatory. After successful completion, personnel will receive their user documentation and may need to apply to the EVMS Radiation Safety Committee for approval to work with radioactive materials. Radiation Safety refresher training must be completed **annually** to be compliant.

If personnel will only be working in the vicinity of radioactive materials (such as animals containing radioactive products), they may complete an abridged training course. While being able to work around radioactive materials, these personnel will not be users and are therefore not permitted to handle radioactive materials.

Other Training

Animal Users

Training requirements for laboratories utilizing animal models can be found on the [IACUC MyPortal](#) page. Additionally, there is a facility orientation and a live training session for all Rodent Users. Please contact the Comparative Medicine Program Director for details and scheduling.

Risk Assessment

Risk assessments are an important responsibility for PIs. The PI, BSO and others share in the risk assessment process. A risk assessment is a method used to:

- Identify the hazardous characteristics of the agent or material involved in an investigator's work, such as
 - Risk Group of the agent or material
 - Route of transmission
 - Agent stability
 - Infectious dose
 - Origin of material
- The activities and research methods that can result in a person's exposure to an agent, for example
 - Work requiring high concentration doses of virus
 - Centrifugation
 - Amplification
- The likelihood such exposure will cause an infection
- The probable consequences of such an infection to personnel, other people or animals, and the environment

The information identified by a risk assessment provides a guide for

- The selection of appropriate Biological Safety Level (BSL) for conducting the research
- Appropriate microbiological practices
- Sufficient safety equipment
- Proper facility safeguards that can prevent laboratory acquired infections

Risk assessments are accomplished through BioRAFT registration reviews. PIs will use the risk assessments to alert their laboratory personnel to the hazards working with infectious agents and to the need for developing proficiency in the use of selected safe practices and containment equipment. Risk assessments are to be conducted at several points. They should be done

- Prior to working with an agent
- At regular intervals during registration approval period or work
- At least annually
- Whenever changes occur in the laboratory, such as
 - A move or renovation
 - A new employee begins working in the lab
 - New agent introduced
 - New or different piece of equipment utilized in the work
 - New techniques or procedures are employed in the work

Successful control of hazards in the laboratory also protects persons not directly associated with the laboratory, such as other occupants of the same building and the public.

Laboratory Inspections

According to the *NIH Guidelines*, periodic laboratory inspections are required in order to ensure biological safety standards are followed (**Section IV-B-3-c-(1)**) and to ensure that research is in compliance with the *Guidelines* (**Section IV-B-2-b-(5)**).

All PIs with approved IBC Registrations (including those granted with IBC Exemptions) will have **annual** inspections. Inspections will be conducted by EH&S. The general procedure for inspections will be as follows:

1. Communication will be made with the laboratory/PI to select a date and time.
2. The inspection will be conducted and recorded through the BioRAFT Inspection module.
3. Within **2 days** after the inspection, a report will be sent to the PI listing any deficiencies.
4. A response to the report will be due within **1 week**. The response should include any corrected deficiencies and plans for corrections not yet made.

These inspections are to ensure compliance not only with safe laboratory practices, but also with each laboratory's submitted and approved registration. All laboratories and spaces listed under a PI will be inspected at the same time. If a laboratory comes up for their Annual Review and has **not scheduled** their inspection with the BSO, the BSO reserves the right to withhold their registration from going through to the IBC until the inspection is scheduled.

Laboratory Procedures

The following are general laboratory guidelines at EVMS.

Standard Practices

- Limit access to the laboratory.
- Lab coats are to be worn at all times in the laboratory. Lab coats should be changed when they become contaminated.
- Do not eat, drink, store food, smoke, handle contact lenses or apply cosmetics in the laboratory. *There is no such thing as a “clean area” inside a laboratory in which to eat and drink.*
- Persons wearing contact lenses should wear non-vented goggles or a face shield. However, it is best to avoid wearing contact lenses if possible.
- Pants or long skirts must be worn in the laboratory. Only closed-toe shoes are to be worn while in the laboratory.
- Remove all protective equipment before leaving the laboratory (lab coat, gloves, etc.).
- Always wear gloves when using biological materials or handling animals. Change gloves often even if you don't think they are contaminated.
- Remove gloves before handling non-contaminated materials.
- Wash hands after removing gloves and before leaving the work area.
- Minimize the production of splashes and aerosols.
- Use sharps only when necessary and dispose of them in appropriate sharps containers.
- Never manipulate sharps or needles in a manner that involves direct contact or directing a movement toward the body.
- Report spills and accidents involving infectious materials to the PI and EH&S immediately.
- Decontaminate work surfaces after every spill of infectious material. Also, decontaminate work surfaces before and after working on them.
- Do not mouth pipette.
- Decontaminate all waste before disposal.

Basic Facilities

Each laboratory at EVMS has the same basic design. The basic laboratory design includes

- A sink for hand washing with hot water, soap and towels located preferably near the lab entrance/exit;
- Easy-to-clean areas;
- Bench tops which are waterproof and resistant to acids, alkalis, organic solvents, and moderate heat;
- Sturdy, liquid-resistant lab furniture which complies with the EVMS Laboratory Furniture Policy;
- Fly screens on windows if they open;
- Doors should open inward, be self-closing, lockable, and kept closed when work is being performed;
- Laboratory rooms should have directional airflow into the laboratory (not into common areas like hallways);
- Do not recirculate exhaust air in animal facilities.

Signs

A Biohazard Warning Sign, having the biohazard symbol, must be posted at each entrance to all laboratories at Biosafety Level 2 and higher. Signs must identify the Biological Safety Level, list the name and phone number of laboratory contacts, and indicate any special requirements for entering and exiting the laboratory (such as immunizations and training). EH&S creates and provides room signs to the laboratories.

The image shows a rectangular sign for Biosafety Level 2. At the top, it says "Biosafety Level 2". Below that is a red biohazard symbol with the text "BIOHAZARD BIOPELIGRO" in bold black letters. Underneath the symbol is the text "AUTHORIZED PERSONNEL ONLY!". Below this is a section for "BIOHAZARD PRECAUTIONS" with a red header and a white box for "Entry / Exit PROCEDURES". At the bottom is an "EMERGENCY CONTACT" table with a red header and two columns: "Name" and "Phone".

EMERGENCY CONTACT	
Name	Phone
ENVIRONMENTAL HEALTH & SAFETY	446-5798
EVMS POLICE DISPATCH	446-5199

EVMS
Environmental Health & Safety

Laundry

For BSL-2 facilities, including clinical areas, it is not necessary to decontaminate laundry prior to transport to a commercial laundry facility. Commercial laundry facilities use water temperatures of at least 160°F and 50-150 ppm of chlorine bleach to remove significant quantities of microorganisms from grossly contaminated laundry.

Each PI or their department is responsible for providing a laundry service if reusable PPE is used in the laboratory. It is the responsibility of the PI to ensure that laundry services for all laboratory employees' lab coats are acceptable and performed at adequate intervals.

In the event laundry becomes soiled (i.e. visibly dirty or stained), the following procedures shall be followed:

1. DO NOT sort, rinse, or soak laundry in the location of use. Employees are not to take contaminated laundry home for any reason.
2. While wearing appropriate PPE, remove the contaminated piece of laundry.
3. Place laundry in an appropriately labeled bag or container at the location where it was used.
 - a. Bag or container must be leak-proof and labeled with the Biohazard symbol.
 - b. *Note:* Commercial laundry bags from a contracted vendor are appropriately labeled and are coated in a liquid-resistant material to prevent leaks.
4. If laundry is wet and presents a reasonable likelihood of leakage to the exterior of a single container, it must be placed in a second container (or "double-bagged").
5. After all soiled laundry has been placed in the appropriate container(s), dispose of used PPE in the medical waste container.
6. All workplace laundry shall be sent to a commercial laundry facility or cleaned in an onsite washing machine at no expense to the employee.

Pest Management

Animals and plants are not permitted in the laboratory unless they are associated with the work being performed. Pest management is the responsibility of EVMS Facilities. To report pest issues, contact the EVMS Campus Housing Manager.

Equipment Management

Equipment being repaired, surplus, or disposed of must be decontaminated. Prior to moving or disposing of biological equipment (refrigerators, freezers, BSCs, incubators, etc.) from its current placement, the equipment must be decontaminated by an EH&S approved method. Due to the contained HEPA filters, BSCs must be decontaminated by either a certified, outside vendor or EH&S. All other equipment may be decontaminated by laboratory staff using an approved chemical decontaminant.

The following procedure should be followed for chemical decontamination of lab equipment.

- Wear appropriate personal protective equipment. At a minimum wear gloves, lab coat, safety glasses with side shields or goggles.
- Remove all specimens and/or laboratory materials.
- Remove all biohazard labels or stickers from the surface of the equipment.
- Clean the surface of the equipment for any radioactive contamination (*if applicable*). Schedule a wipe test with EH&S to ensure that the equipment is free from residual radioactive contamination.
- Be sure that the equipment surface can be safely cleaned with a chemical disinfectant. Make sure that the equipment was not used to store water reactive chemicals, corrosives or strong oxidizers that may incompatibly react during the decontamination process.
- Apply a chemical disinfectant to the surface of the equipment and allow the disinfectant time to inactivate potential contamination.
- Ensure that the surface is rinsed to remove the disinfectant.
- Put the cleaning waste (paper towel, sponge) in a biohazard bag and treat as biohazardous waste.
- Dispose of PPE properly and wash hands thoroughly. Do not open internal compartments of equipment for decontamination.
- Contact EH&S to have the equipment tagged for disposal or moving.

BSCs must be inspected and certified once they have been installed in a new location regardless of when the previous certification expires. The BSC needs to be tested to ensure proper functioning with the new work space and airflow.

Biosecurity

The objective of biosecurity is to prevent loss, theft or misuse of microorganisms, biological materials and research-related information. This is accomplished by limiting access to facilities, research materials and information.

Biosecurity is based upon risk assessment and management methodology; personnel expertise and responsibility; control and accountability for research materials including microorganisms and culture stocks; access control elements, material transfer documentation, training, emergency planning and program management. Each PI shares in the responsibility of securing the materials in their laboratories. Simple mechanisms such as locking a laboratory as you exit and having emergency procedures prepared are part of biosecurity.

Dual Use Research of Concern

Dual Use Research of Concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be

directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security. The United States Government's (USG) oversight of DURC is aimed at preserving the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.

Under the [United States Government Policy for Institutional Oversight of Life Sciences Dual use Research of Concern \(September 2014\)](#), there are *seven (7)* specific experiments and **15** identified agents and toxins which are considered DURC. The covered experiments are:

1. Demonstrate how to render human or animal vaccines ineffective.
2. Confer resistance to therapeutically useful antibiotics or antiviral agents for humans, animals, or crops.
3. Enhance the virulence of human, animal, or plant pathogens, or make non-pathogens virulent.
4. Increase the transmissibility of pathogens.
5. Alter the host range of pathogens.
6. Enable the evasion of diagnostic or detection methods.
7. Enable the weaponization of biological agents or toxins.

Extra scrutiny and precautions should be given to potential dual-use research by both the PI and the IBC. In accordance with the USG Policy, if the EVMS IBC determines research conducted at EVMS falls under the DURC policy, it will:

- A. Establish and implement internal policies and practices that provide for the identification and effective oversight of DURC.
- B. When research is identified by a PI as utilizing one of the agents or toxins, the IBC will initiate an institutional review and oversight process.

Select Agents

The Federal Select Agent Program (FSAP) regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products. Common examples of select agents and toxins include the organisms that cause anthrax, smallpox, and bubonic plague, as well as the toxin ricin. The program is managed jointly by:

- The **Division of Select Agents and Toxins (DSAT)** at the Centers for Disease Control and Prevention (CDC) which is part of the U.S. Department of Health and Human Services (HHS).
- The **Agriculture Select Agent Services (AgSAS)** at the Animal and Plant Health Inspection Service (APHIS), which is part of the U.S. Department of Agriculture (USDA).

DSAT regulates those agents that cause disease in humans, while AgSAS regulates those that can cause disease in animals and plants.

The program currently regulates **67 agents and toxins**. The list is reviewed at least every two years to determine if agents or toxins need to be added to or deleted from the list. A current listing of the Select Agents and Toxins can be found on the FSAP website:

<https://www.selectagents.gov/SelectAgentsandToxinsList.html>.

PIs are to identify all Select Agents and Toxins desired to be used and/or stored in the laboratory in a written communication to EH&S *before* ordering. The BSO will respond each request on an individual basis. The PI is *not* to order or receive any Select Agent or Toxin until given final approval from EH&S and the IBC.

HHS and USDA Select Agents and Toxins
7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS

1. Abrin⁵
2. *Bacillus cereus* Biovar *anthracis**
3. Botulinum neurotoxins^{*,5}
4. Botulinum neurotoxin producing species of *Clostridium**
5. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X₁CCX₂PACGX₃X₄X₅X₆CX₇)^{1,5}
6. *Coxiella burnetii*
7. Crimean-Congo haemorrhagic fever virus
8. Diacetoxyscirpenol⁵
9. Eastern Equine Encephalitis virus^{3,4}
10. Ebola virus*
11. *Francisella tularensis**
12. Lassa fever virus
13. Lujo virus
14. Marburg virus*
15. Monkeypox virus³
16. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
17. Ricin⁵
18. *Rickettsia prowazekii*
19. SARS-associated coronavirus (SARS-CoV)⁴
20. Saxitoxin⁵

South American Haemorrhagic Fever viruses:

21. Chapare
22. Guanarito
23. Junin
24. Machupo
25. Sabia

26. Staphylococcal enterotoxins (subtypes A,B,C,D,E)⁵
27. T-2 toxin⁵
28. Tetrodotoxin⁵

Tick-borne encephalitis complex (flavi) viruses:

29. Far Eastern subtype⁴
30. Siberian subtype⁴

31. Kyasanur Forest disease virus⁴
32. Omsk hemorrhagic fever virus⁴
33. Variola major virus (Smallpox virus)*
34. Variola minor virus (Alastrim)*
35. *Yersinia pestis**

OVERLAP SELECT AGENTS AND TOXINS

36. *Bacillus anthracis**
37. *Bacillus anthracis* Pasteur strain
38. *Brucella abortus*
39. *Brucella melitensis*
40. *Brucella suis*
41. *Burkholderia mallei**
42. *Burkholderia pseudomallei**
43. Hendra virus
44. Nipah virus
45. Rift Valley fever virus
46. Venezuelan equine encephalitis virus^{3,4}

USDA SELECT AGENTS AND TOXINS

47. African horse sickness virus
48. African swine fever virus
49. Avian influenza virus³
50. Classical swine fever virus⁴
51. Foot-and-mouth disease virus^{*,4}
52. Goat pox virus
53. Lumpy skin disease virus
54. *Mycoplasma capricolum*³
55. *Mycoplasma mycoides*³
56. Newcastle disease virus^{2,3}
57. Peste des petits ruminants virus
58. Rinderpest virus*
59. Sheep pox virus
60. Swine vesicular disease virus⁴

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

61. *Coniothyrium glycines* (formerly *Phoma glycinicola* and *Pyrenochaeta glycines*)
62. *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*)
63. *Ralstonia solanacearum*
64. *Rathayibacter toxicus*
65. *Sclerophthora rayssiae*
66. *Synchytrium endobioticum*
67. *Xanthomonas oryzae*

*Denotes Tier 1 Agent

¹ C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α -M1 and α -G1 (shown above) as well as α -G1A, Ac1.1a, α -Cn1A, α -Cn1B; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; “Des X” = “an amino acid does not have to be present at this position.” For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

² A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

³ Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus, west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies *Mycoplasma capricolum* except subspecies *capripneumoniae* (contagious caprine pleuropneumonia), all subspecies *Mycoplasma mycoides* except subspecies *mycoides* small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category.

⁴ For determining the regulatory status of nucleic acids that are capable of producing infectious forms of select agent viruses, please reference guidance at <https://www.selectagents.gov/na-guidance.html>.

⁵ For determining the regulatory status of Recombinant and/or Synthetic nucleic acids that encode for the toxic form(s) of any select toxins if the nucleic acids (i) can be expressed in vivo or in vitro, or (ii) are in a vector or recombinant host genome and can be expressed in vivo or in vitro; please reference guidance at <https://www.selectagents.gov/na-guidance.html>.

BIOLOGICAL SAFETY LEVELS (BSL)

Biosafety levels are standards that specify the combinations of laboratory practices, safety equipment and facility design that are appropriate for the biohazards of an operation. These standards are found in the CDC's *BMBL* and the *NIH Guidelines*. This manual lists a summary of these standards.

Be aware that Risk Groups are *not* the same as Biological Safety Levels. Risk Groups deal only with an organism's characteristics, such as mode of transmission and infectious dose. Determination of a Biological Safety Level includes an organism's Risk Group, but also includes the facility design, required PPE, specific safety practices and hazard to the surroundings.

In addition, there is a distinction between a laboratory and an animal facility or animal room. This distinction exists because of the additional hazards an animal can introduce, such as biting and husbandry. For instance, a biosafety level for a laboratory may be referred to as Biosafety Level 1 (BSL1), while a biosafety level for an animal facility or room may be referred to as Animal Biosafety Level 1 (ABSL1). Because there are few differences, the requirements for both biosafety level types are presented together.

All laboratory work should be evaluated and approved for the biosafety level by the BSO. **EVMS does not currently have appropriate facilities for work at BSL3 and/or BSL4 levels. Therefore, organisms that require such facilities are not handled in EVMS laboratories.**

BSL	Agents	Practices	Safety Equipment (Primary Barrier)	Facilities
1	Not known to consistently cause disease in health adults	Standard Microbiological Practices	None Required	Open bench and sink required
2	<ul style="list-style-type: none"> ➤ Agents associated with human disease ➤ Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure 	BSL-1 practice plus: <ul style="list-style-type: none"> ➤ Limited Access ➤ Biohazard warning signs ➤ “Sharps” precautions ➤ Biosafety manual defining any needed waste decontamination or medical surveillance policies 	<u>Primary Barriers</u> <ul style="list-style-type: none"> ➤ Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials <u>PPE</u> <ul style="list-style-type: none"> ➤ Laboratory coats ➤ Gloves ➤ Face protection as needed 	BSL-1 plus: <ul style="list-style-type: none"> ➤ Autoclave available
3	<ul style="list-style-type: none"> ➤ Indigenous or exotic agents with potential for aerosol transmission ➤ Disease may have serious or lethal consequences 	BSL-2 practice plus: <ul style="list-style-type: none"> ➤ Controlled access ➤ Decontamination of all waste ➤ Decontamination of lab clothing before laundering ➤ Baseline Serum 	<u>Primary Barriers</u> <ul style="list-style-type: none"> ➤ Class I or II BSCs or other physical containment devices used for all open manipulations of agents <u>PPE</u> <ul style="list-style-type: none"> ➤ Protective lab clothing ➤ Gloves ➤ Respiratory protection as needed 	BSL-2 plus: <ul style="list-style-type: none"> ➤ Physical separation from access corridors ➤ Self-closing, double-door access ➤ Exhausted air not recirculated ➤ Negative airflow into laboratory
4	<ul style="list-style-type: none"> ➤ Dangerous/exotic agents which pose high risk of life-threatening disease ➤ Aerosol-transmitted lab infections; or related agents with unknown risk of transmission 	BSL-3 practices plus: <ul style="list-style-type: none"> ➤ Clothing change before entering ➤ Shower on exit ➤ All material decontaminated on exit from facility 	<u>Primary Barriers</u> All procedures conducted in: <ul style="list-style-type: none"> ➤ Class III BSCs or <ul style="list-style-type: none"> ➤ Class I or II BSCs in combination with full-body, air-supplied, positive pressure personnel suit 	BSL-3 plus: <ul style="list-style-type: none"> ➤ Separate building or isolated zone ➤ Dedicated supply and exhaust, vacuum and decon systems ➤ Other requirements outlined in the text

Table 1: BSL Summary (BMBL, 5th edition). To view a complete description of the CDC’s BSLs, visit <https://www.cdc.gov/labs/BMBL.html>.

Biosafety Level 1 (BSL-1) and Animal Biosafety Level 1 (ABSL-1)

BSL-1 is appropriate for work involved with well-characterized strains of viable microorganisms, which have no known or minimal hazard to healthy adults. BSL-1 laboratories do not necessarily have to be separated from the general traffic patterns in the building. Working on bench tops is permitted while using standard practices and wearing protective equipment and clothing such as face shield, gloves and a lab coat when necessary.

Access to the animal facility is limited to persons who have been informed of the hazards. Persons having a higher than normal sensitivity to infection should not be allowed in the animal facility.

Biosafety Level 2 (BSL-2) and Animal Biosafety Level 2 (ABSL-2)

BSL-2 and ABSL-2 correspond to work conducted with organisms causing disease in humans where vaccines and therapies are usually available. Work can be conducted on the open bench unless there will be aerosolization of material or if sterility is needed. Examples of agents and materials that can be worked with in a BSL2 setting include:

- Human tissues and fluids
- Hepatitis B and C virus
- HIV
- *Adenovirus*
- *Staphylococcus aureus*
- *Pseudomonas aeruginosa*

Access to these laboratories and animal facilities is limited to persons who have been informed of the hazards. Persons having higher than normal sensitivity to an infectious agent should not be permitted to enter.

In addition to BSL-1/ABSL-1 requirements:

- Laboratory personnel must have specific training in handling pathogenic agents and be supervised by PIs competent in handling infectious agents and associated procedures
- Access to laboratory is restricted when work is being conducted
- Plants or animals not related to the research should not be allowed in the labs or animal facilities
- Use biohazard warning signs
- Implement a medical surveillance program (*when applicable*)
- Use extra caution with sharps. Sharps protective devices (“safety” devices) should be used when working with human material.
- Use Class II BSCs when there is a likelihood of generating aerosols
- Use the appropriate containment equipment for animals
- If splashing is anticipated, use face protection such as goggles, safety glasses and a NIOSH N95 HEPA-filtered respirator, or a face shield
- Wear a NIOSH N95 HEPA-filtered respirator when unable to contain aerosols
- Use protective laboratory clothing such as laboratory coats or gowns
- An eyewash and an autoclave must be available
- Decontaminate animal cages before washing

While BSL/ABSL-2+ is not an official designation, it is indicated on lab door signs around campus. A BSL-2+ designation indicates the EVMS IBC has determined higher level materials can be utilized in BSL-2 spaces with the addition of committee-approved safety procedures and/or equipment. Although

BSL-3 and BSL-4 facilities are not currently available at EVMS, it is important to know and understand the agents and requirements involved in these Biosafety Levels.

Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3)

BSL-3 and ABSL-3 are for work done with indigenous or exotic agents which can be associated with respiratory transmission and which may cause serious and potentially lethal disease in humans. Vaccines and therapies are not usually available for these microorganisms. Other safety measures such as controlled access and special ventilation systems must be implemented. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents and must be supervised by scientists competent in handling infectious agents and associated procedures. Examples of agents that can be worked with in a BSL3 setting are:

- *M. tuberculosis*
- *St. Louis encephalitis*
- *Coxiella burnetii*

In addition to BSL-2 and ABSL-2 requirements:

- All manipulation of infectious materials must be conducted within BSCs, other physical containment devices, or by personnel wearing appropriate PPE.
- Restrict traffic flow
- Anteroom (changing room) is required
- Use disposable and impermeable laboratory clothing
- Decontaminate all waste
- The entrance must have two sets of self-closing doors and have locks in accordance with institutional policy
- The sink must be hands-free or automatically operated and near the exit
- The interior surfaces of the ceilings, walls and floors must be water resistant and sealed
- The windows must be closed and sealed
- The exhaust system must be ducted and create directional air flow in the laboratory from clean to contaminated areas and discharged outside
- If possible, decontamination methods should be available within the laboratory
- Air from Class II biosafety cabinets may be recirculated, provided the cabinet is certified at least every twelve (12) months
- Aerosol producing equipment must exhaust air through HEPA filters
- Protect vacuum lines with liquid disinfectant traps and HEPA filters

Biosafety Level 4 (BSL-4) and Animal Biosafety Level 4 (ABSL-4)

Work done at BSL-4/ABSL-4 corresponds to dangerous and exotic agents that pose a high individual risk of life-threatening disease, aerosol transmission, or related agent with unknown risk of transmission. No vaccines or therapies are available for these agents. Class III BSCs or air-supplied positive pressure suits (full-body) must be used. This facility must be separate or completely isolated from any other facility. Examples of agents that can be worked with in a BSL4 setting include:

- *Ebola Zaire*
- *Sin Nombre virus*
- *Rift Valley Fever*

This biosafety level includes BSL-3/ABSL-3 requirements, plus:

- The laboratory or animal facility must be in separate buildings or an isolated area within a building
- Access to the facility is tightly controlled, with a logbook or other means of documenting date and time of all persons entering and leaving the laboratory must be maintained
- A room for changing into laboratory clothing must be provided
- Shower before exiting the facility
- Decontaminate all materials and waste before removing them from the facility
- Use Class III biological safety cabinets or partial containment equipment in combination with a full-body, air-supplied respirator
- Use special sterilization procedures
- Sterilize everything before removing from the facility, except for biological materials intended for transfer
- Sterilize all laboratory effluents
- The ventilation system must be dedicated, non-recirculating and have HEPA filters
- Use utility services with backflow protected systems
- Entrance doors must be self-closing and self-locking

DECONTAMINATION: DISINFECTION AND STERILIZATION

To prevent laboratory-induced disease and infection, the number of microorganisms in the open laboratory must be reduced. This reduction is achieved by using a number of chemical and physical mechanisms.

Three mechanisms used to reduce the number of microorganisms are heat, chemical and radiation. Heat treatment is used for **sterilization**, or destroying all microorganisms including spores. Chemical and radiation treatments are used for **disinfection**, or they destroy all microorganisms *except* spores. **Decontamination** is a general term, which can mean either sterilization or disinfection.

Wet Heat (Steam)

Autoclaving, or steam sterilization, involves exposing infectious materials to steam at a specified temperature and pressure for a defined period. In general, gravity displacement autoclaves should be operated at 121°C (250°F) at 15 PSI for 90 minutes. The appropriate autoclaving settings vary according to the type and amount of biological materials as well as the physical characteristics (types of containers) of the load.

The large autoclaves were originally installed as core equipment for use by all research laboratory personnel. As such, these autoclaves are considered facility equipment. The locations of the “core” autoclaves are Lewis Hall 2110, Lewis Hall 3003, Lewis Hall 3163, Jones Institute 362, and Lester Hall 447.

Responsibilities

Physical Facilities is responsible for the installation and repair of the building steam pipes to the core autoclaves.

EH&S is responsible for the certification, repair, and maintenance of the core autoclaves. EH&S has established a preventative maintenance contract with an outside vendor to help ensure the safe functioning of the units. EH&S is also responsible for the monthly spore testing of the autoclaves and for the upkeep of the recording paper.

Laboratory Personnel are to complete Autoclave Training, available on the EVMS BioRAFT system (<https://evms.bioraft.com/raft/training/courses>), before utilizing the core autoclaves. Personnel are also responsible for the general preservation of the machines by using them in a clean and timely manner. By emptying the chamber after a cycle or by not leaving material in the autoclave overnight, the autoclaves can be kept efficiently operational and serviceable to all.

Also, laboratory personnel should enter a record into the autoclave’s log book for each use. There is a separate log book for each autoclave, whether it is utilized for sterilization of equipment or for general use. EH&S collects and stores these log records in Lewis Hall 2142.

For additional safety and operational suggestions, personnel can consult the Autoclave Safety Guidelines, posted on the EH&S MyPortal site as well as in the core autoclave rooms.

Accessibility

Core autoclaves, and the equipment rooms they are housed in, are accessible to all trained EVMS staff. As each technician or investigator completes Autoclave Safety, EH&S will give authorization for badge-controlled access to the room. If improper procedures or incidences dictate, access authorization can be rescinded.

Please contact EH&S at (757) 446-5798 if a problem or concern arises with the autoclaves, so that the autoclaves can return to service as quickly as possible.

Spore Testing Procedure

For autoclave validation testing, follow the procedure below.

1. Plug in incubator at least **30 minutes** before beginning testing process
2. Place biological indicator vial horizontal or cap up in the test tray or appropriate package
3. Place tray or package in the area of the drain on the bottom shelf
4. Process load
5. Remove load from autoclave
 - » Always wear appropriate PPE
6. Allow indicator to stand an additional **10 minutes**
 - » Crushing indicator before cooling may cause ampoule to burst
7. Follow manufacturer's instructions on processing the vial
8. Place lid onto incubator and incubate vials for **48 hours**
9. Record results
10. Place used vials in the medical waste container for disposal off-site

Dry Heat

This method may be used for sterilizing hard surfaces such as glassware. Generally sterilization takes place at 160° - 170°C (320° - 338°F) after 2 – 4 hours. Because each load may contain different types and quantities of objects and infectious material, the time for sterilization may vary. Operational checks and sterilization checks of each load or of like loads should be performed regularly. Sterility checks can be done using an appropriate sterility indicator such as *Bacillus stearothermophilus* spore strips.

Radiation

Ultraviolet (UV) radiation can be used to inactivate microorganisms in the air and on surfaces, such as in biosafety cabinets. The wavelength range used for decontamination is known as the germicidal range and is 210 – 310 nm. UV radiation is not a recommended method of decontamination at EVMS.

The NIH does **not** recommend or support the use of UV radiation in laboratories. Although UV is effective against most microbes, it requires an understanding of its abilities and limitations. The 253.7-nm wavelength emitted by the germicidal lamp has limited penetrating power and is primarily effective against unprotected microbes on exposed surfaces or in the air. It does not penetrate soil or dust. The intensity or destructive power decreases by the square of the distance from the lamp. Thus, exposure time is always related to the distance. The intensity of the lamp diminishes over time. This requires periodic monitoring with a UV meter. The intensity of the lamp is drastically affected by the accumulation of dust and dirt on it. The bulbs require frequent maintenance. In addition, there are safety hazards associated

with the use of UV that require PPE or other safety devices to protect users. UV lights in biosafety cabinets require the cabinet be decontaminated prior to performing maintenance on the system.

Chemical

Chemical decontamination can be done with liquids, vapors and gases. Liquid disinfectants are used to decontaminate work surfaces and liquid waste. Vapors and gases are used to disinfect items that are not easily disinfected or cannot be disinfected without damage by other methods. See [Table 2](#) for a summary of liquid chemical disinfectants. Contact EH&S if using other chemical disinfectants.

A 10% sodium hypochlorite (bleach) solution can be used for most disinfection procedures. A 10% bleach solution equates to 1 part bleach in 9 parts water (e.g. 100 mL bleach + 900 mL water = 1L of 10% bleach solution). To allow for maximum effectiveness, allow a contact time of at least **10 minutes**. Bleach solutions should be prepared *weekly* since they quickly lose their effectiveness.

For large area decontamination, EH&S uses the TOMI Steramist system. This system uses ionized hydrogen peroxide to decontaminate for a variety of organisms. Steramist can be used in laboratories, vivarium rooms, clinical spaces, and in BSCs.

Table 2: Chemical Disinfectants Comparison

Disinfectant	Requirements			Inactivates				Application					Other					
	Dilution	Virus with Envelope ^b	Broad Spectrum ^b	Bacteria	Virus with Envelope	Virus without Envelope	Bact. Spores	Work Surfaces	Glass-ware	Large Area Decon	Liquid for Discard	Penetrating Decon	Eff. Shelf Life ^e	Corrosive	Flammable	Skin Irritant	Eye Irritant	Toxic
<i>Phenolic Compounds</i>	1-5%	10	NE	+	+	^c		+	+				+	+		+	+	+
<i>Chlorine Compounds</i>	5000 ppm^a	10	30	+	+	+	+	+	+		+			+		+	+	+
<i>Ethyl Alcohol</i>	70 - 85%	10	NE	+	+	^c		+	+				+		+		+	+
<i>Isopropyl Alcohol</i>	70 - 85%	10	NE	+	+	^c		+	+				+		+		+	+
<i>Iodophor</i>	25 - 1600 ppm	10	30	+	+	+	+	+	+				+	+	+	+	+	+
<i>Gluteraldehyde</i>	2%	10	30	+	+	+	+					^d +	+			+	+	+

NE - not effective

^a Available halogen (Bleach = 1:10 dilution)

^b Contact time (minutes)

^c Variable results depending on the virus

^d Gas may be flammable or explosive if used improperly

^e approx. 1 week, protected from light and air

*Commercial formulations of these disinfectants are generally available. Principal Investigators should ensure that commercial products are registered with the Environmental Protection Agency (EPA) and that their use is in accordance with the manufacturer's recommendations.

EXPOSURE TO BIOLOGICAL AGENTS

All accidents, exposures, and near miss incidences must be reported to both PMA Care 24 Nurse Call Service and EH&S. EH&S recommends the following guidelines in the event of an exposure to an infectious agent or material:

Intact Skin

1. Remove contaminated clothing.
2. Vigorously wash contaminated skin for at least 1 minute with soap and warm water.
3. Report the event to the PMA Care 24 Nurse Call Service as soon as possible.

Damaged Skin or Puncture Wound

1. Remove contaminated clothing.
2. Vigorously wash contaminated skin for at least 5 minutes with soap and warm water.
3. Report the event to PMA Care 24 Nurse Call Service as soon as possible.

Eye Exposure

1. Immediately flush eyes with water for 15 minutes, preferably using an eyewash.
2. Report the event to PMA Care 24 Nurse Call Service as soon as possible.
3. For after hours, call 911 and seek assistance from Sentara Norfolk General Hospital's Emergency Department.

Ingestion or Inhalation

1. Report the event to PMA Care 24 Nurse Call Service as soon as possible. For after hours, call 911 and seek assistance from Sentara Norfolk General Hospital's Emergency Department.
2. Do not induce vomiting unless advised to do so by a health care provider.

Laboratory Acquired Infections

In the event of a possible laboratory-related illness, consultation between Occupational Health, EH&S, the employee and the employee's supervisor is required for proper medical management and recordkeeping. The following procedures should be followed if an EVMS employee suspects an illness is related to infectious agents in their work area.

1. Treat any exposure site(s) immediately.
2. Contact supervisor and PMA Care 24 Nurse Call Service.
» PMA Care 24 phone: 1-800-411-0153

Reporting Recombinant DNA (rDNA) and Synthetic Nucleic Acid Exposures

In accordance with the *NIH Guidelines*, the following applies to research involving recombinant DNA or synthetic nucleic acids.

Definitions

rDNA and synthetic nucleic acids are defined as:

1. Molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acid

2. 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
3. Molecules that result from the replication of those described in 1 or 2 above.

An “exposure” is any spill or accident involving recombinant or synthetic nucleic acid molecule research that leads to personal injury or illness or to a breach of containment. These kinds of events might include skin punctures with needles containing recombinant or synthetic nucleic acid molecules, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant or synthetic materials occurring outside of a biosafety cabinet. Failure to adhere to the containment and biosafety practices articulated in the NIH Guidelines must also be reported to NIH OSP.

Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated generally do not need to be reported. NIH OSP should be consulted if the IBC investigator, or other institutional staff are uncertain whether the nature or severity of the incident warrants reporting; NIH OSP can assist in making this determination.

Procedure

All potential exposures (accidents, injuries, illnesses, near-misses), *regardless of involving rDNA*, **must be** reported to PMA Care 24 Nurse Call Service as soon as possible. After regular business hours (e.g. evenings, nights, weekends, holidays), exposures must be reported by calling the **PMA Care 24 Nurse Call Service** 1-800-411-0153.

Appendix G of the *NIH Guidelines* specifies certain types of accidents that must be reported on a more expedited basis. Specifically, Appendix G-II-B-2-k requires that spills and accidents in BSL-2 laboratories resulting in an overt exposure must be immediately reported to the OSP (as well as the IBC). In addition, Appendices G-II-C-2-q and G-II-D-2-k require that spills or accidents occurring in high containment (BSL-3 or BSL-4) laboratories resulting in an overt or potential exposure must be immediately reported to OSP (as well as the IBC and BSO).

The *NIH Guidelines* require that “any significant problems, violations, or any significant research-related accidents and illnesses” be reported to OSP **within 30 days**. Reports of incidents can be emailed to NIHGuidelines@od.nih.gov.

BIOHAZARDOUS WASTE

EH&S has prepared these guidelines to assist laboratory personnel in safely and legally managing biohazardous waste. Federal, state and local laws and regulations govern how biohazardous waste must be managed. These guidelines apply to *anyone* who generates biohazardous waste.

What is biohazardous waste?

<i>Biohazardous Waste</i>	Solid waste (including animal carcasses) contaminated with infectious agents known to cause human illness and not contaminated with radioactive materials or hazardous chemicals.
<i>Biohazardous Sharps Waste</i>	Devices capable of cutting or piercing that are contaminated with biohazardous material. Includes: <ul style="list-style-type: none"> • Contaminated hypodermic needles • Scalpels • Razor blades • Contaminated pipette tips and micropipette tips • Broken microscope slides and Pasteur pipettes

What is NOT biohazardous waste?

<i>Radioactive Waste</i>	Or mixtures that contain radioactive components
<i>Chemical Waste</i>	Or mixtures of chemical and biohazardous waste
<i>Bio Waste</i>	Not biohazardous, chemical or radioactive waste, but has the appearance of laboratory waste. Examples include plants, bacteria and viruses used in food production.
<i>Broken Glass</i>	Must not be contaminated with biohazardous, chemical, or radioactive wastes.

Segregating Waste

Segregating wastes at the point of generation is one of the most important steps in properly managing lab waste. Follow these rules to ensure compliance:

- Whenever possible, *do not* combine biohazardous waste with chemical or radioactive waste.
- Separate sharps from other waste by placing them in a puncture-resistant container.
- If different types of wastes are mixed, manage in the following manner (in descending order):
Radioactive → Chemical → Biohazardous → General Trash
- If safe to do so, you may decontaminate the biohazardous component and manage the other waste(s) as appropriate.

Containing Biohazardous Waste

As with all laboratory waste, biohazardous waste must be placed in a properly labeled container as soon as it is generated. Be mindful that the waste generated will be handled by other individuals, such as EH&S staff and medical waste contractors. Follow these steps to safely and legally contain biohazardous wastes.

Sharps Waste

- Place sharps waste in puncture-resistant containers labeled “Sharps” or in commercial sharps containers.
- Keep sharps containers upright and next to the work area (i.e. in the biosafety cabinet while working).
- Do not overfill sharps containers. *Tape sharps containers closed when they are 2/3 full.*

Biohazardous Waste (“Red Bag Waste”)

Place solid biohazardous waste in bags that meet the following requirements:

- Red or clear (with imprinted biohazard warning)
- Imprinted with a biohazard symbol and the words “Biohazardous Waste”
- Mil thickness of at least 1.5 mil
- Imprinted with UN number on the bags, on the box, or in the invoice
- Contained at all times in a secondary container

Secondary containers must:

- Have a biohazard bag lining the container
- Be rigid, leak-proof, puncture resistant
- Have a tight fitting lid
- Be labeled with a biohazard symbol on at least 2 sides
- Keep secondary containers closed unless waste is being added
- Do not use cloth hampers or wire racks as secondary container

Laboratories generating sufficient amounts of biohazardous waste are supplied with red bags and secondary containers once an account has been established with the current medical waste disposal contractor. It is up to the PI to establish an account with the disposal company; contact EVMS Materials Management (757-446-5224) for contract and purchasing information. If the laboratory does not generate biohazardous waste on a regular basis, consult with EH&S to determine whether a laboratory account is prudent.

Biohazardous Waste Pick-up

Biohazardous waste is picked up in two ways.

1. If the laboratory has an account with a medical waste disposal vendor:
 - Contact disposal contractor to schedule a pick-up when the secondary container is 2/3 full
 - Tie the open end of the red bag in a knot, then tape the top of the secondary container closed
2. If the laboratory does not have an account with the disposal company:
 - If the laboratory generates sufficient amounts of biohazardous waste (as determined by EH&S), the laboratory will be instructed to obtain an account with the disposal contractor and set up a pick-up.
 - If the laboratory does not generate sufficient amounts of biohazardous waste (as determined by EH&S), contact EH&S for a biohazardous waste pick-up.

Decontaminating Biohazardous Waste Containers

The law requires all secondary containers be kept clean and in good repair. These include laboratory and waste contractor supplied containers at pick-up locations.

If the laboratory utilizes a temporary, re-usable secondary container, this re-usable container must be cleaned before a new bag can be placed inside. To clean the re-usable container:

- Ensure container is free from encrusted material
- Sanitize container by rinsing with or immersing in a one-percent (1%) solution of household bleach or a quaternary ammonium solution (400 ppm active agent) for 10 minutes.

EMERGENCY PROCEDURES

In the event of a spill of biological material, the individual(s) who caused the spill is responsible for its cleanup. Biohazardous and biohazardous waste spills must be cleaned immediately. Any spilled biohazardous waste and all associated contaminated cleanup debris must be handled as biohazardous waste.

To minimize the consequences of any biological materials spill, work should be conducted on plastic-backed liner to absorb spilled material. A standard biological spill kit should also be on hand in case of a spill.

Spill Kits

A standard biological spill kit should include:

- Chlorine bleach (10%) or some other disinfectant
- Package or roll of paper towels
- Red biohazard bags
- Gloves, preferably nitrile
- Forceps or tongs for picking up broken glass

Spills Inside Biological Safety Cabinets

1. LEAVE BIOLOGICAL SAFETY CABINET TURNED ON!
2. While wearing gloves and lab coat, lay down paper towels over entire spill area.
3. Spray 10% bleach solution on top of paper towels, going from the outer edge of the spill area to the center.
4. Let sit for at least 10 minutes.
5. Spray or wipe cabinet walls, work surfaces and equipment with bleach solution. If necessary, flood drain pans and catch basins below work surface with bleach solution and let stand 10 minutes.
6. Remove paper towels and discard into biohazard container. Pick up any associated broken glass and place in sharps container. Drain catch basin into a container.
7. Re-wipe spill area (including exhaust grill and tray) with water, to prevent pitting. Discard, along with gloves, into biohazard container.
8. Wash hands!

Spills Outside of Biological Safety Cabinets

Small Spills (< 50mL)

1. Wearing gloves and lab coat, cover the spill with paper towels and gently apply bleach solution on top of paper towels, going from the outer edge of the spill area to the center.
2. Let stand at least 10 minutes.
3. Place paper towels in biohazard container. Place any broken glass in sharps container.
4. Re-wipe the spill area with bleach solution or disinfectant. If inside a centrifuge, use bleach solution to disinfect cups and walls. Discard paper towels, along with gloves, into biohazard container.
5. Wash hands!

Large Spills (≥ 50mL)

1. Leave room immediately and close room door.
2. Warn others to stay out of spill area to prevent spread of contamination.
3. Remove any contaminated clothing and put into biohazard bag for autoclaving later. Scrubs should be available to replace contaminated clothing.
4. Wash hands and exposed skin; inform supervisor about the spill.
5. Put on PPE (gloves, lab coat, shoe covers, etc) and assemble clean-up materials.
6. Wait *30 minutes* before re-entering the contaminated area to allow dissipation of aerosols.

7. Cover spill area with paper towels and gently apply bleach solution on top, going from outer edge of the spill area to the center.
8. Let stand 10 minutes.
9. Collect all treated material and discard into biohazard container. Pick up any broken glass with forceps and place into sharps container.
10. Re-wipe the spill area with bleach solution or disinfectant.
11. Wash hands!

Emergency Freezers

EH&S is dedicated to assisting EVMS personnel in the safety and productivity of their work. As part of this endeavor, EH&S maintains and is responsible for several Emergency Freezers.

The Emergency Freezers are utilized as *temporary* cold storage equipment in cases of an individual or laboratory's emergency need. Complete details for Emergency Freezer usage can be found in the Emergency Freezer Procedures, which have been copied into the Appendices of this document.

Please follow the [Emergency Freezer Procedures](#) for access to the -80°C freezers or liquid nitrogen storage:

- During normal business hours, contact EH&S:
 - 757-446-5798
 - ehs@evms.edu
- Outside of regular business hours, call the EH&S Freezer Pager at: **757-415-0014**.
 - When you hear the beep, enter your contact phone number followed by #. Then you may hang up.
 - EH&S will return your page in order to coordinate opening the Emergency Freezer(s).
 - If you decide to arrive on-campus, contact EVMS Police and Public Safety at 757-446-5199, so they can assist with your parking and access needs.

PACKAGING & SHIPPING INFECTIOUS MATERIAL

Packaging and shipping biological and infectious materials are regulated by government agencies and business organizations. The two main entities involved in infectious substances shipping are the International Air Transport Association ([IATA](#)) and the US Department of Transportation ([DOT](#)). Infectious materials and other dangerous goods must always be transported according to the appropriate regulations. ***Before shipping any infectious materials, you must consult with EH&S and complete Shipping Biological Materials training on BioRAFT.***

The following definitions and guidelines comply with *49 CFR 171-180* and IATA's *Dangerous Goods Regulations*.

Definitions

- **Infectious substances** are defined as viable microorganisms, or their toxin, which causes or may cause disease in humans or animals and includes those agents listed in 42 CFR 72.3 and any other agent that causes or may cause severe, disabling or fatal disease. Infectious substance and **Etiologic Agent** are synonymous.
- **Patient specimens** are any human or animal material including, but not limited to, excreta, blood, blood components, tissue and tissue fluids, being shipped for purposes of diagnosis.
- **Biological Products** are products derived from living organisms, which are manufactured and distributed in accordance with the requirements of governmental authorities.
- **Regulated Medical Waste** is waste or reusable material that contains an infectious substance and is generated in the diagnosis, treatment, research or immunization of humans or animals, research pertaining to diagnosis, or treatment or immunization or production of biological products.

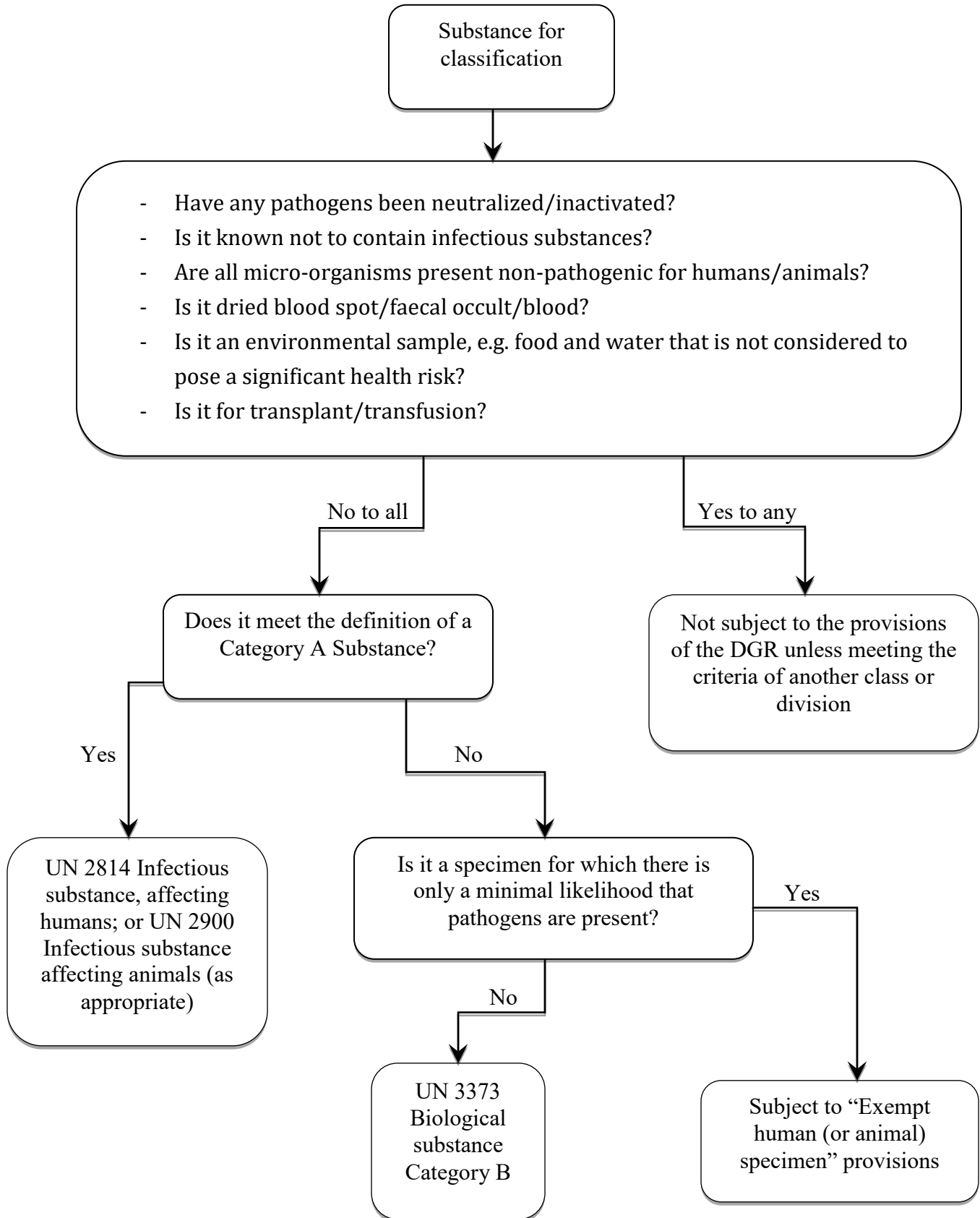
Classification

For the purposes of shipping, biological materials fit into one or more of the following categories:

- **UN2814 or UN2900, Category A infectious substances** – includes agents listed on [IATA Table 3.6.D](#).
- **UN3373, Category B infectious substances** – includes diagnostic specimens and infectious materials not included in Category A.
- **Exempt Human (Animal) Specimen** – patient specimens that have a “minimal likelihood” of containing pathogens.
- **Genetically modified organisms and microorganisms** – organisms and microorganisms whose genetic material has been purposely altered.
- **Biological products** – materials which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes final packaging or distribution, and use for personal health care by medical professionals or individuals.

IATA Infectious Shipping Guide

Classification Flowchart



IATA Table 3.6.D

Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicated
(3.6.2.2.2.1)

UN Number and Proper Shipping Name	Micro-organism
UN 2814 Infectious substance affecting humans	<p><i>Bacillus anthracis</i> (cultures only)</p> <p><i>Brucella abortus</i> (cultures only)</p> <p><i>Brucella melitensis</i> (cultures only)</p> <p><i>Brucella suis</i> (cultures only)</p> <p><i>Burkholderia mallei</i>-<i>Pseudomonas mallei</i>-Glanders (cultures only)</p> <p><i>Burkholderia pseudomallei</i>-<i>Pseudomonas pseudomallei</i> (cultures only)</p> <p><i>Chlamydia psittaci</i>-avian strains (cultures only)</p> <p><i>Clostridium botulinum</i> (cultures only)</p> <p><i>Coccidioides immitis</i> (cultures only)</p> <p><i>Coxiella burnetii</i> (cultures only)</p> <p>Crimean-Congo hemorrhagic fever virus</p> <p>Dengue virus (cultures only)</p> <p>Eastern equine encephalitis virus (cultures only)</p> <p><i>Escherichia coli</i>, verotoxigenic (cultures only)</p> <p>Ebola virus</p> <p>Flexal virus</p> <p><i>Francisella tularensis</i> (cultures only)</p> <p>Guanarito virus</p> <p>Hantaan virus</p> <p>Hantavirus causing hemorrhagic fever with renal syndrome</p> <p>Hendra virus</p> <p>Hepatitis B virus (cultures only)</p> <p>Herpes B virus (cultures only)</p> <p>Human immunodeficiency virus (cultures only)</p> <p>Highly pathogenic avian influenza virus (cultures only)</p> <p>Japanese Encephalitis virus (cultures only)</p> <p>Junin virus</p> <p>Kyasanur Forest disease virus</p> <p>Lassa virus</p> <p>Machupo virus</p> <p>Marburg virus</p> <p>Monkeypox virus</p> <p><i>Mycobacterium tuberculosis</i> (cultures only)</p> <p>Nipah virus</p> <p>Omsk hemorrhagic fever virus</p> <p><i>Poliovirus</i> (cultures only)</p> <p>Rabies virus (cultures only)</p>

UN Number and Proper Shipping Name	Micro-organism
	<p><i>Rickettsia prowazekii</i> (cultures only) <i>Rickettsia rickettsia</i> (cultures only) Rift Valley fever (cultures only) <i>Russian spring-summer encephalitis virus</i> (cultures only) Sabia virus <i>Shigella dysenteriae type 1</i> (cultures only) <i>Tick-borne encephalitis virus</i> (cultures only) Variola virus Venezuelan equine encephalitis virus (cultures only) <i>West Nile virus</i> (cultures only) <i>Yellow fever virus</i> (cultures only) <i>Yersinia pestis</i> (cultures only)</p>
UN 2900 Infectious substances affecting animals	<p>African swine fever virus (cultures only) Avian paramyxovirus Type 1-Velogenic Newcastle disease virus (cultures only) Classical swine fever virus (cultures only) Foot and mouth disease virus (cultures only) Lumpy skin disease virus (cultures only) <i>Mycoplasma mycoides</i>-Contagious bovine pleuropneumonia (cultures only) Peste des petits ruminants virus (cultures only) Rinderpest virus (cultures only) Sheep-pox virus (cultures only) Goatpox virus (cultures only) Swine vesicular disease virus (cultures only) Vesicular stomatitis virus (cultures only)</p>

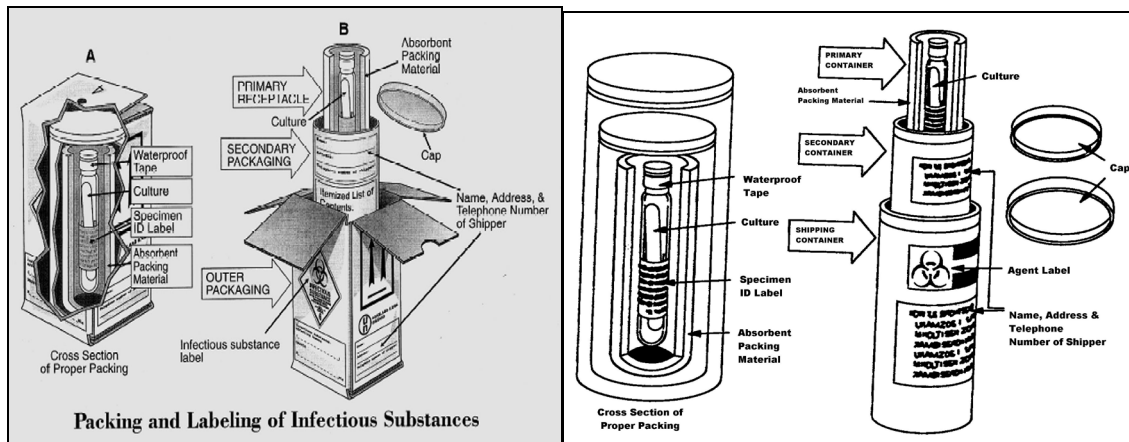
Packaging

All biological materials must be packaged to withstand leakage of contents, shocks, pressure changes and other conditions incident to normal handling and transportation. Contents should not leak to the outside of the shipping container, even if leakage of the primary container occurs.

Specific packaging requirements are determined by which shipping category the biological material(s) fall in to. Generally, a triple packaging system is employed with

- A watertight **primary receptacle**
- A watertight **secondary receptacle**
- **Absorbent material** in between primary and secondary packagings (enough to absorb the entire contents of the primary receptacle)
- A rigid **outer packaging** of adequate strength for its use

Below are two diagrams of the triple packaging system.



Category A Packaging Sample

Category B Packaging Sample

Packaging Volume < 50mL

- Place biological material in a securely closed, water tight primary container (test tube, vial, etc.).
- Wrap primary container in absorbent material (enough to absorb the entire amount of biological material).
- Enclose the primary container and absorbent in a secondary, durable, watertight container. (Several primary containers may be enclosed in a single secondary container as long as the total volume of material does not exceed 50mL.
- Enclose the set of primary and secondary receptacles in an outer shipping container constructed of fiberboard, cardboard, wood or other material of equal strength.
- If packaging with dry ice, see *Packaging with Dry Ice* section below.

Packaging Volume \geq 50mL

- follow the requirements for lesser volumes outlined above
- Place shock absorbent material at top, bottom and sides between the secondary and outer shipping containers. (This material should at least equal the amount of absorbent materials placed between the primary and secondary container).
- Ensure single primary receptacles contain no more than 1L of material; however, two or more primary receptacles (combined volumes not exceeding 1L) may be placed in a single secondary container. The maximum amount of etiologic agent that may be enclosed within a single outer shipping container must not exceed 4L.

Packaging with Dry Ice

- Place dry ice between the secondary and outside containers.
- Place shock absorbent material to prevent the secondary container from becoming loose inside the outer container as the dry ice sublimates.
- Outer receptacle must be designed and constructed to permit the release of carbon dioxide gas and to prevent a build-up of pressure that could rupture the packaging.

Marking and Labeling

Labeling for all packages must include on the outside container:

- Sender and recipient's full name and address
- Proper shipping name and UN ID number of the shipped material
- Proper labels (dependent on classification of shipped materials)
- Class 9 label (if using dry ice)

More markings and labeling may have to be employed for packages, depending on the classification of the material being shipped, such as 24-hour emergency numbers. For assistance, consult the Shipping Biological Materials training presentation or with EH&S.

SHIPPING OPTIONS AND TRANSPORTATION

Registered Mail (or Equivalent)

Per 42 CFR 72.3(f), the following etiologic agents must be shipped using registered mail or an equivalent system, which provides the sender with immediate notification of receipt:

- *Coccidioides immitis*
- Ebola virus
- *Francisella* (Pasteurella) tularensis
- Hemorrhagic fever agents including, but not limited to, Crimean hemorrhagic fever (Congo), Junin, Machupo viruses and Korean hemorrhagic fever viruses
- Herpesvirus simiae (B virus)
- *Histoplasma capsulatum*
- Lassa virus
- Marburg virus
- *Pseudomonas mallei*
- *Pseudomonas pseudomallei*
- Tick-borne encephalitis virus complex including, but not limited to, Russian spring-summer encephalitis, Kyasanur forest disease, Omsk Hemorrhagic fever and Central European encephalitis viruses, Variola minor and Variola major
- Variola major, Variola minor and Whitepox viruses
- *Yersinia* (*Pateurella*) *pestis*

Commercial Carriers

For shipments of biological materials, internationally or domestically, follow the International Air Transport Association (IATA) *Dangerous Goods Regulations*. Within the IATA regulations are the specific carrier's (FedEx, UPS, DHL, etc.) requirements. (Receipt of shipment notice is not required since the shipment is traceable through specific carrier). Follow the specific carrier's requirements in the IATA regulations and contact the carrier's dangerous goods agent prior to shipment for any additional packaging and labeling requirements.

Damaged Packages

Do not accept any leaking or damaged packages. When evidence of leakage or any other damage to packages bearing an Infectious Agents/Biomedical Material label is discovered, the carrier must promptly isolate the package and notify the Director for the Centers for Disease Control and Prevention (CDC) at

1600 Clifton Road NE
Atlanta GA 30333
Telephone: (404) 633-5313

Notice of Delivery Failure

In the event that a package sent by EVMS is not received by the recipient within 5 days following the anticipated delivery of the package, the sender must notify

Biosafety Branch - Centers for Disease Control and Prevention (CDC)
Telephone: (404) 639-7233

Importation/Exportation of Etiologic Agents

Importation of infectious agents, etiologic agents and vectors that may contain these agents is governed by federal regulation. In general, an importation permit is required for any infectious agent known to cause disease to man. This includes, but is not limited to, bacteria, viruses, rickettsia, parasites, yeasts and molds. In some instances, an agent that is suspected of causing human disease also requires a permit.

Any import coming within the above provisions are controlled by the U.S. Public Health Service and will not be released from custody prior to receipt by the District Director of U.S. Customs of a permit issued by the Director of the CDC (42 CFR 71.54). "Etiologic Agent Importation Permits" are issued by the CDC only to the importer, who must be located in the United States.

To obtain an Etiologic Agent Importation Permit, an application must be submitted to the CDC. Applications are found at <http://www.cdc.gov/od/eaipp/importApplication/> or by contacting the CDC directly. Applications can be submitted through both mail and fax. The contact information for CDC Import Permit Program is:

Centers for Disease Control and Prevention
1600 Clifton Road NE
Mailstop A-46
Atlanta GA 30333
Phone: 404-718-2077
Fax: 404-718-2093

PIs transferring or receiving Select Agents must be registered with the CDC and each transfer of a Select Agent must be documented. More information on the CDC's Select Agent Program can be found at <http://www.selectagents.gov/index.html>.

Other Permits

U.S Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) permits are required for the importation or domestic shipping of infectious agents of livestock, poultry and other animal diseases and any materials that might contain these agents. Information for APHIS permits is found at

Animals: http://www.aphis.usda.gov/import_export/animals/animal_import/animal_imports.shtml

Plants: http://www.aphis.usda.gov/import_export/plants/plant_imports/index.shtml

Export of infectious materials may require license from the Department of Commerce (DoC). Exporters of a wide variety of etiologic agents of human, plant and animal diseases, including genetic material and products that might be used for culture of large amounts of agents will require an export license. Information for exporting may be obtained from the DoC Bureau of Industry and Security at <http://www.bis.doc.gov/>.

Abbreviations

APHIS	Animal and Plant Health Inspection Service
BBP	Bloodborne Pathogens program
BMBL	<i>Biosafety in Microbiological and Biomedical Laboratories</i> , 5 th edition (CDC/NIH)
BSC	Biological Safety Cabinet
BSL	Biological Safety Level
BSO	Biological Safety Officer
CDC	Centers for Disease Control and Prevention
DEQ	Virginia Department of Environmental Quality
DHHS	Department of Health and Human Services
DoC	U.S. Department of Commerce
EH&S	Environmental Health and Safety Department
EVMS	Eastern Virginia Medical School
IBC	Institutional Biosafety Committee
IBCA	Institutional Biosafety Committee Administrator
IRB	Institutional Review Board
NIH	National Institute of Health
OPIM	Other potentially infectious materials
OSHA	Occupational Safety and Health Administration
PI	Principal Investigator
PPE	Personal Protective Equipment
rDNA	Recombinant DNA
USDA	United States Department of Agriculture
USPHS	United States Public Health Service