Laboratory Safety Manual

Section 2
Biological Safety

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INTRODUCTION

This chapter provides an overview of biosafety practices and procedures for the safe handling of known biohazards, reasonably anticipated biohazards, and potentially infectious materials. This chapter focuses on Biosafety Levels 1 and 2, as most laboratories handling biological materials at Duke University fall into those designations. A separate manual is available for Biosafety Level 3 laboratories. No work at Biosafety Level 4 is conducted at Duke University.

Biological materials are defined as materials derived from, or produced by, biological organisms such as plants, animals, bacteria, fungi, and other life forms. Under this broad definition, certain biological materials present risks to the health of humans, animals, plants, or products from plants and animals. If not handled appropriately, laboratory workers can infect themselves and transmit to the outside community and environment. These incidents have occurred in the past at various laboratories throughout the world and lessons can be learned from them so mitigations can be put into place to prevent incidents like these from occurring again. The following pages will inform you of how to evaluate your work for biohazardous risks, common mitigation measures, and how to document the process for evaluation by other lab members, institutional groups, and, if needed, outside entities. Questions regarding work with biohazardous material(s) can be discussed with the Occupational and Environmental Safety Office (OESO) Biological Safety Division (biosafety@duke.edu; 919-684-8822).

RISKS AND CONSEQUENCES

All biological materials and procedures have inherent dangers, which we call risk. Risk is the outcome that could occur, so we might say that the risk of a biological material is a disease. The consequence of that risk could be as low as nothing happening, or could be as high as a chronic disease, severe illness, or even death.

ROUTES OF EXPOSURE

A route of exposure is defined as the way people, or other living organisms, come into contact with a hazardous substance. Here, the hazardous substances referred to are biological materials capable of infecting or being toxic to humans. There are four main routes of exposure:

Percutaneous injuries (injection)

Percutaneous injuries can result from needlesticks, cuts, or abrasions from contaminated items. These exposures are particularly serious because of the potential for immediate entry of the biohazardous material into the bloodstream.

Inhalation

Many common laboratory procedures can cause the formation of droplets or aerosols of infectious material and can enter the individual's body through the respiratory pathway. Droplet or aerosol generators are not limited to centrifuges. Some of these procedures include the use of vortexes, pipettes, flipping open Eppendorf tubes, blenders and sonicators.

Mucous membrane contact

Mucous membrane includes the surfaces on your mouth, eyes, and nose. Most infections, whether community or occupationally acquired, occur through exposure of infectious materials to the mucous membrane. Mucous membrane exposures can result from splashes to the eyes, nose, or mouth, or by inadvertent inoculation via contaminated hands.

Ingestion

Accidental ingestion of biohazardous materials can result from improper personal hygiene in the laboratory. It is important to wash hands after removing gloves and before leaving the laboratory.

CLASSIFICATION OF AGENTS ACCORDING TO RISK

Biological materials are assigned to a Risk Group based on several factors, including the risk they pose to human health and the environment, the severity of disease caused by the agent, the availability of vaccines, treatment, or prophylaxis, routes of exposure, how easily or quickly the biological material can disseminate through a population, and the consequences of an infection. There are 4 risk groups, in which Risk Group 1 biological materials are the least risky, with low individual and community risk, and Risk Group 4 biological materials are the most risky, with high individual and community risk. The partial list below highlights some biological materials and their risk group.

Although there are 4 Risk Groups and 4 Biosafety Levels (BSL), it is not a one-to-one relationship. Choosing a biosafety level will be explored in more detail later in the manual. Ultimately, the Occupational and Environmental Safety Office (OESO), Biological Safety Division will make the final BSL assignment. If further assistance is needed in interpreting BSL requirements, contact the OESO-Biological Safety Division at 919-684-8822. There are no Biosafety Level 4 labs at Duke.

Risk Group (RG)	**Description**	**Examples**
Risk Group 1 (RG1)	Agents that are not associated with disease in healthy adult humans	*Sacchromyces cerevisae* Non-pathogenic *E. coli* *Bacillus subtilis* Canine hepatitis virus
Risk Group 2 (RG2)	Agents that are associated with human disease which is rarely serious or for which preventive and therapeutic interventions are often available	*Salmonella typhimurium* *Pseudomonas aeruginosa* Pathogenic *E. coli* Respiratory syncytial virus (RSV)
Risk Group 3 (RG3)	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)	*Yersinia pestis* *Francisella tularensis* Hantavirus West Nile virus
Risk Group 4 (RG4)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic intervention are not usually available (high individual risk and high community risk)	Ebolavirus Marburg virus Hendra virus

STANDARD LABORATORY PRACTICE AND TECHNIQUES

Biosafety Levels

Biosafety levels (BSLs) consist of combinations of laboratory practices and techniques, safety equipment including personal protective equipment (PPE), and laboratory facilities with engineering controls. Each combination is specifically appropriate for the operations performed, the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity. The levels are summarized in a table at the end of the descriptions, and more detailed information can be found in the latest edition of the *Biosafety in the Microbiological and Biomedical Laboratories*, published by the National Institutes of Health (NIH)/Center for Disease Control and Prevention (CDC) (https://www.cdc.gov/labs/BMBL.html).

BSL-1 is suitable for work involving well-characterized agents not known to consistently cause disease in immuno*competent* adult humans, and present minimal potential hazard to laboratory personnel and the environment. All bacterial, parasitic, fungal, and viral agents which have been assessed for risk but do not belong to a higher risk group can be safely handled at BSL-1. Be aware that many agents not ordinarily associated with disease are opportunistic pathogens and may cause infection in young children, the elderly, pregnant, and immunocompromised individuals.

BSL-2 builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that: 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) **all procedures in which infectious aerosols or splashes may be created are conducted in a biosafety cabinet (BSC) or other physical containment equipment.**

BSL-3 is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal diseases through the inhalation route of exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agent and must be supervised by scientists competent in handling infectious agents and associated procedures. All procedures involving the manipulation of infectious materials must be conducted within a BSC or other physical containment devices. A BSL-3 laboratory has special engineering and facility design features that aid in the biocontainment of the agent.

Duke University does not work with RG4 agents and does not operate a BSL-4 laboratory.

All four BSLs are summarized in the table below for proper handling of biohazardous materials.

BSL	*Practices*	*Safety Equipment (Primary Barriers)*	*Facilities (Secondary Barriers)*
1	Standard microbiological practices	None required	Open bench top, sink required
2	BSL-1 practices plus: • limited access • biohazard warning signs • sharps precautions • biosafety manual defining waste decontamination or medical surveillance policies	Primary barriers: Class II biosafety cabinets or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPE: laboratory coats, gloves, face protection as needed	BSL-1 plus: • non-fabric chairs and other furniture easily cleanable • autoclave available • eyewash readily available
3	BSL-2 practices plus: • controlled access • decontamination of all wastes • decontamination of lab clothing before laundering Inactivation of material before removal from laboratory • Shower-out procedures when working with some agents • post-exposure baseline serum	Primary barriers: Class II biosafety cabinets or other physical containment devices used for all manipulations of agents; PPE: solid front gowns or coveralls, double gloves, shoe covers and respiratory protection as needed	BSL-2 plus: • physical separation from access corridors • hands-free handwashing-sink • self-closing double door access • exhaust air not recirculated • negative airflow into laboratory • eyewash readily available in lab
4	BSL-3 practices plus: • clothing change before entering • shower on exit • all material decontaminated on exit from facility	Primary barriers: All procedures conducted in Class III biosafety cabinets or Class II biosafety cabinets in combination with full-body, air supplied positive pressure suit	BSL-3 plus: • separate building or isolated zone • dedicated supply/exhaust, vacuum and decon system **NOTE: There are no BSL-4 labs at Duke University**

Summarized from Biosafety in Microbiological and Biomedical Laboratories, 6th ed., CDC/ NIH, 2020: (https://www.cdc.gov/labs/BMBL.html)

Biohazard Warning Signage

A sign incorporating the universal biohazard symbol with the word 'Biohazard', as shown in the image below, **must be posted** at the entrance to the laboratory when infectious agents are present. Equipment used for infectious biological agents (Risk Group 2 or 3) must also be labeled with the biohazard symbol, including waste containers, incubators, centrifuges, and biosafety cabinets. The label or sign must be

fluorescent orange, orange-red, or red, with the symbol and lettering in a contrasting color. The requirements for the door sign at each biosafety levels are described below.

BIOHAZARD

For BSL-1 the door sign may include the name of the agent(s) in use, and the name and phone number of the laboratory supervisor or other responsible personnel.

For BSL-2 and -3 the posted information on the door sign must include the name of the agent(s), laboratory's biosafety level, supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory.

Personal Protective Equipment

Once a biological hazard has been identified, the supervisor and employee must agree on the appropriate personal protective equipment (PPE) to be worn while working with the biological material. Keep in mind that PPE must be treated as the last resort of protection, ensuring that engineering controls, work practices and appropriate administrative controls are in place. PPE may include, but is not limited to gloves, face protection, lab coats and gowns, respirators, and shoe-covers/booties. Supervisory personnel are responsible for the initial demonstration and periodic oversight of proper use of the PPE for staff under their supervision. Appropriate PPE should be donned before handling potentially hazardous biological materials and removed immediately and replaced if gross contamination of the PPE occurs. PPE is removed before exiting the laboratory and is not worn in non-lab areas.

Eye and Face Protection

Appropriate face protection is worn if work is performed outside a biological safety cabinet when splash or splatter of infectious substances or other biological materials is anticipated. Such equipment would include but is not limited to goggles, side-shielded safety glasses and chin-length face shields.

Gloves

Gloves are worn when handling biohazardous materials. Disposable gloves can provide an adequate barrier between the lab employee and most biohazardous materials. Double gloves and/or cut-resistant

gloves should be considered when handling sharp items and biohazardous materials. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Gloves should not be worn when touching door handles in common areas.

Lab Coats and Gowns

Long-sleeved lab coats or gowns must be worn to protect skin and street clothes from contamination. In circumstances when splash or splatter is anticipated, the garment must be resistant to liquid penetration. A cuffed lab coat or gown (or lab coat and cuffed disposable sleeve covers) must be worn when working with potentially infectious materials. A solid front gown or coveralls must be worn when working at BSL-3. Facility-specific scrubs may be required in some instances.

Reusable lab coats should be laundered on-site or by a laundering service set up by the employer, at no cost to the employee. Personnel must never launder lab coats or gowns at home.

Soiled clothing being collected for laundering should be placed in a leak-resistant container (e.g., biohazard bag). If minor contamination is present, laboratory clothing should be decontaminated (i.e. disinfecting, neutralizing, autoclaving) in the laboratory before being sent to the launderer. If grossly contaminated, disposing with laboratory waste may be the best option. Soiled laundry should only be handled by individuals wearing appropriate PPE and should never be taken home. Discuss options for outside laundry service with your departmental business manager.

Respirators

Respirators, when selected appropriately for the respective hazard and worn correctly, can provide protection against hazardous material that affect the individual through the respiratory route. When engineering controls (i.e., BSCs) are not available to provide adequate protection against aerosolized agents or when mandated by federal regulations, respirators shall be worn. Duke's Respiratory Protection Program requires that employees be medically cleared, fit-tested if using a filtering respirator (N95), and trained on proper usage and care of the respirator before being allowed to wear one.

Disposable Shoe-covers/Booties

When significant splash and splatter are anticipated, shoe-covers/booties should be considered based on risk assessment. Prior to exiting the laboratory, these must be removed and disposed of properly.

Handwashing

Hands should be washed as soon as possible when they come in contact with potentially infectious materials. Hands should also be washed as soon as feasible after gloves are removed and before exiting the laboratory. Hands must be washed vigorously for 20 full seconds with mild soap.

Eating, Drinking, Smoking, Applying Cosmetics and Handling Contact Lenses

Eating, drinking, smoking, applying cosmetics, applying chapstick, and handling contact lenses is prohibited in work areas in which potentially infectious materials are being manipulated. Food and drink must not be stored in refrigerators in which laboratory materials are kept.

Housekeeping

Good housekeeping in laboratories reduces the risk of accidents occurring. Work benches should be kept clutter-free and aisles should always be free of trip hazards. Benches and BSCs should be wiped down with an approved disinfectant at least once a day and immediately after a spill of potentially infectious materials.

Pipetting

Pipetting infectious agents can lead to personnel exposures by inhalation, contact, or ingestion if not performed properly. The following are a few safety precautions to be followed when pipetting in the laboratory:

1) Never mouth pipette; pipetting aids should always be used
2) Pipette contents should be allowed to run down the wall of the container, making sure not to release the contents from a height
3) Place absorbent paper on benchtops to absorb any accidental dripping of infectious materials from pipette tips
4) Place disposable pipettes into pipette disposal boxes which have been lined with an autoclave bag, and then steam sterilize/autoclave (see Waste Management Section)

Sharps

The use of needles, glass pipettes, glass slides and cover slips, scalpels, and lancets should be eliminated, when possible. Appropriate precautions should be taken to avoid percutaneous injuries. These items should be disposed of immediately after use by placing them in a conveniently located, appropriate puncture-resistant container aka “sharps container”. Bending, recapping, or clipping of needles is prohibited. If recapping is necessary, a mechanical device or the one-handed scoop method must be used. If you have any questions regarding these methods or need guidance with alternatives, contact the Biological Safety Division at 919-684-8822. Plasticware should be used whenever possible, such as plastic graduated cylinders, funnels, aspirators, etc. Safety devices should be used when available (e.g., mylar-coated capillary tubes, Eclipse safety needles).

Decontamination

The purpose of decontamination is to make an area, device, item, or material safe for further handling in the context of being reasonably free from a risk of disease transmission. A decontamination procedure can range from sterilization to simple cleaning with soap and water. Sterilization, achieved with the use of an autoclave, is to make an item, device, or solution completely free of all living microorganisms. The following includes a description of the four main categories of physical and chemical means of decontamination used at Duke.

Heat

Wet heat is the most dependable method of sterilization. Steam autoclaving is the most convenient method available to Duke laboratories for decontaminating biological waste and sterilizing glassware and media. **Note: Autoclaves that are used for decontamination of biohazardous wastes should be monitored for the efficacy of treatment. This is accomplished using biological indicators.** The generator of the waste (the lab) is responsible for performing and documenting this testing. *See Waste Management in Section VII of the University Safety Manual.*

Chemical Liquid Disinfection

Many types of chemical liquid disinfectants are available under a variety of trade names. The most practical use of liquid disinfectants is for surface decontamination. Always check that the disinfectant is effective against the biological material you are working with and pay attention to the concentration and contact time listed for the material. Most contact times are "wet" contact times, which means that the surface must stay wet for the entire contact time. This may mean re-applying the disinfectant to reach the proper contact time. Disinfecting agents included in the category include but are not limited to, quaternary ammonium compounds, phenolic compounds, halogens, aldehydes, alcohols, and amines. **A tuberculocidal disinfectant or diluted household bleach should always be used for decontamination when human materials are handled.**

When **household bleach** is used for the decontamination of spills, a fresh solution (at least 1:10 household bleach) must be prepared. Bleach solutions used for routine surface decontamination must be *made at least weekly*. **Each solution container must be labeled with either a made-on or an expiration date and the word "corrosive".**

Vapors and Gases

The use of vapors and gases as decontamination methods usually involve the decontamination of biological safety cabinets but can also be used for whole room or building decontamination. Agents used in this category include ethylene oxide, formaldehyde gas, hydrogen peroxide, and peracetic acid. These decontamination methods must be done safely in order to protect the workers in the area, therefore it should be done through a professional service or contact the Biological Safety Division for more guidance.

Radiation

Ultraviolet radiation (UV) is sometimes used in biological safety cabinets for inactivating contaminants, but because of the low penetrating power of UV, dusty or soiled areas may limit its usefulness in the laboratory. Because UV can cause serious burns to eyes and skin, it must not be used when work areas are occupied. UV as a decontamination method is not recommended due to its ability to cause serious burns, degrade materials over time, as well as its limited power to penetrate dust. It also must be calibrated to a certain wavelength, which is oftentimes not done. Do not rely on just radiation for your disinfection process in the laboratory setting.

HUMAN BLOOD, BLOOD PRODUCTS, TISSUES, AND BODY FLUIDS

In 1991, the Occupational Safety and Health Administration (OSHA) issued a standard to minimize the risk of occupational exposure to bloodborne pathogens (e.g., HIV, Hepatitis B). The regulation, titled The Bloodborne Pathogens Standard, mandates several provisions for those working with materials that are human-derived, such as human blood, blood products, other bodily fluids, and any unfixed tissues. The full text of the Duke University Bloodborne Pathogen Exposure Control Plan can be found here. The plan must be readily available to all employees working with those materials mentioned above. This includes all employees working with primary human cell lines, or human cell lines that have not been tested for human pathogens.

Universal Precautions

Universal precautions are defined as handling all human blood, body fluids, tissues, and cell lines as if they are infectious. This calls for the use of appropriate protective measures to reduce or eliminate the risk of occupational exposure.

Hepatitis B Vaccination

All employees working with human blood, blood products, fresh tissues, bodily fluids, or cell lines shall be offered the Hepatitis B vaccine by the employer at no cost to them. If they have previously had the vaccine, documentation of prior vaccination can be sent to Eleanor Hardy (eleanor.hardy@duke.edu). If an employee should decline the vaccine, they must sign a waiver which is kept on file by Employee Occupational Health and Wellness (EOHW). For more information about the vaccine, contact EOHW at 919-684-3136.

EOHW Blood and Body Fluid Exposure Hotline

All potential exposures to potentially infectious materials are to be reported immediately by calling 115 from a Duke landline phone or 919-684-8115 from any phone. It is important that exposures are reported as soon after the incident as possible because some post-exposure treatments are time sensitive.

Safety Training

All employees who work with materials (primary and well-characterized human cells, tissues, blood) covered by OSHA's Bloodborne Pathogen Standard are to receive initial and annual safety training. Biosafety Level 2 (BSL2) includes Bloodborne Pathogens training and is available as online training modules. Laboratory-specific training is the responsibility of the Principal Investigator. Written standard operating procedures (SOP) for biological materials used at BSL2 are required, must be re-reviewed and approved by OESO Biological Safety every 3 years, and supplement this general lab safety manual for your lab-specific training.

BIOHAZARD SPILL CLEAN-UP

Spill Response for Biological Materials at BSL-1 or BSL-2

The following procedures should be followed to ensure proper spill clean-up of blood, body fluids and cultures of biological hazards at Biosafety Level 1 or 2.

1. Alert people in immediate area of spill.
2. At a minimum, wear disposable gloves, lab coat and face protection.
3. If broken glass is present, use forceps to remove and place glass in sharps collection container.
4. Cover spill with paper towel or other absorbent material.
5. Carefully pour a freshly prepared 1:10 dilution of household bleach (or other effective disinfectant) around the edges of the spill and then into the spill in a circular motion. Avoid splashing.
6. Allow a 20-minute contact period for bleach (or as indicated as effective contact time for different disinfectants).
7. Use paper towels to wipe up the spill, working from the outer edges into the center.
8. Clean spill area again as indicated in steps 5 and 6.
9. Depending on the size and concentration of the spill, a third disinfection (steps 5 and 6) may be warranted.
10. Discard disinfected disposal materials. Items that do not contain large amounts of bleach may be autoclaved according to the Medical Waste Management Policy before disposal.

Spill Response for Biological Materials at BSL-3

Spill Inside BSC

1. If sharps are present, use tongs to remove sharps, placing them in a puncture-proof container.
2. Cover spill with absorbent material.
3. Carefully pour appropriate disinfectant around the spill and then into center.
4. Allow appropriate contact time.
5. Use absorbent material to wipe up spill.
6. Continue working and disinfect BSC at end of work as usual.

Spill Outside BSC

1. While wearing PPE for the area, take out spill kit.
2. Put a sign on the door warning others not to enter due to a spill.
3. If sharps are present, use tongs to remove sharps, placing them in a puncture-proof container.
4. Cover spill with absorbent material.
5. Carefully pour appropriate disinfectant around the spill and then into center.
6. Allow appropriate contact time.

7. Use absorbent material to wipe up spill.
8. Repeat steps, including waiting for the appropriate contact time.
9. Put all used materials into a biohazard waste bag. Close bag, and double bag. Disinfect the outside of the bag before autoclaving to remove from BSL-3 laboratory.
10. Tell supervisor and safety representative about the spill. They will contact OESO Biological Safety to report the spill.

WASTE MANAGEMENT

Appropriate waste handling practices at Duke University and Medical Center are based on compliance with OSHA regulations for protection of personnel who must handle the waste, and the North Carolina Medical Waste Regulations for appropriate disposal.

There are three primary methods for disposing of biological waste at Duke. These methods include autoclaving, incineration, and chemical disinfection.

Waste Disposal Methods

Autoclave

Autoclaving is usually the most convenient choice for labs since autoclaves are readily available throughout most research laboratory buildings. Training should be provided and documented by supervisor or another knowledgeable person prior to using the autoclave. Ensure that an autoclave-safe bag and autoclave-safe pan is used to prevent the plastic from melting and damaging the autoclave. Using the autoclave in a shared space is a responsibility that must be taken seriously. All users must adhere to the safety protocols when using the autoclaves. See *Medical Waste Management* in Section VII of the University Safety Manual for instructions.

Incinerate

Incineration of biological waste is a viable option for all biological waste; however, coordination with other departments is necessary to utilize this option. Some departments have set up contracts with Stericycle or other outside vendors for incineration services. This must be coordinated through your business administrator. For incineration of medical lab waste, contact Environmental Services' Biomedical Waste Division (919-681-9700) for pick-up. The Division of Laboratory Animal Resources must be contacted (919-684-5212) for animal carcass disposal.

Chemical Disinfection

Chemical disinfection is a treatment option for liquid biological waste. An example is household bleach, but do not mix bleach with incompatible chemicals. Do not autoclave bleach. The disinfectant must be effective against the biological material it is treating, and the appropriate contact time must be allowed for effective disinfection/inactivation. Follow manufacturer instructions.

Vacuum flasks should be set up as a double flask system, with an inline HEPA filter or equivalent between the second flask and the house vacuum system (see diagram below). They should be situated on the inside of the BSC (or on the floor, but “upstream” from the valve). Vacuum flasks should be in secondary containment, especially when they are on the floor. An inline HEPA filter or equivalent is required to protect the house vacuum system when working with biological materials or bleach and recommended for other hazardous materials. This filter is intended to keep any aerosols and liquids out of the vacuum system and prevent any damage to the house system. The vacuum flasks need to be

labeled with the contents, hazards, and whether it is waste, as applicable. A disposal frequency should also be added to the label. If bleach has been added to the container, be sure to include this on the label. Bleach should be added to the vacuum flask immediately before work begins, so that it can disinfect the contents as they are added. Additionally, after sitting for the necessary contact time of the disinfectant, vacuum flasks should be emptied using appropriate disposal methods. Please be sure to close the vacuum valves when vacuum is not needed.

Citation: Figure 11. Protection of a house vacuum, Appendix A, BMBL 6th ed.

Biological Waste Categories and Treatment

Sharps

Needles, syringes with attached needles, capillary tubes, slides and cover slips, scalpel blades, razor blades, and broken glassware that are contaminated with biological material should be placed in a plastic puncture-resistant container, also known as a sharps container. There are two acceptable methods for disposal of sharps containers: 1) autoclave before disposal or 2)contract with an outside service for pickup and disposal.

Pipettes

Plastic pipette tips and serological pipette tips used to process human body fluids or cultures of infectious agents should be placed in a puncture-resistant box that is labeled with the biohazard symbol and lined with an autoclavable bag that has the biohazard symbol on it. Once filled, these boxes should be placed in an autoclavable bag with the biohazard symbol on it and autoclaved before disposal. Non-infectious pipettes should also be placed in a puncture-resistant container before disposal; however, it is not necessary to autoclave.

Microbiological/Molecular Waste

Includes cultures and stocks of etiologic agents and recombinant DNA/transgenics. Solid waste should be placed in an autoclavable bag that has the biohazard symbol on it and autoclaved before disposal.

Liquid biological waste (no hazardous chemicals) can be autoclaved or chemically treated (i.e., bleach) before disposal down the drain. Do not mix bleach with incompatible chemicals.

Specimens of human blood/body fluids and Other Potentially Infectious Material (OPIM)

Containers of blood/body fluids less than 20 milliliters (ml) and tissue cultures can be placed in an autoclavable bag that has the biohazard symbol on it and autoclaved before disposal. Greater than 20 ml should be treated as applicable using a different method listed in this chapter.

Tissue Culture Waste (Animal and Human)

All solid waste should be discarded in autoclavable bags that have the biohazard symbol on them and autoclaved before disposal. Liquid waste can be chemically disinfected (bleach) before disposal down the drain. The waste should not contain other chemicals that are incompatible with bleach or other disinfectants used.

Anatomical/Pathological Waste

Organs, limbs, animal carcasses etc., must be incinerated (not autoclaved) for proper treatment. All large, human-derived anatomical/pathological waste should be submitted to Environmental Services' Biomedical Waste Division (919-681-9700). Animal carcasses should be disposed of through the Division of Laboratory Animal Resources (919-684-5212).

Non-contaminated glass

Broken glass items should be discarded in a bag-lined heavy-duty cardboard box (usually labeled "broken glass") and taped shut before disposal. Do NOT use cardboard boxes with "biohazard" symbols printed on them, which implies biohazardous waste requiring special treatment. **Keep in mind that these boxes are very heavy if filled to the brim. Consider smaller glass disposal boxes or disposing the boxes when the box is at a manageable weight and not full.**

Solid Disposable Supply Wastes

Disposable gloves, gauze, paper wrappings, parafilm, etc., that are not visibly contaminated. Decontamination is not required before disposal; however, these items should be placed in leakproof containers (i.e., a sturdy plastic bag).

LABORATORY EQUIPMENT

Biological Safety Cabinets (BSCs)

BSCs are the most commonly used primary containment devices in microbiological laboratories. There are three classes of BSCs: Class I, II, and III. When combined with appropriate microbiological techniques, each Class provides different levels of protection. All BSCs rely on High Efficiency Particulate Air (HEPA) filtration to provide their protection. The HEPA filter is a device which removes particulates and microorganisms from the air. These filters remove 99.97% of all particulates 0.3 microns in diameter and have greater efficiency for particles greater or less than 0.3 microns.

Class I BSC

Provides both personnel and environmental protection. However, they do not provide product protection needed for sterile tissue culture work. Class I BSCs are suitable for work with low to moderate-risk agents.

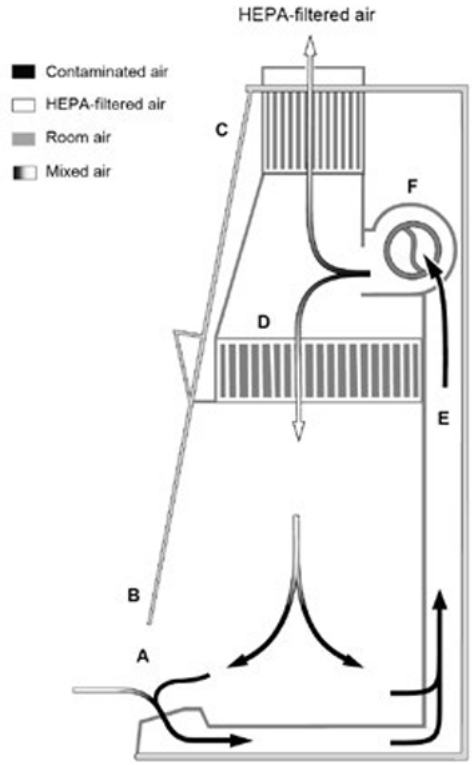
Class II BSC

Provides environmental, personnel, and product protection. The main difference between Class I and II cabinets is HEPA filtration of the airflow down and across the work surface of a Class II cabinet. This provides for a sterile working area. These are the most commonly used BSCs at Duke.

When using a Class II BSC, keep front and rear perforated grills free of clutter. Cluttered grills can cause a disruption of airflow which can compromise personnel, environmental, and product protection. Avoid sudden movements in and out of the cabinet. Also, avoid installing BSCs near windows or frequently used doorways. Doing so can disrupt airflow. Gas burners should not be used in the BSC. The heat from the burners disrupts airflow, the flame can damage the HEPA filter, and gas can build up inside the workspace due to the recirculation of air. Volatile chemicals and volatile radionuclides should not be used unless approved by the Occupational and Environment Safety Office. Do not store items on top of the cabinet. The HEPA filter could get damaged, and the balance of airflow could be disrupted. Do not eat, drink, chew gum, or smoke near the cabinet. Doing this could result in the ingestion of hazardous materials. Wipe down the cabinet interior with a surface disinfectant before and after all manipulations.

The image below shows how a Class II BSC functions under normal operations.

Class II, Type A BSC
A. Font Opening
B. Sash
C. Exhaust HEPA filter
D. Supply HEPA filter
E. Common plenum
F. Exhaust blower



Class III BSC

Gas tight BSCs provide the highest level of environmental, personnel and product protection. A Class III BSC, also referred to as a glove box, provides a complete physical barrier between the product and personnel. These cabinets are used for high-risk biological agents when absolute containment is required.

Certification of Biological Safety Cabinets

BSCs are to be certified by one of the Duke Procurement office "approved vendors". These vendors are National Sanitation Foundation (NSF) certified and have demonstrated expertise in certifying and maintaining BSCs. For more information on certification of BSCs, contact OESO Biological Safety Division at 919-684-8822.

All BSCs must be certified annually. All newly purchased BSCs and any BSCs that are moved must be certified before they can be used.

Relocating a BSC

Before a BSC is moved to another Duke Campus location, the need for gas decontamination is determined by the work that has been conducted in the BSC. If only Risk Group 2 or lower biological materials were used, then the following must be done:

1. Double wipe down with an appropriate disinfectant, inside and outside.

2. Except for the feet or legs, the BSC must not be dismantled during the move.

When is gas decontamination required?

If the BSC was used for work with infectious agents with the potential for aerosol transmission (i.e. vaccinia virus, influenza virus, etc.), the BSC must be decontaminated by the certified vendor with a disinfecting gas **prior to maintenance or relocation** of the BSC.

Before a BSC is moved to surplus or is dismantled, gas decontamination must be completed by the certified vendor.

Clean Benches

Laminar Flow Clean Benches should never be used when handling cell culture materials, drug formulations, potentially infectious materials, or any other potentially hazardous materials. The worker will be exposed to the materials being manipulated on the clean bench, potentially resulting in hypersensitivity, toxicity, or infection, depending on the materials being handled.

Horizontal laminar-flow clean benches are designed to protect the product from contamination. It moves air from the back of the unit through HEPA or ULPA filters to the front of the work surface. Horizontal airflow “clean benches” must never be used as a substitute for a biological safety cabinet (BSC).

Vertical flow clean benches may be useful, for example, when a clean area is needed for the preparation of intravenous solutions. It moves air from the top of the unit through HEPA or ULPA filters down to the work surface.

Centrifuges

Centrifuges are commonly used in the laboratory environment. Centrifuges must be properly used and maintained to ensure safe operation. The following are suggested practices:

- Refer to the owner's manual for routine maintenance requirements.
- Perform a visual inspection prior to each use (note unusual cracks, irregularities, or wear).
- Verify proper loading of specimens to maintain balance.
- After starting, listen for unusual noises or vibrations until the programmed speed is reached. If unusual noise or vibrations are heard, and you suspect something is wrong, turn off the centrifuge immediately. You may need to do this by unplugging the cord. Do not open the centrifuge until you are certain it has stopped. Allow time for potential aerosols to settle before opening. Refer to the owner’s manual or call a service technician to address the issue. The

centrifuge must be thoroughly surface decontaminated with an appropriate disinfectant before service by the technician.

Perform routine decontamination of interior surfaces using an appropriate disinfectant. Immediate decontamination is required when visible contamination is noted.

Prevent the release of aerosols when centrifuging infectious materials that are spread via the aerosol route or with high titer/concentrated infectious materials by using "safety devices", (i.e., sealed buckets, safety trunnion cups, and sealed heads). Safety cups must be opened in a BSC after centrifuging such materials to avoid the release of aerosols into the room.

Spills should be addressed immediately by following established biological spill procedures. Special precautions should be taken when broken glass or other sharps may be involved. Use a mechanical device to pick up sharps. Do not use your hands.

Homogenizers and Blenders

These items are commonly used in laboratories, and both are considered producers of aerosols. Safety-sealed homogenizers and blenders are commercially available and should be used when working with agents known or suspected of being transmitted through aerosols. The purpose of these items is to contain any aerosols created during work procedures. These safety devices may be used on the open benchtop; however, they must be opened in a BSC. All non-sealed devices must be used exclusively in a BSC.

RECOMBINANT AND SYNTHETIC NUCLEIC ACIDS

Since the inception of recombinant and synthetic nucleic acids (hereafter referred to as rDNA) technology, scientists have been concerned over the possibility that artificially constructed rDNA could be biologically hazardous if not handled appropriately or released into the environment. These concerns prompted the development of the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) on rDNA research in May of 1976, and it has been updated as needed to reflect changes in technology. The most recent revision is available at https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Researchers at Duke University who construct and/or handle materials containing recombinant DNA molecules must comply with the requirements of the NIH Guidelines. NIH Guidelines are applicable to all rDNA research conducted or sponsored by an institution that receives ***any*** support for rDNA research from the NIH. Research at Duke must be registered with the Duke Institutional Biosafety Committee (IBC) to determine that the research is being conducted in accordance with the NIH Guidelines and applicable biological safety practices. All rDNA research receiving funding through Duke University but conducted outside of the US must be registered with the Duke IBC and comply with any rules of the host country. The NIH Guidelines provide guidance for containment and safe practices of various categories of rDNA research. The following information and procedures are developed to assist Duke University researchers with the documentation of this compliance.

Generally, experiments requiring the use of recombinant biological agents should be handled under the same BSL requirements as the wild-type agent. For example, the handling of adenoviral vectors should be performed under BSL 2 conditions.

What is rDNA?

The NIH Guidelines defines recombinant and synthetic nucleic acids 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;
(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.

At Duke, rDNA work may include:

1. Plasmids and viral vectors
2. Any synthetic DNA or RNA
3. Any RNA produced from rDNA, including messenger RNA (mRNA), small interfering RNA (siRNA), micro-RNA (miRNA), small hairpin RNAs (shRNA), etc.

4. Genetically modified organisms (animals, plants, bacteria, viruses, fungi, etc.). This includes creation, crossbreeding, or manipulation of transgenic animals and plants.

5. Any such material obtained from another researcher or source

The Institutional Biosafety Committee (IBC)

The NIH Guidelines requires that an IBC be established at any institution receiving NIH funding for rDNA research to oversee all rDNA research at that institution and ensure that such work is compliant with the Guidelines.

The mission of the Duke University IBC is to ensure that all rDNA research conducted at the institution or sponsored by the institution is conducted in compliance with the NIH Guidelines.

The Duke University IBC has responsibility for such research throughout the Duke Health System, Medical Center, and University. IBC members are appointed by the Vice President for Research and Innovation. The Duke Occupational and Environmental Safety Office staff will support the IBC in carrying out its mission. The IBC is authorized to inspect research facilities, approve research practices and procedures, and take actions, such as the enforcement of cessation of laboratory or clinical research activities, in the event of an unsafe workplace situation.

Principal Investigator (PI) Responsibilities

The PI makes an initial determination of the required levels of physical and biological containments, and practices and procedures in accordance with the NIH Guidelines. If there are any questions regarding whether particular research should be registered with the IBC, please contact the Biosafety Officer at biosafety@duke.edu or 919-684-8822.

If your research is not exempt, submit the appropriate paperwork for the proposed work (see rDNA Registration Process below).

The Principal Investigator:

1. Is responsible for adherence to all requirements of the NIH Guidelines, including required safety practices

2. Submits an annual update of the continuing protocols to the IBC

3. Provides training to all laboratory workers regarding the potential hazards of the work and precautions to be taken

4. Investigates and reports any significant problems or illnesses pertaining to the operation and implementation of containment to the Biological Safety Officer for review by the IBC

5. Ensures that all lab workers experiencing occupational exposures to rDNA material will report such exposures to Employee Occupational Health and Wellness (EOHW).

6. Complies with any shipping requirements for rDNA molecules.

7. Ensures that laboratory workers who work with animals participate in the Duke Health Surveillance for Animal Handlers.

The rDNA Registration Process

All research that is not exempt from compliance with the NIH Guidelines must be registered with the IBC. Non-exempt manipulation of rDNA includes but is not limited to crossbreeding to create a new strain of animal or plant, rDNA in viral vectors or human cells, and rDNA in clinical human trials.

1. Submit the appropriate documents as needed to the IBC. Templates are below.

    a. rDNA form

    b. SOP for BSL2/ABSL2 labs

    c. Plasmid/Vector Table

2. Clinical Trials Involving rDNA products: **every** human trial requires its own review by the Duke Institutional Review Board and the IBC, even if the same rDNA material is used in multiple trials.

Large Scale

The NIH Guidelines define large-scale work as research or production as greater than 10 liters of culture. Research involving such amounts is subject to additional precautions and work practices, which can be found in Appendix K of the NIH Guidelines. The IBC will outline the additional precautions needed at Duke.

Plants

Work involving recombinant plants or plant pathogens is subject to additional precautions, work practices, and facility requirements, which can be found in Appendix L of the NIH Guidelines. The IBC will outline the additional precautions needed at Duke.

Animals

Work involving whole animals, those which have stable introduction of recombinant or synthetic nucleic acids into the germ line (transgenic animals) and experiments involving viable recombinant or synthetic nucleic acid molecule-modified microorganisms administered to whole animals is subject to additional precautions, work practices, and facility requirements, which can be found in Appendix M of the NIH Guidelines. The IBC will outline the additional precautions needed at Duke.

Recombinant DNA Waste Management

rDNA and transgenic organisms must be treated the same as medical or infectious waste before disposal. Organisms must be rendered inviable before disposal. When an animal covered by Appendix M containing rDNA or a rDNA-derived organism is euthanized or dies, the carcass must be appropriately disposed to avoid its deliberate or inadvertent use as food for human beings or animals unless food use is specifically authorized by an appropriate Federal agency. See the waste management policy for more information.

Incident Response and Reporting

The NIH requires institutions to report incidents involving rDNA materials including exposures to personnel, loss, theft, or release.

1. Report any loss, theft, or release involving rDNA materials to OESO Biological Safety at 919-684-8822.
2. Report any human exposure to rDNA to Employee Occupational Health and Wellness (EOHW, 919-684-8115) and to OESO Biological Safety (OESO, 919-684-8822). Complete the Report of Occupational Injury or Illness form.

Training

A variety of training is essential to ensure good laboratory practices. OESO training is available at the https://sms.duhs.duke.edu/onlinetraining/ (Online Training) website.

1. General Laboratory Safety is required for all lab workers.
2. Lab-specific orientation and training is provided by the P.I.
3. Biosafety Level 2 (BSL2) training is for those who handle infectious material or other potentially infectious material (OPIM) that poses a splash, splatter, or percutaneous exposure hazard.
4. Bloodborne Pathogens training is required for those who handle materials of human origin (i.e. primary and well-established cell lines). This training is included in BSL2 training for lab workers.
5. Animal/Biosafety Level 3 (A/BSL3) training program for work within higher containment
6. Plant containment training (Phytotron website)
7. Animal handlers training (IACUC Website)

SELECT AGENTS AND TOXINS

Introduction

The Select Agents and Toxins are a list of viruses, bacteria, fungi, and toxins that are regulated by the Federal Select Agent Program (FSAP) under the Select Agent Regulations. On December 13, 2002, regulations were published to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188. CDC prepared the Select Agents and toxins list after receiving extensive input from scientists representing 21 Federal government entities. The Department of Health and Human Services (HHS) Secretary considered the following criteria for establishing the list:

- The effect on human health of exposure to the agent or toxin.
- The degree of contagiousness of the agent or potency of the toxin and the methods by which the agent or toxin is transferred to humans. The availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin.

The regulations apply to the possession, use, and transfer of these Select Agents and Toxins, and to rDNA experiments involving those agents and toxins which pose a threat to public health and safety. The regulations that govern Select Agents and Toxins are 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73. The list is segregated by their potential targets: humans, humans and animals, animals only, and plants only, and is subjected to review by an inter-governmental committee at least every two years and will be updated as needed. The Duke Select Agent webpage with entity-specific details can be found here: Duke Select Agent Program.

All Select Agents and Toxins at Duke must be ordered and obtained through OESO Biological Safety Division even if you are transferring it to and from a collaborator. For more information, contact the Select Agent Program Responsible Official (RO) at 919-684-8822.

Roles and Responsibilities

Responsible Official (RO)

The Select Agent and Toxin Regulations require that a Responsible Official (RO) is designated at each institution where select agents and toxins are shipped, received, and/or possessed. The Director of OESO Biological Safety Division serves as the RO for Duke University. At least one Alternate Responsible Official (ARO) may be designated by the RO. The primary responsibility of the RO, under the Duke Select Agent Program, is to oversee the registration of the laboratory with the Federal Select Agent Program and assure that all requirements of compliance are met.

Select Agent Program Principal Investigator

The Principal Investigator (PI) is held responsible for assuring that s/he registers all possessions, transfer, and receipt of Select Agents and Toxins through OESO Biological Safety. S/He is also responsible for assuring that the laboratory fully complies with all prescribed safety policies and procedures. Consequently, the PI must work closely with the RO to ensure compliance with this standard.

Compliance

Compliance with the regulations requires that the RO obtain a registration certificate for the procurement, storage, and work with select agents and that the PI agrees to conduct all activities as described in the registration application. All work objectives with the select agents and toxins must be submitted to the FSAP. The documentation required is described in the regulations and includes entity-specific plans addressing security, incident-response and biosafety, background checks on those authorized to access select agents, laboratory inspections, and inventory recordkeeping, among other requirements.

The Federal Select Agent Program has developed a helpful website that provides guidance on the Select Agent Regulations, FAQs, Required Forms, and Resources: http://www.selectagents.gov/.

How Do Researchers Register Select Agents?

Researchers planning on handling any of the Select Agents or Toxins **must** contact the Duke University Responsible Official (Director of the Biological Safety Division, OESO) to begin the registration process with the Federal Select Agent Program. Call 919-684-8822 for assistance.

What toxins are regulated as select toxins and what quantities are exempt?

Work with select toxins is regulated by the Federal Select Agent Program unless the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified. The limits can be found on the Federal Select Agent webpage. **Although only amounts greater than the maximum permissible limit must be registered with CDC/APHIS through the Duke Select Agent Program, any amount of these toxins must be ordered through the OESO - Biological Safety Division Select Agent Ordering Website: (http://www.safety.duke.edu/biological-safety/select-agents-biological-toxins).** Furthermore, all amounts of select toxins must have an approved Biosafety SOP, be kept secure, the inventory must be kept up-to-date every time a manipulation is made (including dilutions), and is subject to the Due Diligence clause of the Select Agent Regulations.

Dual Use Research of Concern (DURC) and Pathogens with Enhanced Pandemic Potential (PEPP)

Introduction

Life sciences research has far-reaching scientific advances and benefits to society; however, some research could be misapplied to pose a threat to public health and safety, agricultural crops and other plants, animals, the environment, and/or national security. This subset of life sciences research is subject to greater risk assessment and review by institutional committees and federal funding agencies, pursuant to the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (2024 USG Policy)[1]. The Duke University Dual Use Research of Concern (DURC)-Pathogens with Enhanced Pandemic Potential (PEPP) Policy articulates the practices and procedures required to ensure that Duke University is fully compliant with the 2024 USG Policy.

All research conducted at Duke University defined as Category 1 or Category 2 (as defined below) research is subject to this policy, regardless of the source of this funding.

Duke Compliance Process

Duke University has created a DURC-PEPP Policy and instructed multiple groups within Duke University on oversight processes to comply with the 2024 USG Policy for Oversight of DURC and PEPP and the accompanying USG DURC-PEPP Implementation Guidance. The groups and their responsibilities are outlined below.

Principal Investigator

- Review your research for DURC/PEPP potential at the grant proposal stage and on an ongoing basis using the PI Self-Assessment form
- If there is a concern for DURC/PEPP potential, notify the ICDUR (Dr. Antony Schwartz) at biosafety@duke.edu or 919-684-8822.
- More information can be found on the Duke Safety website

Laboratory Staff

- Receive and maintain education and training on all research oversight policies and processes
- On an ongoing basis, review your research for DURC/PEPP potential

Institutional Review Entity (IRE)

- The Duke Institutional Biosafety Review Committee (IBRC) functions as Duke's IRE
- More information can be found on the Duke Safety website

PACKAGING AND SHIPPING BIOLOGICAL MATERIALS

Although several agencies have published regulations or guidelines for the proper packaging and shipment of biological materials, the International Air Transport Association's (IATA) Dangerous Goods Regulations (DGR) governs all international shipments. Furthermore, all air transport of regulated biological materials (including domestic flights) must strictly adhere to the DGR. For this reason, the OESO provided training is primarily focused on compliance with these regulations.

Training

All personnel involved in the process of shipping biological materials must receive proper training initially and at least every two years thereafter. Training is provided through the OESO website's "online-training" link. The training is titled Shipping Biological Materials. The Training Supplement Guide includes checklists and a summary of the most relevant training content for properly classifying, packing and labeling a shipment. Note that the information provided in the Training Supplement Guide may not include all relevant shipping criteria and is not intended to be used without first completing the shipping training.

Permitting import or export of agents or vectors of human disease

Importation and exportation of infectious materials and vectors that may contain them is regulated by federal law. When an infectious agent is being imported into or exported out of the United States, it may need a permit which is issued either by the United States Centers for Disease Control and Prevention Import Permit Program. Permits are issued only to the importer/exporter that is in the United States. Permit applications are available through the Duke University Export Controls Office: https://export.duke.edu/

The permit, along with the proper packaging and labeling, will expedite clearance of the package of infectious materials through US Customs and Border Protection (CBP).

Import or export of etiologic agents of animals and plant pests

The United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) regulates the importation and interstate transfer of animal products and agents which may pose a risk to animals or plants. A permit must be obtained prior to the receipt of any material that could pose a potential risk to animals or plants. The permitting procedures are coordinated through the Duke University Export Controls Office: https://export.duke.edu/.

Shipping Select Agents

As stated in the “Select Agents and Toxins” section above, all researchers who possess or plan to possess select agents must be registered with the Federal Select Agent Program through the Duke Select Agent Program. For more information, see the Select Agent Section earlier in this document. For a list of

restricted agents and other Select Agent Program requirements, see the following: https://www.selectagents.gov/

The Director of OESO's Biological Safety Division will serve as Duke's Responsible Official (RO) for select agents. All Federal Select Agent Program registrations must be facilitated through the RO. Transfers and shipping of select agents and toxins must be done by OESO Biological Safety staff, and overseen by the RO. To contact the RO, call 919-684-8822.

Proper Shipment of Non-Regulated Liquids

Provisions must be made to ensure that all non-regulated liquids (i.e., buffers, water, etc.) are properly packaged to prevent leakage during transport. The packaging must be of good quality, and strong enough to withstand the shocks normally encountered during transport. A triple-packaging system must be utilized. The following must be met:

- Liquid is placed in a **leak-proof primary container.**
- **Absorbent material** must be placed around the primary container (enough to absorb the entire contents of the primary container.
- Primary container(s) and absorbent material(s) are placed into **leak-proof secondary container**.
- Inner packages (primary and secondary containers) are placed into a sturdy outer container (i.e., cardboard box). Cushioning material is added between the secondary container and outer shipper if deemed necessary.

LABORATORY BIOSECURITY

Laboratory biosecurity protects the materials used in the lab from loss, theft, or intentional misuse. Principal investigators should take reasonable steps to ensure that their labs are secure by:

Providing for physical security

- Lock the laboratory door whenever the lab is left unattended.
- Determine what materials should be subject to inventory accountability measures and what records should be maintained. Toxins listed under the Select Agent and Toxin list must be secured always, have a complete up-to-date inventory logbook, and be prepared to show the inventory to evaluators and regulators. Records must be kept for a minimum of three years.
- Store materials with the highest hazard potential in locked cabinets, refrigerators, etc. Toxins listed in the Select Agent and Toxin list must be kept secure, with at least one layer of security.
- Storage equipment (i.e., refrigerator, freezer) that is/are not contained within a space or lab that has restricted access (e.g., hallway) should be fashioned with a lockable device to prevent access by the public.
- Integrating laboratory security measures into lab specific policies and procedures (i.e., standard operating procedures (SOPs)).

Personnel Management

- Identify the roles and responsibilities for employees who handle, use, store, and transport hazardous materials during the process of selection and hiring lab staff.
- Develop policies for personnel and visitor identification, visitor management, and access procedures.

Reporting Security Incidents

- Report incidents or possible incidents, such as undocumented visitors, missing hazardous materials, and unusual or threatening phone calls or behavior to Duke Police (919-684-2444).

The Occupational and Environmental Safety Office (OESO) will:

- Assist in evaluating security risks or developing security measures for the laboratory.
- Assist with the development of SOPs.

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APPENDICES

OSHA Occupational Exposure to Bloodborne Pathogens Standard

Duke University Bloodborne Pathogens Program

Duke Laboratory Safety Training

Duke University Institutional Biosafety Committee (IBC)

Recombinant DNA FAQs

Duke University's Select Agents & Toxins Program

Duke University Medical Waste Management Policy

Federal Select Agents and Toxins Program