Laboratory Safety Manual

Introduction

FORWARD

Duke University is committed to providing a safe work environment for learning, teaching and research. The Occupational and Environmental Safety Office (OESO) promotes workplace safety through various policies and programs, many of which are outlined in this manual. The following sections are meant to provide general laboratory safety procedures.

Each laboratory is a unique environment, and site-specific hazards must be addressed by each supervisor/principal investigator when establishing proper work practices. It is each laboratory professional's duty to conduct their work in a responsible manner, and to take all necessary precautions to protect themselves and others in the area from exposures to hazardous materials. **Upon request and during laboratory audits, OESO will assist in performing a risk assessment for procedures of moderate to high risk, aid the lab in evaluating the risk, and help with the development of written standard operating procedures (SOP)**.

If work practices currently being employed in your laboratory do not comply with those in this manual, please make the necessary changes. An OESO representative can be reached for questions by calling 919-684-8822 or 919-684-2794.

Important Numbers

Emergency Numbers

- Medical Emergency: 911
- Duke University Police: 911 from a campus phone; 919-684-2444 from a cell phone
- Chemical Spill: 911 from a campus phone; 919-684-2444 from a cell phone
- Radioactive Materials Spill: 911 from a campus phone; 919-684-2444 from a cell phone
- Occupational Exposure: 115 (on campus), 919-684-8115 (off campus or from cell phone)
- To report workplace safety concerns/ unsafe working conditions: 919-684-2794

Safety

- Occupational & Environmental Safety (administration): 919-684-2794
- Contractor/Work-Site Safety: 919-684-5996
- Biological/Laboratory Safety: 919-684-8822
- Fire Safety: 919-684-5609
- Radiation Safety: 919-684-2194
- Ergonomics: 919-668-(ERGO)3746

Regulated Laboratory Waste

- General Questions: 919-684-8822
- Environmental "Room" Services' Biomedical Waste Division (Medical Center Sharps Boxes/Red Bags): 919-681-2727
- Chemical Waste: 919-684-2794
- Radioactive Waste: 919-684-2794
- Animal Carcasses: 919-684-5212

Occupational Hygiene & Safety (919-684-5996)

- General Questions
- Asbestos Abatement
- Noise/Air Monitoring
- Reproductive Health Risks at Work
- Respiratory Protection

Other

- Employee Occupational Health and Wellness (EOHW) 919-684-3136
- Environmental Services Uniform Room (Lab Coat Laundering): 919-684-3784
- Division of Laboratory Animal Resources: 919-684-2797
- Grants & Contracts: 919-684-3030
- University Maintenance: 919-684-2122
- Medical Center (buildings) Maintenance: 919-684-3232

Laboratory Safety Manual

Section 1
General Safety

INTRODUCTION

PURPOSE

This section has been prepared to provide Duke University laboratory personnel with information about general requirements related to safety and prevention of injuries in laboratories. Laboratory personnel are reminded that the policies in the University Safety Manual apply in the lab environment.

HAZARDS ADDRESSED

This section primarily addresses equipment and hazards that may cause physical injury such as cuts, burns, slips/trips/falls, traumatic injury, or electrical shock. Subsequent chapters address exposure to hazardous biological materials and chemicals. Radioactive materials and lasers are covered in the Radiation Safety Manual and the Laser Safety Policy.

DEFINITIONS

High Risk Procedures – Lab procedures which pose significant risk of serious injury or major property damage if an unexpected event were to occur (such as a utility outage or equipment failure/misuse) and/or which

- May expose research personnel to hazardous energy (e.g., electricity or high pressures).
- Require specialized training not covered by another Duke Safety policy.
- Require specialized personal protective equipment in addition to gloves, lab coats, eye/face protection and/or thermal protective aprons or sleeves (for example, fall protection).

Laboratory - A facility for scientific experiments, research, or teaching where equipment and/or materials are designed to be easily and safely manipulated by one person. Laboratory work may involve relatively small quantities of hazardous materials used on a non-production basis, or experimental equipment generating hazardous energy (such as pressure, microwaves, or heat) on a small scale. The equipment and/or materials used in a laboratory are not part of a production process, nor in any way simulate a production process. In a laboratory, "protective laboratory practices and equipment" are available and in common use to minimize the potential for employee exposure to hazardous materials or energy.

Protective laboratory practices and equipment – Those laboratory procedures, practices and equipment accepted by laboratory health and safety experts as effective, or that the employer can show to be effective, in minimizing the potential for employee exposure to hazardous materials or hazardous energy.

RESPONSIBILITIES

It is the responsibility of the Principal Investigator to ensure the safety of persons working or volunteering in his/her laboratories.

Department Heads shall:

- Ensure compliance with all safety requirements within their departments.
- Establish criteria and processes for Departmental review of hazard assessments/lab-specific Standard Operating Procedures for High Risk Procedures.

Principal Investigators (Research Labs)/**Directors** (Clinical Labs) shall:

- Ensure compliance with all safety requirements within the laboratory or laboratories.
- Provide direction and support to the Laboratory Safety Coordinator, if one is designated, or undertake the responsibilities of the Laboratory Safety Coordinator if no one is designated for that role.
- Perform a hazard assessment and develop/approve lab-specific Standard Operating Procedures for all high-risk procedures.
- When it is required by the department, submit High Risk Procedure hazard assessments for departmental review and maintain documentation that this review was completed.
- Before allowing minors or non-Duke employees to volunteer or work in the laboratory, submit and receive approval using the "Workplace Safety Statement for Minors and Non-Employees at Duke". The PI must ensure compliance with the policy on Minors/Non-Employees in Work Areas.

Laboratory Safety Coordinators shall:

- Work with the Principal Investigator to develop and document necessary laboratory-specific standard operating procedures.
- Read and be familiar with this section of the Laboratory Safety Manual.
- Train laboratory employees and students when there is new laboratory-specific safety information or when a new employee or student is assigned to the laboratory. Document training as described under Laboratory-specific Training. Training must be documented for all paid employees (graduate students, post-docs, paid work study, or other wage or salaried personnel) in the laboratory; it is recommended that training be documented for non-paid students as well. *Examples of topics to be included in the training are detailed under Laboratory-specific Training.*
- Coordinate interaction with the Occupational and Environmental Safety Office, Employee Occupational Health and Wellness, and other Duke departments or outside agencies as needed for laboratory audits, incident/accident investigation, medical care, and emergency response.
- Post the Emergency Response and Incident Reporting Guide (available from OESO – 919-684-2794) in the lab near the door or main laboratory telephone.

Laboratory Employees and Students shall:

- Plan and conduct laboratory operations in accordance with federal regulation and applicable University safety policies (in this manual, the University Safety Manual, the Radiation Safety Manual, and the Laser Safety Policy).
- Abide by all policies and procedures described in any department or laboratory-specific policies.

- Report all injuries, other incidents, and unsafe conditions to their supervisor and PI, and to the appropriate university support groups as described in the Laboratory Emergency Response and Incident Reporting Guide.

The Occupational and Environmental Safety Office (OESO) shall:

- Develop and provide general laboratory safety training.
- Conduct periodic safety audits of laboratories.
- Investigate laboratory accidents and injuries.
- Review and provide input on safety measures for High Risk Procedures when requested by the PI or Department.

Employee Occupational Health and Wellness shall:

- Provide medical care for employees who have been injured.

GENERAL HAZARD INFORMATION AND TRAINING

Required Hazard Awareness Training

General Lab Safety Training:

Each laboratory employee (including P.I.s) and student shall be required to take a general laboratory safety course online before beginning work in the lab and annually thereafter.

Other General Training:

Laboratory employees or students exposed to general hazards that are not covered in the general laboratory safety training may be required to take other applicable safety trainings offered by the Occupational and Environmental Safety Office. Examples include:

- Vehicle Safety Policy training and Defensive Driver training for laboratory personnel who operate Duke Vehicles.
- Lockout-Tagout training for laboratory personnel who may perform service or maintenance on equipment where the unexpected start-up, energization, or release of stored energy could occur and cause injury. (See the Hazardous Energy Control Policy for more information.)
- Hearing Protection or Hearing Conservation training for employees exposed to hazardous noise. (See OESO Online Training Page for links to these courses.)
- Ladder Safety training where step ladders or extension ladders are used. (See OESO Online Training Page for a link to this course.)

Laboratory-specific Training:

The Principal Investigator or Laboratory Safety Coordinator shall conduct laboratory-specific hazard awareness training for each laboratory employee or student before that person begins working in the lab. This hazard awareness training shall be reviewed as necessary and any time a new hazard is introduced. Records shall be kept to indicate topics covered, name of person providing training, persons in attendance, and the date.

Examples of information to be covered (when applicable) in laboratory-specific training are listed below:

- The location and contents of the Laboratory Emergency Response and Incident Reporting Guide.
- Departmental or lab-specific incident reporting requirements.
- Location of emergency equipment such as fire extinguishers and fire alarm pull stations.
- Location of the lab's emergency assembly point (EAP). (See the site-specific fire plans online for EAPs for campus buildings.)
- Proper use and disposal of razor blades or other sharps (including broken glass disposal boxes).
- Safe use and storage of stepladders or stools.
- Equipment or areas requiring hearing protection.
- Safe use of laboratory equipment.
    - For any laboratory equipment, refer to the equipment manual for safety instructions.

  - For electrical equipment, including extension cords, see the Electrical Safety Policy.
  - For machine tools, see the Academic Shop Policy.
- Safety procedures for Fieldwork.
- Appropriate methods for disposing of various types of waste generated in the lab.
- Laboratory standard operating procedures for any High Risk Procedures.

Required Sources of General Hazard Information

Equipment Hazard Labels:

When there are hazard labels on purchased equipment (such as labels indicating possible electrical shock, sharp edges, or pinch points), laboratories shall not remove or deface these labels.

If laboratories produce or assemble equipment that could cause injury, warning labels are recommended.

Equipment Manuals:

If laboratory equipment is provided with a manual that includes safety warnings, the manual (or at least the safety warnings) must be accessible to laboratory personnel. Laboratories are encouraged to maintain a list of equipment manuals that contain safety information and to require staff to sign indicating that they have read the applicable safety information for the equipment they will use.

GENERAL SAFETY PROCEDURES FOR THE LABORATORY

Introduction

This section covers common safety concerns noted in laboratories. Where applicable, policies in the University Safety Manual are referenced for detailed requirements.

Consideration of Safety during Procurement

When purchasing laboratory equipment, consider the safety of laboratory personnel. Considerations include:

- Presence of engineered safeguards – When possible, choose equipment that isolates users from heat, sharp edges, pinch points, hazardous energy (such as ultraviolet light, microwaves, or other energy sources), and hazardous materials. If laboratory personnel will maintain equipment, consider their safety during maintenance activities as well as normal operations.
- Noise – When possible, choose equipment that generates less noise. If equipment produces noise levels over 85 dBA, see the Occupational Noise Exposure Policy for requirements.
- Ergonomics – When possible, choose equipment that:
    - Allows users to maintain neutral postures,
    - Adjusts for multiple users,
    - Minimizes repetitive activities, and
    - Runs automatically instead of requiring manual operation.

Safe Work Practices

General Housekeeping, Storage and Use of Equipment, and Maintenance

Keeping the laboratory clean, organized, and functioning properly can help to prevent incidents and injuries. General housekeeping, storage, and maintenance practices are described below.

- Never obstruct access to exits and emergency equipment such as eyewashes, drench hoses, and safety showers.
- Keep the work area clean and uncluttered, with equipment and hazardous materials properly stored.
- Secure or position benchtop equipment so that it will not be knocked over.
- Keep drawers and cabinets closed and cords and cables off the floor to avoid tripping hazards. Use cable management devices to bundle cords and cables together under desks and lab benches.
- Keep items off the floor to allow your housekeeping service to clean effectively, and to reduce the risk of trips and falls.
- Keep aisles clear of stored materials.
- Arrange workspace efficiently to allow personnel to maintain neutral postures, minimize repetitive activities, and minimize forces required while working.
- Promptly clean up spills and dropped materials/equipment to avoid slip hazards. (For chemical spills, see the Chemical Safety Chapter).

- Keep sink traps and floor drain traps filled with water at all times to prevent the escape of sewer gas into the laboratory. Alternately, contact your maintenance provider to fill infrequently-used traps with linseed or other oil that is safe for sewer disposal (since the oil will evaporate less rapidly than water).
- Keep sharp or pointed tools properly sheathed or otherwise stored safely when not in use.
- Hang clothing in proper locations; it should not be draped over equipment or benches.
- Do not store excess cardboard boxes, equipment boxes, Styrofoam, or lab equipment under lab benches or above shelves/cabinets throughout the lab. This can be a safety as well as a fire hazard.
- Promptly notify the laboratory safety coordinator or PI and contact your maintenance or equipment service provider when lighting, vacuum lines, or other laboratory equipment is not functioning properly. Until the repair is completed, tag the affected equipment as "out of service". Advise maintenance/service personnel of hazards they may encounter during repair.

Working alone –

Prior approval of the Principal Investigator is required for working alone after hours.

Generally, it is prudent to avoid working alone in a laboratory. Individuals working alone should make arrangements with other lab personnel to check on them periodically, or ask security guards to check on them. High Risk Procedures must not be performed by personnel working alone.

Unattended experiments –

High Risk Procedures should not be left unattended, but if circumstances require that the experiment run when the lab is not occupied, seek the approval of the Principal Investigator or laboratory safety coordinator in advance.

Water taps should not be left open and unattended because of the potential for flooding. This includes running tap water for cooling, or filling tanks or other containers with water.

Safe use and disposal of sharps –

Handle and store laboratory glassware with care to avoid damage; do not use damaged glassware. Dispose of broken glassware using broken glass disposal boxes.

Choose safe cutting devices – use of straight razors should be avoided in favor of safety scalpels or other alternatives. Straight razors should not be used when a safer cutting device (e.g., scissors, box cutter) is more appropriate.

Uncontaminated razor blades and needles must be disposed of in puncture-resistant hard-sided sharps disposal boxes. If red sharps boxes are used, mark out any biohazard warnings and write "not a biohazard" on the box. For safe disposal of contaminated sharps, see the Biological Safety or Chemical Safety Sections, or the Radiation Safety Manual, as appropriate.

Safe use of laboratory equipment –

In general:

- Use equipment only for its designated purpose.
- Be familiar with the manufacturer's instructions before using.

- Inspect equipment for damage; do not use damaged equipment.

Use of laboratory equipment requiring highly specialized training shall be considered a high risk procedure if accidental misuse of the equipment could cause injury or damage to the building. Lab-specific standard operating procedures, including training for operators, must be developed and approved by the PI.

Electrical safety –

Included below are requirements from the Electrical Safety Policy that are commonly applicable to laboratories. See the Electrical Safety Policy for further details and additional requirements.

- Extension cords
    - Extension cords shall not be used as substitutes for permanent wiring. Extension cords may remain in place for no more than 30 days if they are in continuous use and otherwise comply with requirements for extension cords. Contact the appropriate maintenance department to install permanent wiring where needed.
    - Extension cords shall not be plugged into one another so as to increase the overall reach.
    - All extension cords purchased or in use shall be the three wire type and have a minimum wire size of 14 AWG.
- Power strips
    - Power strips may be used to supply office equipment.
    - Power strips shall not be plugged into one another so as to increase the overall reach or number of available outlets.
    - All power strips purchased or in use shall have a cord 6 feet or less in length, a 15 amp circuit breaker/fuse, and a surge protector.
- Extension cords and equipment cords shall not be run through doorways or in any other manner that may result in damage to the cord unless cord protectors are in place.
- The purchase or use of cube taps to expand the capacity of an outlet is prohibited.

Some laboratories may have other electrical hazards present and may therefore require additional electrical safety precautions. Specifically:

- Use of high voltage power supplies shall be considered high risk procedures requiring PI approval.
    - Written lab-specific safety procedures, approved by the PI, shall be developed. These may reference the manufacturer's instruction manual, but must include specific instructions for the experiment being conducted.
    - Any personnel working with high voltage power supplies shall be trained on the hazards and shall be familiar with manufacturer-supplied safety information and lab-specific procedures.
    - Warning signs shall be in place when high voltage power supplies are in use.

- Where laboratory personnel maintain or service hard-wired electrically-powered laboratory equipment, the Hazardous Energy Control Policy applies. For more information and to arrange required training, see the OESO webpage on Lockout/Tagout and contact OESO – Occupational Hygiene and Safety at 919-684-5996.
- Labs are reminded that the Electrical Safety Policy requires that electrical installations, modifications, and repairs are to be made only by Duke-employed electricians and other trades performing electrical work within the scope of their trade, or authorized contractors.
- If the lab will create or modify electrically-powered equipment, see paragraph below on *"Controlling exposure to hazardous energy"*.

Safety during field research–

Refer to the Fieldwork Safety Policy and Fieldwork Safety Plan Template for requirements and guidelines related to fieldwork. The Safety Guidelines for Fieldwork provides reference information that may be useful for researchers conducting field research.

Safe use of machine tools and portable power tools –

Refer to the Academic Shop Policy for requirements and guidelines related to use of machine tools and portable power tools in the laboratory environment.

Safe use of vehicles–

Refer to the Vehicle Safety Policy for requirements and guidelines related to driving Duke-owned or leased vehicles and for the Corporate Risk policy on use of personal vehicles for Duke business.

Controlling exposure to hazardous energy –

Where laboratory personnel maintain laboratory equipment connected to compressed air, steam, electricity or other hazardous energy sources, the Hazardous Energy Control Policy may apply. For more information and to arrange required training, see the OESO webpage on Lockout/Tagout and contact OESO – Occupational Hygiene and Safety at 919-684-5996.

Procedures that could expose personnel to hazardous energy (in the case of equipment failure or misuse) will be considered high risk procedures requiring a hazard assessment and/or written standard operating procedure. The hazard assessment/written SOP will require the approval of the PI and, in many cases, the department.

Where labs create or modify equipment that uses hazardous energy (including electricity, compressed air, steam, vacuum, etc.), the creation or modification of the equipment and its initial testing will be considered a High Risk Procedure requiring the review of the PI. The lab planning to create or modify such equipment will seek guidance from the department to determine if departmental review and approval will be necessary. A hazard assessment shall be performed, and the review and approval thereof shall be documented in writing and kept with the hazard assessment.

Personal Protective Equipment (PPE)

This section covers personal protective equipment for general physical hazards commonly present in laboratories. For PPE requirements and recommendations for hazardous materials and lasers, see the Biological Safety or Chemical Safety Sections of this Manual, or the Radiation or Laser Safety Manuals, as appropriate.

Laboratory procedures that require specialized personal protective equipment, such as personal fall arrest systems or arc-flash clothing, are considered high-risk procedures. A hazard assessment, written laboratory-specific procedures, and PI approval are required. In some cases, Departmental approval may also be required. OESO may be consulted for advice on specialized PPE and/or review of procedures.

Gloves –

- Thermal gloves should be worn for contact with hot surfaces such as (dry) equipment being removed from ovens or autoclaves, or the inside of a hot oven or autoclave.
- Heat-resistant impermeable gloves must be worn for handling hot liquids. Standard autoclave gloves are not appropriate.
- Cryo-gloves must be worn when retrieving materials from cryogenic freezers.
- Leather or cloth work gloves should be worn to protect the hands from scrapes, scratches, or splinters during materials-handling activities.
- Cut-or puncture-resistant gloves should be worn when working with sharps. If these gloves reduce dexterity, consider wearing a cut-or puncture-resistant glove only on the non-dominant hand. If working with chemicals or infectious materials and sharps, wear the cut- or puncture-resistant glove under the disposable glove. If the outer glove is damaged, remove both pairs of gloves and wash hands thoroughly before continuing.
- Gloves should be worn when working around UV light sources to prevent skin exposure.

Eye/face Protection –

Safety goggles should be worn when working with glassware under reduced or elevated pressures and when handling glassware or liquids at high temperatures. If the risk of splash is high, a face shield should also be worn. Safety glasses should be when there is a risk of eye injury from projectiles.

Skin protection –

If work in the laboratory may expose the skin to cuts, scratches, or burns, laboratory workers should minimize exposed skin through their choice of personal clothing and/or use of a lab coat.

If there is a risk of splash with hot water, wear a standard lab coat, rubberized apron and heat-resistant impermeable gloves.

Foot protection –

Closed-toed shoes should be considered standard attire for laboratory work, especially if there is a risk of dropping hot liquids or laboratory materials, or if materials-handling carts are used.

Hazard Assessment & Documentation of Approval for High-Risk Procedures:

When planning research involving High Risk Procedures (see definitions), the PI (or designee) must perform a hazard assessment and/or develop a laboratory-specific Standard Operating Procedure, which must be approved by the PI, and in some cases by the Department, before beginning work. Documentation of approval must be kept with the hazard assessment/lab-specific SOP. For Chemical High Risk Procedures, see the Chemical Safety Chapter.

PREPARING FOR AND RESPONDING TO EMERGENCIES

Preparedness

Types of incidents

Each lab should consider the types of incidents that could have an adverse effect on people, research efforts, property, and/or the environment and engage in planning efforts aimed at mitigating the impact of the emergency (for example, arranging for critical laboratory equipment to be maintained on emergency power) and on the necessary response for each situation.

Response actions

For possible incidents, the lab should consider and prepare for the response actions that will be needed. Evacuation of the lab may be necessary in some emergency situations. Therefore, lab personnel need to be familiar with how to get out of the building in the event of an emergency, and the location of the lab's designated Emergency Assembly Point. Emergency Assembly Points in "The Site-Specific Fire Plans" for campus buildings can be found on Fire Safety's website at http://www.safety.duke.edu/laboratory-safety/fire-safety.

Written plan

Where a response will be needed at the time of an emergency, a written plan should be prepared by the lab, describing the actions that will need to be taken.

Resources and Equipment

Each lab should make sure that it has the equipment and other resources available to implement its emergency plans. The following resources will be necessary for all research and clinical labs; if additional resources are needed, the Laboratory Safety Coordinator and PI should identify those resources in the written emergency plan, and make sure that they are available.

Emergency Response & Incident Reporting Guide –

Each lab should post an up-to-date copy of the Duke Laboratory Emergency Response and Emergency Reporting Guide near the exit and/or primary telephone for the lab. This guide lists emergency contacts and procedures for various types of incidents.

Emergency Contact Information –

Each laboratory unit or department should keep emergency contact information for laboratory personnel, especially the Principal Investigator and Laboratory Safety Coordinator. The purpose of this information is twofold:

- In the event of a fire, flood, or other emergency affecting the lab, to allow emergency response personnel to reach someone in the lab; and
- In the event of a lab-related or other incident requiring a member of the lab to seek medical attention, to allow the Lab Safety Coordinator, PI, or department representative to reach a family member or friend of the affected personnel.

To facilitate contact with the lab in case of emergency (such as fire or flooding in the lab), labs should also post contact information (including after-hours phone numbers) for key laboratory personnel on or near the door to the lab. OESO has a laboratory door sign template that may be used.

Fire extinguishers –

See the Fire Safety Section of the Laboratory Safety Manual for information on the types of fires and appropriate fire extinguishers.

Emergency Response

Most of the following information is also found in the Duke Laboratory Emergency Response and Incident Reporting Guide, which should be posted near the main exit and/or mail telephone for each lab. Contact OESO Laboratory Safety at 919-684-8822 if you need a copy of this Guide.

Personal Injury

- All work-related injuries and illnesses (including chemical spills onto the body), regardless of the severity, must be reported to the supervisor.
- If needed, obtain medical care from the nearest Employee Occupational Health and Wellness location (call 919-684-3136 for more information (after hours, call 919-684-8115)), or through one of the other providers listed at http://www.hr.duke.edu/benefits/medical/workcomp/medical.php.
- Complete a Report of Work-related Accident, Injury or Illness.
- See the Workers' Compensation website for additional information, or call Workers' Compensation at 919-684-6693.

Fire

See your building's site-specific fire plan (available on the OESO website) for emergency procedures related to a fire.

Other incidents affecting property or the environment

For EMERGENCIES that may impact building integrity and/or harm people:

- Evacuate the immediate area. If the entire building needs to be evacuated, follow the procedures in your Site-Specific Fire Plan.
- On campus: Call 911 from a campus phone or 919-684-2444 from any phone. Off campus: Call 911.

For other incidents/accidents that do not pose immediate danger to people or the environment, call 919-684-2794 to report the incident. If maintenance support is needed, contact your maintenance provider.

LABORATORY START-UP, AUDITING AND CLOSEOUT

This section has been included to provide guidance to all principal investigators (PIs) and laboratory managers on appropriate start-up, auditing, and close-out procedures. It is imperative that these procedures be followed to ensure compliance with all applicable federal, state and local requirements.

Instructions for Principal Investigators (PIs)

Background

It is the responsibility of each Principal Investigator (PI) to be aware of all applicable safety requirements. Failure to follow safety requirements may lead to an unsafe occupational setting. Such non-compliance may also result in fines from external regulatory agencies such as the Occupational Safety and Health Administration (OSHA).

Procedures

New PIs must complete the "Notice of Laboratory Occupancy" form and fax to the OESO at 919-681-7509 (prior to arrival if possible). Once notice is received, an OESO representative will contact the PI to schedule a visit to the laboratory, at which time all applicable safety policies and procedures will be discussed. Every effort will be made to schedule the on-site visit within the first week of occupancy. Thereafter, laboratory safety audits will be conducted on a periodic basis.

- **Laboratory Door Signs with Emergency Contact Information**

  Each laboratory room should have emergency contact information posted at the door. In the event of an emergency, such as a fire or hazardous spill, response personnel will need to contact those responsible for the laboratory. The sign should include the names of the principal investigator (PI), the lab manager, and a department contact. Office and after-hour phone numbers and/or other contact information should be provided on the sign. Also, any special instructions the PI would like emergency personnel to be aware of can be listed on the sign. **An example of an emergency contact information sign can be found at** http://www.safety.duke.edu/ergonomics/computer-ergonomics/laboratory-door-signs-emergency-contact.

The following special requirements may be applicable to your laboratory operations. See the links for more information and/or call OESO-Laboratory Safety Program 919-684-8822 for guidance.

- **Lab-specific Chemical Hygiene Plan** *(required of all labs that use chemicals)***:** Each laboratory must have a Laboratory-Specific Chemical Hygiene Plan, list of Particularly Hazardous Substances (PHSs) used in the lab, and lab-specific Standard Operating Procedures (SOPs) for any PHSs and nanomaterials used in the lab.

- **Chemical Reporting and Toxic Substance Control Act:** The Department of Homeland Security (DHS) promulgated the Chemical Facility Anti-Terrorism Standards (CFATS) in 2007. This program was designed to secure the nation's chemical infrastructure by identifying high risk chemical facilities and requiring them to implement risk-based performance standards and other requirements. Facilities that manufacture, use, store or distribute certain "chemicals of interest" are covered by these requirements.

  Because of the way DHS defined chemical facilities, colleges and universities such as Duke have to comply with this regulation. To determine if we must institute additional security measures, OESO must determine Duke's aggregate quantities of these chemicals. For most of the chemicals on the list, we have determined that our aggregate quantities are well below the DHS thresholds. However, the list includes some chemicals that Duke has or could have in quantities close to the thresholds. These chemicals, along with other chemicals that are tightly regulated by the Environmental Protection Agency, are on Duke's "Targeted Chemical Reporting List".

  The Toxic Substance Control Act (TSCA), administered by the Environmental Protection Agency (EPA), was established to ensure that the human health and environmental effects of chemical substances are identified and properly controlled prior to placing these materials into commerce (Fact Sheet). Although research laboratories such as those found at Duke University are exempted from many of the requirements of this act, certain provisions still apply.

  For compliance with Chemical Reporting and TSCA, complete the annual report found on the Laboratory Safety and Waste Management System found by going to www.safety.duke.edu, selecting "Laboratory Safety", then "Lab Safety and Waste Management".

- **Chemical Waste Disposal**: All new PIs must carefully review the Duke Chemical Waste Policy. If any chemical waste will be produced, information on proper disposal can be found at: http://www.safety.duke.edu/environmental-programs/hazardous-waste.

- **Application for Possession of Radioactive Materials:** An application must be submitted to the Radiation Safety Officer (RSO) for the use of all radioactive materials. Only after the application has been reviewed and approved by the RSO, shall the laboratory be allowed to purchase or use radioactive materials. Information on how to become an "authorized user" can be found at: https://vmw-oesoapps.duhs.duke.edu/RadSafety/new_au.asp. Contact Radiation Safety Division 919-684-2194 for more information.

- **Registration for Work with Recombinant DNA:** Experiments involving the utilization of rDNA may require approval by the Duke University Institutional Biosafety Committee (IBC) prior to submission to outside agencies and the initiation of experimentation. PIs should refer to the rDNA chapter of the Biological Safety Section of this manual and/or contact OESO - Biological Safety Division 919-684-8822 for more information. To go directly to the rDNA project registration form click here.

- **Written standard operating procedures (SOP) for work with biohazards and/or hazardous chemicals:**
  - Biosafety Level 2 (BSL2) SOP:
  - Hazardous Chemical SOPs

- **Personal Protective Equipment Hazard Assessment:** The PPE Hazard Assessment form must be completed for any required PPE that is not covered in the Lab Safety Manual and lab-specific SOPs.

Laboratory Closeout

Procedures

All laboratory closeouts must be conducted in accordance with standard procedures for the removal of hazardous materials. The OESO, Biological Safety Division (919-684-8822 or labsafety@dm.duke.edu) should be notified as soon as the laboratory closeout/relocation is anticipated (preferably 3-4 months), no less than 30 days prior to the departure date. Notice is given by completing the Laboratory Closeout Notice and forwarding it to labsafety@dm.duke.edu (information is on the form). Upon receipt, the OESO will provide specific instructions for proper shut-down to the laboratory's assigned safety contact. The departing/relocating principal investigator shall be held fully responsible for all Institutional requirements. The laboratory will be cleared for new occupancy only after all requirements are met.

If proper notification is not given, the principal investigator and/or the department will be held responsible for all cost incurred for safe disposal of remaining hazardous material wastes.

The following is a list of requirements which must be met for each class of hazardous agents used before a laboratory is released by the OESO.

Biological Hazards

1. All biological materials (e.g. blood, fresh tissue, bacterial cultures) must be removed from the laboratory by disposing according to Institutional policy, by shipping to another facility while conforming to the approved shipping regulations, or by transferring to another PI. This includes those materials stored in refrigerators, freezers, incubators and cold rooms.
2. All equipment which has come in contact with potentially infectious materials must be properly decontaminated and labeled with the "Laboratory Equipment Statement of Hazard Assessment".
3. All biological waste must be properly decontaminated and disposed of appropriately (autoclave, etc.).
4. All benchtops or other work surfaces on which biological materials were manipulated must be wiped down with an approved disinfectant.
5. The OESO shall determine the appropriate decontamination method for all biological safety cabinets. If formaldehyde gas decontamination is deemed necessary, the departing PI will be financially responsible.

Chemical Hazards

1. All chemical containers must be labeled with the chemical name or a best description of the compound and hazard warning.
2. All chemicals not transferred to another Duke laboratory will be considered chemical waste. Contact OESO-Environmental Programs (919-684-2794) to discuss disposal options.
3. Chemicals being shipped or transferred to another facility must be packaged and labeled according to approved regulations.
4. All benchtops and equipment (including fume hoods) must be cleaned of visible contamination using a compatible cleaning method (e.g. detergent/water solution, ethanol, etc.).
5. All equipment which has come in contact with hazardous chemicals must be properly decontaminated and labeled with the "Laboratory Equipment Statement of Hazard Assessment".
6. Compressed gas cylinders must be returned to their supplier (e.g. National Welders). Cylinders owned by the PI (e.g. lecture cylinders) may be submitted to the OESO-Environmental Programs for proper disposal.

Radiological Material Hazards

1. Notify the Radiation Safety Officer, at 919-684-2194, of intention to terminate authorization.
2. Dispose of all radioactive materials by one of the following methods:
   - Materials can be transferred to another authorized user while complying with all license restrictions of that user. Approval from the Radiation Safety Officer is required prior to radioactive material transfer.
   - Materials can be disposed of through the OESO-Environmental Programs Division.
   - Materials can be shipped to a non-Duke licensee while conforming to all applicable shipping regulations. Radioactive materials will be prepared for shipment by the Radiation Safety Division. *Note: There will be notification/acceptance requirements at the new facility.*

3. Perform a thorough radiation contamination survey of the laboratory, including equipment, to determine if allowable contamination levels are achieved. Those areas found to exceed the allowable limits must be decontaminated and resurveyed until within allowable limits.

APPENDICES

Laboratory Startup/Closeout/Relocation Notices

Laboratory Safety Manual

Section 2
Biological Safety

Table of Contents

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.

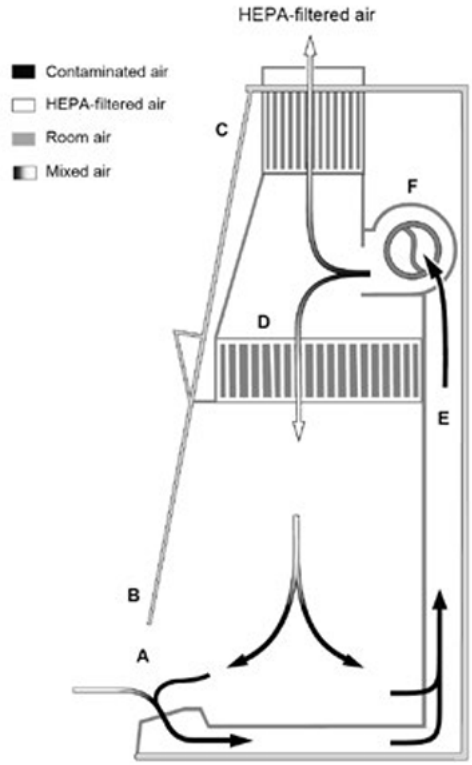
Class II BSC

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.

REFERENCES

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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

Laboratory Safety Manual

Section 4
Waste Management

INTRODUCTION

PURPOSE

Duke University must take precautions to protect its employees, visitors, students, neighbors and the environment from the improper disposal of chemical, and radioactive, and medical wastes.

RESPONSIBILITES

Departments shall:

- Ensure that all waste generators within their department comply with the chemical, radioactive, and medical waste management polices outlined in Section VII of the Duke University Safety Manual.

Occupational and Environmental Safety Office (OESO) Environmental Programs Division:

- Assures that **chemical and radioactive wastes** are appropriately handled and disposed of in accordance with State and Federal laws.

Chemical Waste –
The Resource Conservation and Recovery Act of 1976 established requirements for the management of chemicals deemed to be hazardous to the environment. Specifically, such waste must be managed from its generation (cradle) to its final destruction (grave). Duke University/Medical Center is classified as a large quantity generator of hazardous waste. A detailed list of responsibilities and procedures for the management of chemical wastes can be found in Section VII of the Duke University Safety Manual.

Radiological Waste –
The Nuclear Regulatory Commission (NRC) established requirements for the management of radioactive materials including wastes. Specifically, radioactive waste must be monitored similarly to all other radioactive materials under a license from the NRC or the State approved program. Duke University holds two broad licenses allowing the use of isotopes up to atomic number 83. Researchers who wish to use radioisotopes are licensed by the Radiation Safety Division of the OESO. A detailed list of responsibilities and procedures for the management of radiological wastes Section VII of the Duke University Safety Manual.

Medical Waste – Refer to Section2, Biological Safety, Chapter 6 Waste Management.

Laboratory Safety Manual

Section 3
Chemical Safety

Duke Chemical Hygiene Plan

INTRODUCTION

PURPOSE

All laboratories using hazardous chemicals are required to comply with 29 CFR 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories*. This standard requires that the employer develop a written Chemical Hygiene Plan (CHP) capable of protecting employees from the health hazards associated with hazardous chemicals in the laboratory.

This section of the Laboratory Safety Manual is Duke University's general CHP and is intended to highlight general laboratory practices that are necessary for protecting workers from exposure to hazardous chemicals. **In addition, each laboratory will develop a written laboratory-specific chemical hygiene plan that will be made available to all laboratory staff**.

DEFINITIONS

Definitions for selected terms used in this policy are included below. Please see paragraph (b) of OSHA's Occupational Exposure to Hazardous Chemicals in Laboratories standard (29 CFR 1910.1450) for additional definitions related to the chemical hygiene program.

Chemical Hygiene Plan – A written program developed and implemented by the employer which sets forth procedures, equipment, personal protective equipment and work practices that (A) are capable of protecting employees from the hazards presented by hazardous chemicals used in that particular workplace and (B) meets the requirements of paragraph (e) OSHA's Hazardous Chemicals in Laboratories Standard (29 CFR 1910.1450).

Chemical Hygiene Officer – An employee who is designated by the employer, and who is qualified by training or experience, to provide technical guidance in the development and implementation of the provisions of the Chemical Hygiene Plan.

Chemical High Risk Procedures – Lab procedures that pose significant risk of serious injury or major property damage if a malfunction were to occur (such as a utility outage, runaway reaction, container failure, or chemical spill/release) and/or which require any of the following:

- Engineering controls more specialized than good room ventilation, chemical fume hoods, biological safety cabinets and/or local exhaust such as snorkel or canopy hoods.[1]
- Personal protective equipment in addition to gloves, lab coats, eye/face protection and/or chemical or thermal protective aprons or sleeves.
- Chemical-specific first aid treatments or antidotes.

Designated Area – An area which may be used for work with "select" carcinogens, reproductive toxins or substances which have a high degree of acute toxicity. A designated area may be the entire laboratory, an area of a laboratory or a device such as a laboratory hood.

Hazardous Chemical – Any chemical which is classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, pyrophoric gas, or hazard not otherwise classified.

Health hazard – Includes chemicals that are classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific organ toxicity (single or repeated exposure); or aspiration hazard. The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A of the OSHA Hazard Communication Standard (HCS).

Laboratory - A facility where the "laboratory use of hazardous chemicals" occurs. It is a workplace where relatively small quantities of hazardous chemicals are used on a non-production basis.

Laboratory scale – Work with substances in which the containers used for reactions, transfers, and other handling of substances are designed to be easily and safely manipulated by one person. "Laboratory scale" excludes those workplaces whose function is to produce commercial quantities of materials.

Laboratory use of hazardous chemicals – Handling or use of such chemicals in which all of the following conditions are met:

- Chemical manipulations are carried out on a “laboratory scale”;
- Multiple chemical procedures or chemicals are used;
- The procedures involved are not part of a production process, nor in any way simulate a production process; and
- “Protective laboratory practices and equipment” are available and in common use to minimize the potential for employee exposure to hazardous chemicals.

[1] More specialized engineering controls include (but are not limited to) inert-atmosphere glove boxes used for employee safety, ventilated gas cabinets, oxygen monitors, and/or toxic gas monitors.

Medical Consultation – A consultation which takes place between an employee and a licensed health care provider for the purpose of determining what medical examinations or procedures, if any, are appropriate in cases where a significant exposure to a hazardous chemical may have taken place.

Particularly Hazardous Substances (PHSs)– PHSs include common chemicals that are "select" carcinogens, reproductive toxins, highly acute toxins, as well as substances that are highly reactive.

Physical hazard – A chemical that is classified as posing one of the following hazardous effects: explosive; flammable (gases, aerosols, liquids, or solids); oxidizer (liquid, solid, or gas); self-reactive; pyrophoric (liquid, or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; or in contact with water emits flammable gas; or combustible dust. The criteria for determining whether a chemical is classified as a physical hazard are in Appendix B of the Hazard Communication Standard.

Protective laboratory practices and equipment – Those laboratory procedures, practices and equipment accepted by laboratory health and safety experts as effective, or that the employer can show to be effective, in minimizing the potential for employee exposure to hazardous chemicals.

Safety Data Sheets (SDSs) – Written or printed material concerning a hazardous chemical that is prepared in accordance with the OSHA Hazard Communication Standard.

RESPONSIBILITIES

Department Heads shall:

- Ensure compliance with all requirements for chemical safety and hygiene within their departments.
- Provide direction on the departmental approach to developing and implementing laboratory-specific Chemical Hygiene Plans.
- Establish criteria and processes for Departmental review of hazard assessments/laboratory-specific Standard Operating Procedures for chemical High Risk Procedures. Departmental reviews must be documented in writing; documentation is to be kept with the Laboratory-Specific Chemical Hygiene Plan.)

Principal Investigators (Research Labs)/Directors (Clinical Labs) shall designate a Laboratory Chemical Hygiene Officer (CHO) and shall support the Laboratory CHO by:

- Ensuring compliance with all requirements for chemical safety and hygiene within the laboratory or laboratories.
- Provide direction and support to the Laboratory CHO on implementing laboratory-specific Chemical Hygiene Plans and related documentation, and in completing the Targeted Chemical Report.
- Perform a hazard assessment and develop/approve lab-specific Standard Operating Procedures for all chemical high risk procedures. Written documentation of approval is to be kept with the Laboratory-Specific Chemical Hygiene Plan.
- When required by the department, submit High Risk Procedure hazard assessments for departmental review.

Laboratory Chemical Hygiene Officers shall:

- Develop the Laboratory-Specific Chemical Hygiene Plan for the lab, and ensure implementation (such as training and coordinating audits).
- Compile all applicable information listed in the Laboratory-Specific Chemical Hygiene Plan "Checklist" and append to the plan.
    - The inventory of PHSs and written SOPs are the responsibility of the Lab CHO unless these responsibilities have been delegated to another employee.
    - The appended information must be reviewed and updated annually along with the plan itself; this review will be documented by signing the "Annual Review and Updates" section of the Laboratory-Specific Chemical Hygiene Plan.
- Train laboratory employees and students when there is new information or when a new employee or student is assigned to the laboratory. Document training using the "Laboratory-specific chemical hygiene training documentation" form provided in the Laboratory-Specific Chemical Hygiene Plan. Training must be documented for all paid employees (graduate students, post-docs, paid work study, or other wage or salaried personnel) in the laboratory; it is recommended that training be documented for non-paid students as well. *Topics to be included in the training are detailed on the training documentation checklist.*
- Read and be familiar with the University Chemical Hygiene Plan (CHP) (this section of the Laboratory Safety Manual).

- Be familiar with additional universal requirements of this program, such as hazardous waste disposal and departmental emergency planning.
- Complete the Targeted Chemical Report to meet Department of Homeland Security (DHS) and Environmental Protection Agency (EPA) requirements, unless this responsibility has been delegated to another employee.
- Coordinate interaction with the Occupational and Environmental Safety Office, Employee Occupational Health and Wellness, and other Duke departments or outside agencies as needed for laboratory audits, incident/accident investigation, medical examinations, exposure monitoring, and emergency response.
- Post the Emergency Response and Incident Reporting Guide (available from OESO – 919-684-2794) in the lab near the door or main laboratory telephone.
- Prepare Safety Data Sheets for chemicals produced in the laboratory for inter-laboratory use, unless this responsibility is delegated to another laboratory employee.

Laboratory Employees and Students shall:

- Plan and conduct laboratory operations in accordance with this Chemical Hygiene Plan and the Laboratory-Specific documentation.
- Read, at a minimum, all parts of the CHP that are listed on the "Training Documentation" form.
- Check off all sections from the "Required Reading List" in the "Laboratory-specific chemical hygiene training documentation" form once they have been read.
- Sign the "Laboratory-specific chemical hygiene training documentation" form.
- Abide by all policies and procedures described in both the Duke Chemical Hygiene Plan (this chapter of the Lab Safety Manual) and the Laboratory's CHP.
- Report all chemical spills, injuries, illnesses, possible over-exposures, other incidents, and unsafe conditions to their supervisor and to the appropriate university support groups as described in the Duke Chemical Hygiene Plan and Laboratory Emergency Response and Incident Reporting Guide.

The Occupational and Environmental Safety Office (OESO) shall:

- Review the Duke University Chemical Hygiene Program annually and update as needed.
- Develop and provide general laboratory safety training.
- Conduct exposure assessments and evaluate exposure control measures as necessary.
- Provide emergency response for chemical spills.
- Investigate laboratory accidents, including injuries and exposures.
- Maintain employee exposure records.
- Develop a list of chemicals which require additional control measures (Particularly Hazardous Substances).
- Review and approve high risk procedures specified in the Laboratory-Specific Chemical Hygiene Plan.
- Conduct periodic safety audits of laboratories.

Employee Occupational Health and Wellness shall:

- Provide medical consultation and surveillance as needed.
- Provide medical care for employees who have been injured or exposed to hazardous agents in the lab.

Maintenance Departments shall:

- Annually certify chemical fume hoods.
- Maintain chemical fume hoods and chemical fume hood monitors in working order.

LABORATORY-SPECIFIC CHEMICAL HYGIENE PLAN

Each laboratory shall develop written documentation of the following:

- The identity of the laboratory and names of the Department Head and Departmental Safety Coordinator, the Principal Investigator or Director, and any other person responsible for implementation of the site-specific chemical hygiene plan
- The name of the chemical hygiene officer (or lab safety coordinator) for the lab
- Contact information and emergency numbers for responsible parties
- Location of Safety Data Sheets (SDSs)
- Inventory of Particularly Hazardous Substances. (A broader chemical inventory is encouraged.)
- Lab-specific strategies for controlling exposures and hazards
- List of generic and lab-customized Standard Operating Procedures that are relevant for the lab
- If applicable, a summary of chemical High Risk Procedures and documentation of approval, along with written hazard assessments and/or lab-specific SOPs for each
- Lab-specific information for chemical waste disposal
- Emergency Procedures
- Sign-off page to indicate that the CHP is accurate and has been reviewed (and updated as needed) on an annual basis
- Documentation of laboratory-specific chemical hygiene training

The above requirements can be met by completing the Laboratory-Specific Chemical Hygiene Plan template and appending any additional required documentation.

CHEMICAL HAZARD INFORMATION AND TRAINING

Required Hazard Awareness Training

General Lab Safety Training:

Each laboratory employee and student shall be required to take a general laboratory safety course online before beginning work in the lab and annually thereafter.

Laboratory-Specific Training:

The Principal Investigator or Laboratory Chemical Hygiene Officer shall conduct laboratory-specific hazard awareness training for each laboratory employee or student before that person begins working in the lab. This training must cover all items specified in the laboratory-specific training checklist, included with the Laboratory-Specific Chemical Hygiene Documentation. This hazard awareness training shall be reviewed as necessary and any time a new hazard is introduced. The PI or Laboratory CHO shall review staff knowledge at least every three years to verify that staff can perform their assigned tasks safely.

Laboratory Chemical Hygiene Officer Training:

The Laboratory Chemical Hygiene Officer (LCHO) from each lab will be required to attend a one-time in-person Chemical Hygiene Officer Training provided by OESO. This course will review resources available to help the LCHO to develop lab-specific SOPs and deliver lab-specific training.

Required Sources of Chemical Hazard Information

Labels:

All containers of hazardous chemicals purchased from a vendor, supplied by another laboratory group, or supplied to another laboratory group must be labeled with the following information:

- Product identifier;
- Signal word;
- Hazard statement(s);
- Pictogram(s);
- Precautionary statement(s);
- Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party.

Laboratories shall not remove or deface these labels. Chemical containers complying with the previous version of the OSHA Hazard Communication Standard need not be re-labeled.

Workplace containers must be labeled, tagged, or marked with either:

- The required information from the label on the original container (see above label requirements), or
- The product identifier AND words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the chemicals and which, in conjunction with the other information immediately available, will provide employees with specific information regarding the hazards of the chemical.

Safety Data Sheets (SDSs):

A Safety Data Sheet (SDS) is written or printed material concerning a hazardous chemical that is prepared in accordance with the OSHA Hazard Communication Standard. It is intended to provide lab personnel and emergency responders with information that will help them work with that substance in a safe manner. The SDS includes information such as ingredients, physical and health hazards, relevant exposure limits, handling and storage recommendations, physical and chemical properties, reactivity, toxicity, first aid, fire-fighting and accidental release measures.

SDSs must be provided by all chemical manufacturers and importers for each hazardous chemical that they produce or import. SDSs are available online for most major manufacturers; smaller manufacturers may distribute paper copies with the product.

Labs must retain copies of any SDSs that they receive, and must provide employees with access to SDSs for all chemicals in the laboratory. Labs may use the SDS resources available on the OESO website to help them locate SDSs.

Electronic availability of these documents is an acceptable alternative to hardcopies only if the Principal Investigator or Laboratory Chemical Hygiene Officer has ensured that all laboratory personnel have demonstrated the ability to locate the necessary information and there is a backup means for obtaining an SDS in the case of failure of the primary electronic system.

Inventory of Particularly Hazardous Substances:

Each laboratory is required to maintain an inventory (list) of all Particularly Hazardous Substances. Laboratories are encouraged to include other chemicals on the inventory as well.

Particularly Hazardous Substances are those chemicals which may present extreme risk potential to laboratory workers if not handled appropriately; therefore, these substances may require additional controls when used in the laboratory. A list of Particularly Hazardous Substances (PHSs) has been prepared by the Occupational and Environmental Safety Office. This list includes common chemicals that are "select" carcinogens, reproductive toxins, and highly acute toxins. This list also includes substances that are highly reactive such as explosives, flammable solids, peroxide formers, oxidizers, and compounds that are reactive with air or water. Note that the OESO list of PHSs is not an all-inclusive list. Many other chemicals that are not listed may also possess extremely hazardous properties. Laboratories are responsible for assessing the hazards of chemical materials that they may use or synthesize, and to take appropriate steps to implement safety controls.

Regulations, Polices, and Procedures:

Occupational Exposure to Hazardous Chemicals in Laboratories standard – The Occupational Safety and Health Administration published this standard, which requires employers to inform laboratory employees of chemical hazards and to limit employee exposures to these hazards. All laboratory employees must have access to this standard.

Occupational Exposure Limits (OELs) – The OELs are airborne concentrations that have been determined to be safe for employees for a set period of time. The Occupational Safety and Health Administration (OSHA) has published Permissible Exposure Limits (PELs) for a number of chemicals, and the American Conference of Governmental Industrial Hygienists (ACGIH), a professional organization, has published

Threshold Limit Values (TLVs). PELs and/or TLVs, or exposure limits published by other countries, may be specified in the SDS. Employees must be familiar with exposure limits for the chemicals in use in the lab.

Duke University Safety Manual – Laboratory employees must be familiar with the various policies in the Duke University Safety Manual. Of particular relevance for chemical safety, the Hazardous Materials chapter contains valuable definitions and guidance related to safe storage of hazardous materials, including flammables, compressed gas cylinders, cryogens, corrosives, and liquefied petroleum gases.

Chemical Information for Materials Produced in the Laboratory:

Intra-laboratory use of chemicals of known composition – when a chemical of known composition is produced and determined to be hazardous, the principal investigator or laboratory chemical hygiene officer must ensure that personnel who use this chemical are provided with appropriate training and controls.

Intra-laboratory use of chemicals of unknown composition – when a chemical of unknown composition is produced in the laboratory, it must be considered a "Particularly Hazardous Substance" and handled accordingly. Each investigator or laboratory supervisor has the responsibility to identify and characterize these unknown chemicals as soon as possible so that it may be determined whether or not they are hazardous.

Chemicals produced for inter-laboratory use – If a lab produces a chemical for distribution outside of the laboratory, then all requirements of OSHA's Hazard Communication Standard (29CFR1910.1200) must be met. The provisions of this standard are presented in Duke's Hazard Communication Policy and include hazard determination, development of labels, and preparation of Safety Data Sheets.

Labs may contact the OESO Occupational Hygiene and Safety Division (919-684-5996) for additional information about the required content of labels and SDSs.

Recommended Chemical Safety Resources

Prudent Practices in the Laboratory:

Published by the National Research Council, this book is an essential resource for chemical hygiene and safety. Particularly useful are the Laboratory Chemical Safety Summaries included for many common laboratory chemicals in Appendix B.

Safety in Academic Chemistry Laboratories:

Published by The American Chemical Society, volume 1 (for students) and volume 2 (for faculty and administrators) provide a basic overview on preventing chemical-related accidents in the lab.

OESO website:

There are a number of useful resources on the OESO webpage. Many of the links relevant to laboratory employees are organized on the Laboratory Safety page under "Chemical Hygiene". Note also that the OESO website provides access to toxicology information through the Registry of Toxic Effects of Chemical Substances. To access this, go to the Chemical Hygiene page, click on "SDS Resource-CCOHS", and then click on the "RTECS" link on the left side of the page.

SAFE USE OF CHEMICALS

Overview of general strategy (hierarchy of controls)

The general strategy for keeping employees safe during work with chemicals (or other workplace hazards) is to use a hierarchy of controls that places emphasis on keeping hazards out of the workplace when possible. When use of hazardous chemicals is necessary, the preferred controls are those which remove the hazard from the workplace or place a barrier between the worker and the hazard (engineering controls) followed by work practices and personal protective equipment (PPE), which require more effort on the part of the individual employee.

Elimination/substitution of hazards

When planning research or clinical laboratory activities, consider the hazards of the chemicals that will be used. If possible, select an alternative procedure that uses less hazardous chemicals, or that substitutes a less hazardous form of the same chemical. Here are some examples:

- Phosphate assay: Some phosphate assay methods require heating perchloric acid, which can create explosive crystals in fume hood ductwork. Instead, use a method that does not call for perchloric acid, or purchase a phosphate assay kit.
- Acrylamide gels: Acrylamide is a Particularly Hazardous Substance (possible human carcinogen). Avoid potential exposure to acrylamide powder by purchasing precast polyacrylamide gels.
- Xylene: Consider using PARAclear or another environmentally-safe clearing agent instead of xylene to reduce exposure and disposal concerns.
- Other examples: See OESO's Safer Alternatives webpage for other recommended substitutions.

Controlling Exposures & Hazards – General Strategies

Engineering Controls:

Engineering Controls are designed to move an air contaminant away from employees and/or to contain or isolate the hazard to prevent exposure. Some common types engineering controls are discussed below.

Chemical Fume Hoods –

Chemical fume hoods are the primary containment devices used to protect personnel and the laboratory environment from hazardous or irritating chemicals that may become airborne through volatilization or aerosolization.

- Use a chemical fume hood when working with
    - Particularly Hazardous Substances that are volatile or that are in powder form,
    - Other volatile compounds,
    - Chemicals with a strong odor, or
    - Other materials as indicated by the chemical- or lab-specific Standard Operating Procedure.
- Follow these work rules when working in a chemical fume hood:

  - Make sure your fume hood has been certified within the last year. If not, contact your maintenance provider so that they can arrange for certification (often through a contractor).
  - Check the air flow monitor before each use. It should show that the hood is under negative pressure. (An alarm should sound if flow is too low.) See instructions below if the hood is not functioning correctly.
  - Keep the fume hood clear of clutter – only those materials necessary to the procedure at hand should be placed inside the hood's work space. Additional objects in the work space may affect the hood's air flow pattern and compromise employee safety.
  - Elevate large equipment that must be in the hood at least two inches off the base of the hood interior. This will help air flow as intended inside the hood.
  - Route service connections (vacuum, electrical cords, etc.) under the airfoil so that they don't interfere with the operation of the sash.
  - Keep vertical sashes in the lowest practical position while working. For hoods with horizontal sash panels, one panel of the horizontal sash should be positioned between the user's body and the work in the hood. (The user should reach around the sides of this panel to work.)
  - Perform work tasks at least 6-8 inches behind the hood opening.
  - Close the hood sash when not in use.

- *A special note for working with perchloric acid – Using perchloric acid in a standard fume hood can lead to accumulation of explosive perchlorate salts in the ductwork. Before using heated (>150°C) OR concentrated (>85%) perchloric acid in any chemical fume hood, contact OESO at 919-684-8822 for approval.*
- If your fume hood is not functioning properly, stop working in the hood, then close the sash and label the hood to indicate that it is not working. If hood contents could create a hazardous situation in the room (even with the sash down), leave the room and contact OESO at 919-684-2794. Once the immediate hazard has been addressed, remove hazardous materials from the hood & store in a safe place, and complete the Laboratory Certification of Hazard Assessment, then call your maintenance provider to request repair. The maintenance provider may request that the inside of the hood be cleaned, depending on the nature of the repair.
- If the lights or plumbing (water, sink drain, air, vacuum, or gas) in the hood are not working, remove hazardous materials from the hood & store in a safe place, then call your maintenance provider to request repair. The maintenance provider may request that the inside of the hood be cleaned, depending on the nature of the repair.

Biological Safety Cabinets –

BSCs provide filtered air inside the cabinet, and filter the air that leaves the cabinet. Though some biological safety cabinets are exhausted, their exhaust ducts may be under positive pressure. These cabinets are primarily intended to protect employees from biological hazards and should not be used for

chemical hazards unless there is no chemical fume hood available and the use has been approved by OESO.

Local Exhaust ventilation –

Local Exhaust ventilation can be used where there is a localized source of chemical vapors that can be captured. Examples include snorkel-type exhaust and downdraft sinks. Local exhaust should only be installed with the involvement of the facilities group for your building (Facilities Management Department for University buildings, or Engineering and Operations for Medical Center buildings) and with the approval of OESO.

Isolation devices –

These devices physically separate a contaminant-generating process from the work environment. These will often involve a sealed acrylic box, and may be combined with local exhaust.

Process modification –

This involves changing the temperature or pressure at which an experiment is conducted, or using an inert gas or other change in the experimental procedure to reduce the likelihood of exposure or other incident.

Procurement Controls:

Procurement Controls involve controlling employee exposures by making chemical purchasing decisions that enhance employee safety. For example, labs should

- *Order only needed amounts* – Order an amount that will be used in the foreseeable future; don't order larger quantities for the bulk discount. Having a larger amount on hand means that there is a greater potential for a harmful exposure (or, in the case of flammables, a fire), and may lead to additional disposal costs in the future.
- *Order a less hazardous form of the same chemical* – Use the logic below to help choose the least hazardous physical form that will work for your application.
    - Dilute solutions are generally safer than more concentrated solutions.
    - Aqueous solutions are generally safer to handle than powders requiring reconstitution.
    - Pellets, tablets, granules, or flakes are generally safer to handle than powders.
- *Purchase the chemical in a safer container* – Order chemicals in shatter-resistant containers or other containers that enhance employee safety.
    - Shatter-resistant containers – When ordering corrosives or highly flammable chemicals, choose containers that are less likely to break, such as metal, plastic, or PVC-coated glass. These options will reduce the risk of exposure or fire if the container is dropped.
    - Pre-weighed vials with rubber septum – When ordering hazardous powders, consider purchasing in a pre-weighed vial with a rubber septum. This eliminates the need to handle the powder, as the diluent can be injected directly into the container.
- *Check the existing inventory before ordering* – Maintain a chemical inventory so that lab members can check the availability of a chemical in the lab before ordering more.
- *Consider borrowing* – If you need only a small amount of a chemical, consider asking another lab if you can use or borrow some, rather than purchasing a supply for your lab.

Work Practice Controls:

Housekeeping –

General housekeeping is often overlooked, but is very important in keeping laboratory employees safe. See the General Housekeeping, Storage of Equipment, and Maintenance requirements in the General Safety Section. In addition:

- Wipe down benchtop surfaces regularly to avoid contaminating the work or employees' clothing.
- Replace bench liners when visibly contaminated.

Working alone –

Working alone with hazardous chemicals should be avoided if possible. If working alone will be necessary, seek the approval of the principal investigator or laboratory safety coordinator, and make sure that someone in the lab knows your plans.

Unattended experiments –

Experiments involving hazardous chemicals should not be left unattended, but if circumstances require that the experiment run when the lab is not occupied, seek the approval of the Principal Investigator or laboratory safety coordinator in advance.

Safe use and disposal of sharps–

Handle and store laboratory glassware with care to avoid damage; do not use damaged glassware since this could lead to chemical exposure. Dispose of broken glassware using broken glass disposal boxes.

Razor blades and needles must be disposed of in puncture-resistant hard-sided sharps disposal boxes. If red sharps boxes are used, mark out any biohazard warnings and write "not a biohazard" on the box.

Contact OESO Environmental Programs at 919-684-2794 to determine if chemically contaminated razor blades, needles, and glassware needs to be disposed of as chemical waste.

Safe use of laboratory equipment –

- Use equipment only for its designated purpose.
- Be familiar with the manufacturer's instructions before using.
- Inspect equipment for damage; do not use damaged equipment.

Manipulating chemicals –

Plan your work to minimize hand (glove) contact with chemicals. Handle chemicals in closed containers whenever possible, use care when pouring, and use tools that minimize glove contact with the chemical. Where contact with chemicals is unavoidable, select gloves that are impermeable to that chemical. You can consult one of the glove penetration guides found on OESO's webpage for Personal Protective Equipment.

Food and drink –

Food and drink shall not be consumed or stored in areas used for laboratory operations. If food and drink are to be allowed in the laboratory at all, there must be designated clean areas and all employees must observe good hygiene in these areas (no gloves, no contaminated objects moved from other parts of the lab into these areas).

Personal hygiene –

- Wash hands before donning and after removing gloves, and any time that hands may be contaminated. In order to avoid contaminating "clean" surfaces, remove gloves before handling objects such as doorknobs, keyboards, telephones, and other objects that will be handled by coworkers without gloves.
- Wash hands before eating, drinking, smoking, or applying cosmetics.
- Wear standard personal protective equipment (detailed below) when in the lab and remove any contaminated PPE before leaving the laboratory area.

Minimizing exposures for maintenance personnel –

- Maintenance personnel have access to laboratory rooms to perform routine tasks (such as changing light bulbs or inspecting eyewashes) and repair hoods, sinks, vacuum lines, and other lab equipment. They may not be familiar with the hazards of laboratory chemicals or the abbreviations that may be used on workplace container labels. Also, the maintenance task could accidentally cause containers in the work area to tip over, creating a hazard for both maintenance and lab personnel. Therefore, lab workers must remove chemicals from areas where maintenance will need to work, and clean surfaces in those areas to limit exposure. The Laboratory Certification of Hazard Assessment will need to be filled out and posted on the equipment needing repair.
- If maintenance personnel enter the lab for routine tasks, lab personnel will need to move chemicals away from the maintenance work area and may need to answer questions about hazardous materials that have been used around that equipment.
- To facilitate the ability of maintenance to contact lab personnel during maintenance tasks (or emergencies), labs should post contact information for key lab personnel on or near the door to the laboratory.

<u>Storage/Transport/Disposal:</u>

Chemical storage –

- Store chemicals in quantities that are as low as practical.
- Make sure that all chemical containers are labeled according to requirements listed on page 8 .
- Store chemicals in compatible storage groups, and away from incompatibles – compatibility information should be included on the chemical's SDS.
    - For additional guidance, check the list of Compatible Storage Groups in *Prudent Practices in the Laboratory* (National Research Council).
    - Store acids and bases separately.
    - Store flammables and oxidizers separately.
    - Store corrosives away from metal (unless the metal has a corrosion-proof coating). Do not store corrosives under the sink.
    - Store water reactives away from sinks and water-based solutions.

- Follow the storage guidelines outlined in the Duke University Safety Manual Chapter on Hazardous Materials for flammable and combustible liquids, compressed gas cylinders, cryogens, corrosives, and liquefied petroleum gases.
- Use unbreakable secondary containers (e.g., a bin) for high-hazard materials (including all PHSs).
- Periodically examine stored chemical containers for container and label integrity. Faded or damaged labels should be replaced. Leaking or damaged containers should be disposed of through OESO Environmental Programs (919-684-2794).

Transporting chemicals –

- Take precautions to avoid dropping or spilling chemicals.
    - When possible, have chemical purchases delivered directly to the laboratory.
    - Make sure that chemical containers are sealed during transport.
    - Carry breakable containers in specially-designed bottle carriers or leak-resistant, unbreakable secondary containers.
    - When transporting chemicals on a cart, use a cart that is suitable for the load and one that has high edges to contain leaks or spills. The cart should be capable of negotiating uneven surfaces without tipping the chemical container or the cart.
    - Transport chemicals by traveling least-trafficked routes. When possible, use freight elevators.
    - Gas cylinders must be strapped to a hand truck specifically designed for that purpose. Cylinder cover caps must be in place.
- If transporting large amounts of chemicals for a laboratory move, (or any amount of chemicals on a public road), contact the OESO Environmental Programs Division of OESO at 919-684-2794 for consultation on safe packaging and compliance with federal, state, and local laws.
- Shipping of chemicals must be done in compliance with all applicable federal, state, and local laws. Contact the OESO Environmental Programs Division of OESO at 919-684-2794 for consultation on safe packaging and compliance with these laws.

Managing chemical wastes –

- All laboratories that produce chemical waste must understand and follow the requirements of Duke University's Chemical Waste Policy and the Laboratory Chemical Waste Management Practices. These policies cover procedures and timelines for chemical waste pickup.
- For more information on becoming a registered chemical waste generator, contact OESO Environmental Programs at 919-684-2794or see the OESO Environmental Programs' webpage describing the Waste Pickup Request System (part of the Laboratory Safety and Waste Management System).
- Any questions about chemical waste disposal should be directed to OESO Environmental Programs at 919-684-2794.
- Chemicals shall never be disposed of in the trash or via sanitary sewer without the prior written approval of OESO Environmental Programs.

- Avoid storing chemical wastes on the floor to reduce risk of spills. If storage on the floor is unavoidable, place the waste bottle in secondary containment.

Administrative Controls:

Work removal –

In some circumstances, it may be necessary to remove an employee from the workplace, or restrict employees from performing specific laboratory tasks that may adversely affect their health. In most cases, these restrictions will be related to employee sensitivity to chemicals or allergens in the workplace. In very rare circumstances, restrictions or work removal may be required because an employee has been overexposed to an OSHA-regulated material in the laboratory. In all cases, Employee Occupational Health and Wellness will be involved in determining the specific restrictions and/or work removal plan.

Scheduling –

In some cases, scheduling may be used to reduce the intensity of exposure that any given employee has to a particular task in the laboratory. Scheduling a variety of tasks in a day will help to reduce ergonomic risk factors from static postures or repetitive motions. OESO does not recommend limiting employees' daily chemical exposures by rotating employees or spreading high-hazard work over a longer time than would normally be used – instead, engineering controls and work practices should be used to control chemical exposures.

Limiting access to the laboratory –

- Laboratory work areas with hazardous chemicals should be secured when unattended.
- If the laboratory plans to have visitors, they must be accompanied by laboratory personnel, and the Duke Policy on Minors/Non-employees in Work Areas must be followed.

Personal Protective Equipment (PPE) and Standard Work Attire:

Laboratories must comply with the Personal Protective Equipment Policy in the Duke University Safety Manual, including the requirement to complete PPE Hazard Assessments. In cases where PPE requirements are documented as part of general guidelines (as below), or specific written Standard Operating Procedures (SOPs), there is no need to duplicate this documentation on a PPE Hazard Assessment Form. However, in cases where there are unique hazards not addressed by the general guidelines or written SOPs used by the lab, use of the PPE Hazard Assessment Form is required. Employees must be trained on use of PPE as outlined in the PPE Policy, whether appropriate PPE is documented in this policy, a chemical-specific SOP, on the PPE Hazard Assessment Form, or elsewhere.

See below for standard laboratory PPE and guidelines describing when to use additional PPE. Additional information on PPE is available on the OESO PPE webpage.

Gloves –

Disposable nitrile gloves (4 to 8 mils thick) should be worn when manipulating chemicals in containers, but they are not appropriate for heavy contact with many laboratory chemicals. In general, nitrile gloves offer better chemical protection than latex gloves, and eliminate the risk of latex sensitivity.

(Employees with sensitivity to nitrile should check with Employee Occupational Health and Wellness and/or OESO for other glove recommendations.)

In some situations, disposable nitrile gloves may not offer adequate protection, including

- Use of acids or organic chemicals, or heavy contact with any chemicals – Standard nitrile gloves offer good protection for dry chemicals and water-based solutions, but only limited protection against some acids and many organic chemicals. These gloves are not appropriate for heavy contact or total immersion with any chemicals. Use glove selection guides or manufacturer's recommendations to select a glove appropriate for the work being performed. This is especially important for tasks involving extended glove contact with chemicals.
- Work with sharps or puncture/scratch hazards – If working with chemicals around glassware or sharps, it is important to protect your hands (and your chemical gloves) from cuts and scratches because non-intact skin is more vulnerable to chemical exposures. In these cases, it is advisable to wear a cut- or puncture-resistant glove under your chemical-resistant glove. If the outer glove is damaged, remove both pairs of gloves and wash hands thoroughly before continuing.
- Work with hot liquids or cryogens – see the protective clothing section for guidance.

NOTE: Replace gloves that have been exposed to chemicals or that appear worn.

Lab Coat/skin protection –

Standard lab coats should be worn (buttoned) whenever there is a possibility of splashes, spills, or other clothing contamination to lab personnel. Additional protective clothing may be indicated in some situations, including:

- Risk of splash with corrosive materials or chemicals that may absorb through the skin - In addition to the standard lab coat, impermeable aprons, sleeves and shoe coverings (or an impermeable coverall), should be worn.
- Risk of splash with cryogens – In addition to the standard lab coat, wear an insulated apron and cryogen gloves.
- Risk of splash with hot liquids – In addition to the standard lab coat, wear a rubberized apron and heat-resistant impermeable gloves. Standard autoclave gloves are not appropriate for handling hot liquids.
- Risk of fire – Instead of the standard lab coat, a fire retardant lab coat should be considered for laboratory work involving pyrophorics or large quantities of flammable materials.

Eye/face protection –

Safety goggles should be worn whenever there is a risk of chemical splash, when working with glassware under reduced or elevated pressures, when handling cryogens, when handling potentially explosive compounds, and when handling glassware or liquids at high temperatures. If the risk of splash is high, a face shield should also be worn. Safety glasses should be worn at other times in the laboratory when chemicals are being used.

Footwear –

Closed-toed shoes should always be worn in laboratories. Shoes with a closed heel are recommended.

Respirators –

In situations where the laboratory fume hood or local exhaust does not adequately prevent inhalation exposure, respirators may be necessary. Use of respirators requires medical clearance, annual training, and (in most cases) an annual fit test. For more information, contact the OESO Occupational Hygiene and Safety Division at 919-684-5996.

Standard Work Attire –

The choice of personal clothing for laboratory work can also influence personal safety in the laboratory. Laboratory workers should normally:

- Minimize exposed skin.
- Wear closed-toed shoes.
- Confine long hair and loose clothing.
- **If working with flammable materials, avoid wearing flammable clothing (such as many synthetics).**

Controlling Exposures & Hazards – Strategies for Specific Chemicals and Hazard Classes

Standard Operating Procedures (SOPs):

A Standard Operating Procedure (SOP) describes how to handle a hazardous chemical safely, including the amount and concentration to be used, how to obtain or create the working solution, and special handling procedures, engineering controls, and personal protective equipment. A written SOP is required when the general safe use guidelines outlined in this chapter are not sufficient to protect employees from chemical hazards.

Standard Operating Procedures (SOPs) for various hazard classes and some specific chemicals have been created by OESO and are accessible from the OESO SOPs and SOP Templates website. These SOPs are considered part of the Duke University Chemical Hygiene Plan. Labs should check the website for the most current list of SOPs and templates.

General SOPs–

Many of the SOPs on the OESO SOPs and SOP Templates website can be used in the format provided, without modification by the lab. Requirements for laboratory-specific SOPs are indicated below.

Laboratory- specific SOPs–

Laboratory-specific, customized SOPs must be created for chemicals or procedures that pose unique hazards that are not covered in or differ from the general SOPs and/or the general strategies presented in this section.

Labs that use Particularly Hazardous Substances (click link to website for definitions and lists) or nanomaterials must have written SOPs for the safe use of these materials. SOPs for working with such hazards must include concentration and quantity, provisions for establishing a “designated work area”,

containment devices, and decontamination procedures. Procedures may be written for groups of PHSs with similar hazards and control methods.

Work with certain PHS materials may be considered High Risk Procedures. See below on "Hazard Assessment and Documentation of Approval for Chemical High Risk Procedures".

Labs may produce customized SOPs for certain classes of Particularly Hazardous Substances as long as the chemicals grouped into a single SOP are handled in the same way AND as long as lab personnel can determine the hazards associated with each chemical covered (by referencing other readily available resources). Lab personnel must be able to determine which SOP(s) they should follow for the hazardous chemicals they use.

In creating customized SOPs, labs may use or modify the general SOPs and SOP Templates posted on OESO's website. Alternate formats may be used, as long as the SOP includes relevant information from the sections included in the OESO SOP Templates. Note that contact information for Duke support departments are important parts of the SOPs for Duke labs. Therefore, if Duke labs use SOPs from other institutions, the contact information for that institution's support departments must be removed and information on the relevant Duke departments must be added.

SOPs may be kept electronically or on paper, as long as they are accessible to all lab members.

Laboratory employees are expected to be familiar with and to follow the generic and laboratory-specific SOPs relevant for their laboratory work.

Hazard Assessment & Documentation of Approval for Chemical High Risk Procedures:

When planning research involving chemical High Risk Procedures (see definitions in Chapter 1 of this Section and examples in the Lab-Specific Chemical Hygiene Plan), the PI (or designee) must perform a hazard assessment and/or develop a laboratory-specific Standard Operating Procedure, which must be approved by the PI, and in some cases by the Department or OESO, before beginning work. Any chemical High Risk Procedures need to be documented in the Laboratory-Specific Chemical Hygiene Plan.

PREPARING FOR AND RESPONDING TO EMERGENCIES

Preparedness

Types of incidents

Each lab should consider the types of incidents that could have an adverse effect on people, research efforts, property, and/or the environment and engage in planning efforts aimed at mitigating the impact of the emergency (for example, arranging for critical laboratory equipment to be maintained on emergency power) and on the necessary response for each situation.

Response actions

For possible chemical-related incidents, the lab should consider the response actions that will be needed, such as use of spill pads, additional personal protective equipment, and emergency equipment, as well as reliance on Duke-wide resources.

Evacuation of the lab may be necessary in some emergency situations, including some chemical spills. Therefore, employees need to be familiar with how to get out of the building in the event of an emergency, and the location of the lab's designated Emergency Assembly Point. Emergency Assembly Points for campus buildings can be found on Fire Safety's website.

Written plan

Where a response will be needed for a chemical-related emergency, a written plan should be prepared by the lab, describing the actions that will need to be taken. This should be included in the Laboratory-Specific Chemical Hygiene Plan.

Resources and Equipment

Each lab should make sure that it has the equipment and other resources available to implement its emergency plans. The following resources will be necessary for all research and clinical labs; if additional resources are needed, the Laboratory Safety Coordinator and PI should identify those resources in the written emergency plan, and make sure that they are available.

Emergency Response & Incident Reporting Guide –

Each lab should post an up-to-date copy of the Duke Laboratory Emergency Response and Emergency Reporting Guide near the exit and/or primary telephone for the lab. This guide lists emergency contacts and procedures for various types of incidents.

Emergency Contact Information –

Each laboratory unit or department should keep emergency contact information for laboratory personnel, especially the Principal Investigator and Chemical Hygiene Officer. The purpose of this information is twofold:

- In the event of a fire, flood, or other emergency affecting the lab, to allow emergency response personnel to reach someone in the lab; and
- In the event of a lab-related or other incident requiring a member of the lab to seek medical attention, to allow the Lab Safety Coordinator, PI, or department representative to reach a family member or friend of the affected personnel.

To facilitate contact with the lab in case of emergency (such as fire or flooding in the lab), labs should also post contact information (including after-hours phone numbers) for key laboratory personnel on or near the door to the lab. OESO has a laboratory door sign template that may be used.

Eyewashes, drench hoses, and safety showers –

See the Duke Safety Manual Policy on Emergency Eyewash and Shower Equipment for more information on requirements for placement and testing of these emergency drench devices.

- It is very important for laboratory employees to be familiar with the location of the nearest eyewash/drench hose unit and/or safety shower. This must be covered in laboratory-specific training.
- Use the Weekly Eyewash Maintenance Log Sheet or other means to document that the weekly check required in the Emergency Eyewash and Shower Policy has been completed.

Spill response kits –

Spill kits with appropriate instructions, adsorbents, and protective equipment must be made available in the laboratory so that laboratory employees may safely clean up a minor chemical spill of chemicals found in that lab. **(Mercury spills are never considered minor – they always require OESO response.)** It is the responsibility of the Laboratory Chemical Hygiene Officer to ensure that it is stocked with needed supplies, and that all employees know where the kit is stored and are trained on how to use it.

Chemical spill cleanup materials can be purchased from most scientific and safety supply vendors. A typical stock for a lab kit might include:

- Spill pads appropriate for your lab
- Neutralizers
- Chemical resistant gloves appropriate for chemicals in the lab

Laboratory employees generally will not have respiratory protection available to them and should not clean up spills that involve hazardous concentrations of chemicals in the air.

Laboratory employees should be familiar with the hazards (including volatility) of the chemicals they work with and should have a sense of the likely need for spill clean-up assistance from the OESO Spill Response Team or other group, and how to contact available outside assistance. (See Emergency Response section below).

Fire extinguishers –

See the Fire Safety Section of the Laboratory Safety Manual for information on the types of fires and appropriate fire extinguishers. Labs using potentially flammable metals should contact OESO Fire Safety for information on how to obtain an appropriate Class D extinguisher.

Antidotes –

Some laboratory chemicals have acute exposure effects that may be relieved or minimized by an antidote. The laboratory should work with Employee Occupational Health and Wellness (919-684-3136) to determine if there are any counter-indications. For example, those who work with hydrofluoric acid (HF) must stock calcium gluconate gel to be used as first aid in case of an HF burn. (Medical attention should still be sought immediately for HF burns.)

Emergency Response

Most of the following information is also found in the Duke Laboratory Emergency Response and Incident Reporting Guide, which should be posted near the main exit and/or mail telephone for each lab. Contact OESO Laboratory Safety at 919-684-8822 if you need a copy of this Guide.

Minor chemical spills (those that the laboratory staff is capable of handling without assistance)

- Alert people in the immediate area of the spill.
- Avoid breathing vapors from spill.
- Turn off ignition and heat sources if spilled material is flammable.
- Put on appropriate personal protective equipment, such as safety goggles, suitable gloves, and long-sleeved lab coat.
- Confine spill to small area.
- Use appropriate kit to neutralize and absorb acids and bases.
- Use appropriate kit or spill pads for other chemicals.
- Collect residue, place in appropriate container, and dispose as chemical waste (call 919-684-2794 for waste collection).
- Clean spill area with water.

Chemical spill on body

- Flood exposed area with running water from faucet, drench hose or safety shower for at least 15 minutes.
- Remove all contaminated clothing and shoes.
- Follow instructions under Personal Injury, below.

Hazardous material splashed in the eye

- Immediately rinse eyeball and inner surface of eyelid with water continuously for 15 minutes.
- Forcibly hold eye open to effectively wash behind eyelids.
- Follow instructions under Personal Injury, below.

Major chemical spills

- Alert people in the area to evacuate.
- Turn off ignition and heat sources if spilled material is flammable.
- On campus: Call 911 from a campus phone or 919-684-2444 from any phone. Off campus: Call 911.
- Attend to injured or contaminated persons and remove them from exposure.
- Have a person knowledgeable of the area available to assist emergency personnel.

Mercury spills

For spills on campus, call OESO Environmental Programs Division at 919-684-2794; after hours, call Duke Police at 919-684-2444. For spills off campus, follow local procedures or call 911.

Personal Injury

- All work-related injuries and illnesses (including chemical spills onto the body), regardless of the severity, must be reported to the supervisor.
- If needed, obtain medical care from the nearest Employee Occupational Health and Wellness location (call 919-684-3136 for more information (after hours, call 919-684-8115)), or through one of the other providers listed here.
- Complete a Report of Work-related Accident, Injury or Illness.
- See the Workers' Compensation website for additional information, or call Workers' Compensation at 919-684-6693.

Fire

See your building's site-specific fire plan (available on the OESO website) for emergency procedures related to a fire.

Other incidents affecting property or the environment

For EMERGENCIES that may impact building integrity and/or harm people:

- Evacuate the immediate area. If the entire building needs to be evacuated, follow the procedures in your Site-Specific Fire Plan.
- On campus: Call 911 from a campus phone or 919-684-2444 from any phone. Off campus: Call 911.

For other incidents/accidents that do not pose immediate danger to people or the environment, call 919-684-2794 to report the incident. If maintenance support is needed, contact your maintenance provider.

MEDICAL CONSULATIONS

General

Exposure-related medical examinations

All laboratory personnel exposed to hazardous chemicals are given the opportunity to receive a medical examination or consultation under the following circumstances:

- Whenever an employee believes they have developed signs or symptoms associated with exposure to a hazardous chemical.
- Whenever an employee is involved in a spill, leak, explosion, or accidental release during which hazardous over-exposures may have occurred.
- Whenever occupational exposure monitoring indicates exposures above regulated levels.

Medical Consultations

Any employee may obtain a free medical consultation regarding concerns about chemical or other occupational exposures by contacting Employee Occupational Health and Wellness at 919-684-3136. Students should contact Student Health at 919-681-WELL (-9355).

Reproductive Health Consultation

It is the intent of Duke University to provide a laboratory work environment which compromises neither the reproductive health of laboratory workers, regardless of gender, nor the health of the fetus. See the Reproductive Health Policy in the Duke University Safety Manual or the OESO Reproductive Health website for more information.

Chemical specific

Work with biologically-derived toxins

There are vaccines that can reduce susceptibility to some of the biologically derived toxins, including botulinum toxin and tetanus toxin. There are also post-exposure regimens for some of these toxins. Employees working with toxins that have available vaccines or post-exposure treatments must contact Employee Occupational Health and Wellness (EOHW) at 919-684-3136 to discuss (and obtain, if desired) the vaccine and/or to arrange for EOHW to have the post-exposure treatment on hand.

Work with 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine (MPTP)

Employees working with MPTP will need to undergo medical surveillance at EOHW (919-684-3136), and will likely be prescribed selegiline to use in case of exposure (to help counteract the Parkinsonism symptoms associated with MPTP exposure).

Work with other chemicals for which unusual and/or rapid post-exposure treatment may be needed

Laboratory employees working with other chemicals which may require post-exposure treatment should consult with EOHW before beginning work to determine medical surveillance requirements and to make other arrangements.

Respirator medical clearance

Respirator Medical Clearance Questionnaire

Employees wearing respirators will be asked to complete a respirator medical clearance questionnaire (required by OSHA). It will be reviewed by a nurse. If significant health concerns are noted, the nurse may contact the employee with questions, or may schedule a medical consultation/examination at EOHW for the employee. Employees who wear respirators must contact EOHW if they experience a change in their medical condition that may affect their ability to wear their respirator. For more information, see the Duke Respiratory Protection Policy.

EXPOSURE MONITORING

OESO will conduct hazard assessments which, based on the properties and use of the chemical, may include quantitative measuring of air concentrations. Employees concerned about possible exposures should contact the OESO Occupational Hygiene and Safety Division at 919-684-5996. The decision to conduct exposure monitoring shall be based on

- The hazard potential of the chemical,
- The amount of the chemical used,
- The type and effectiveness of control measures that are in place, and
- The presence of over-exposure indicators such as odor, visual appearance, or symptoms of exposure.

CHEMICAL SECURITY, COMMUNITY RIGHT-TO-KNOW, AND TOXIC SUBSTANCES CONTROL

In addition to the requirements mentioned earlier in this section and enforced by the Occupational Safety and Health Administration, Duke is subject to chemical regulations enforced by the Department of Homeland Security (DHS) and the Environmental Protection Agency (EPA). Both of these agencies have regulations which require Duke to keep track of aggregate quantities of certain chemicals on campus. Specifically, DHS enforces the Chemical Facility Anti-Terrorism Standards (CFATS), intended to limit unsecured quantities of chemicals that could be used in terrorism. The EPA enforces the Emergency Planning and Community Right-to-Know Act (EPCRA), intended to support emergency planning by local and state agencies. Furthermore, the EPA also enforces the Toxic Substances Control Act (TSCA), which regulates the introduction of new chemicals into the United States.

To enable OESO to keep track of aggregate quantities of the chemicals regulated by the CFATS and EPCRA standards, laboratories are required to report their on-hand quantities of some of these chemicals in an annual Targeted Chemical Report, completed in the Laboratory Safety and Waste Management System (found under Laboratory Safety at www.safety.duke.edu. The chemicals on this list are ones commonly used in research and those with low thresholds for reporting. As part of the annual Targeted Chemical Report, laboratories will also complete the TSCA Applicability Form, which consists of five questions that will determine each lab's TSCA compliance requirements. Please see the OESO website for more information about TSCA.

Laboratory Safety Manual

Section 5
Use of Laboratory Animals

INTRODUCTION

PURPOSE

Proper care and use of laboratory animals is not only the humane thing to do, it is the law. Together, Duke's Institutional Animal Care and Use Committee (IACUC) and Division of Laboratory Animal Resources (DLAR), maintain a program which assures compliance with the Animal Welfare Regulations and the Public Health Service Policy on Humane Care and Use of Laboratory Animals. For information about regulatory compliance or to request a copy of the Duke University Manual for Animal Research, contact the DLAR at 919-684-2797.

Employees working with animals in a research environment may be exposed to a variety of occupational risks including animal bites and scratches, needle sticks, back injuries from lifting large items, exposure to zoonotic agents, allergens, or hazardous chemicals, etc. In order to prevent accidents or exposures from occurring, all employees must understand the risks involved with such work, and must also be familiar with basic safety precautions for work with animals.

All proposed work involving animals must first be reviewed and approved by Duke's IACUC before work can begin. The IACUC's homepage is found at: http://vetmed.duhs.duke.edu/

All orders for vertebrate animals must be placed by the DLAR. Purchase orders will be accepted only if accompanied by an approved Animal Use Protocol number.

ANIMAL HANDLING

All employees who work with live animals are required to complete the Placement Health Review for Animal Handlers. This form will be reviewed by Employee Occupational Health and Wellness (EOHW), which administers all applicable medical surveillance. For more information, contact EOHW at 919-684-3136.

Personnel Training:

Duke's IACUC provides animal care and use training sessions which are mandatory for all animal handlers. Required sessions are available online. These trainings provide detailed instruction on both regulatory compliance and basic husbandry. Because hazards vary from lab to lab, it is also necessary for each principal investigator (PI) to provide site-specific instructions for conducting animal work safely. This would include information on any etiologic agents, chemical hazards, radiation hazards, behavioral concerns of a particular animal species, etc. In addition to identifying the risks, the PI is also responsible for providing appropriate personal protective equipment such as lab coats, disposable gloves, goggles and face shields.

Husbandry (DLAR website):

Animals shall be provided nutritionally adequate food, potable, non-contaminated water and a sanitary environment in which the animal's health shall not be affected.

Injections:

All sharps shall be disposed of immediately after use in an approved sharps container. Needles shall not be broken, bent, or recapped before disposal. A one-handed recapping procedure may be incorporated only after approval by the OESO-Biological Safety Division 919-684-8822. Physical restraint procedures should be developed and practiced to prevent accidental autoinoculation while at the same time reducing stress on the animal.

Animal Restraint:

Proper restraint and handling techniques are essential for reducing stress to laboratory animals, while at the same time allow animal care workers to perform their work with less chance of being scratched, bitten, kicked, etc. Animals can be restrained either manually or with restraint devices. It is the responsibility of the PI to train their staff on proper restraint for each species used.

Changing Bedding:

Precautions should be taken, while changing animal bedding, to minimize or eliminate the aerosolization of hazardous agents which may have been shed by the animal. The use of a biological safety cabinet (BSC) or chemical fume hood should be used when changing animals dosed with hazardous agents. Many allergens can also be aerosolized during bedding changing. Some options include the use of a cage changing station, or decontaminating the soiled bedding before disposal by placing the whole cage in a

biohazard bag and then autoclaving it. Cage changing stations are not appropriate for animals dosed with biohazardous material and autoclaving may not be appropriate for those dosed with chemical toxins. **Please read and adhere to the procedures in the written standard operating procedures (SOP) for handling animals dosed with these hazardous materials.**

Allergens:

Laboratory animal allergies and associated asthma are among the most common conditions affecting individuals who work with laboratory animals. Typically, allergies to animals result from repeated exposure to an animal's dander, urine, saliva, serum, or other body tissues. Symptoms can range from mild (e.g. itchy or runny nose and eyes) to severe (e.g. shortness of breath or red, itchy wheals on skin).

Levels of airborne allergens tend to rise significantly with certain activities such as changing or cleaning animal cages. To reduce the levels of airborne allergens, OESO recommends using:

- Ventilated hoods (cage changing station, biological safety cabinet (BSC), or chemical fume hood) for cage changing
- Dust-free bedding, or
- Filtered caging systems.

If these options aren't available or feasible for a particular situation, then personal respiratory protection may be required. Contact Occupational Hygiene and Safety (919-684-5996) for more information about respirators. Make an appointment with Employee Occupational Health and Wellness (919-684-3136) or Student Health (919-681-WELL) if you have allergy concerns.

Carcass Disposal:

All **non-radioactive** animal carcasses are to be collected by the DLAR staff and incinerated. For more information, contact the DLAR at 919-684-5567.

Radioactive carcasses and their associated lab waste (i.e. bedding, excreta, sharps, etc.) are to be bagged and sealed in 3 mil plastic bags. **Make sure that all sharps are contained in a puncture resistant container before placing in plastic bags!** Once properly barcoded, the bags are refrigerated in a lined 30 gallon plastic drum. All packaging and labeling materials are provided by the OESO. For more information contact the OESO- Environmental Programs Division at 919-684-2794.

WORKING WITH HAZARDOUS MATERIALS

Standard operating procedures (SOPs) must be developed and approved by OESO for any work which involves the use of hazardous materials in animals. Such procedures shall detail the safe handling of the animal throughout the duration of exposure.

- For work with biological agents in animals, see the Guide for Developing an SOP for the Use of Biohazards in Animals. Contact Biological Safety Division (919-684-8822) for assistance.

Animal Biosafety Levels (ABSL):

Work involving the exposure of animals with biological materials must be conducted at the appropriate containment level to ensure adequate protection of personnel and the environment. The following table summarizes the Center for Disease Control and Prevention's four animal biosafety levels.

ABSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to cause disease in immunocompetent adult humans	Standard animal care and management practices, including appropriate medical surveillance programs	As required for care of each species	Standard animal facility • non-recirculation of exhaust air • directional air flow recommended
2	Associated with human disease. Hazard: autoinoculation, ingestion, mucous membrane exposure	ABSL-1 practices plus: • limited access • biohazard warning signs • sharp precautions • biosafety manual • decontamination of all infectious wastes and of animal cages prior to washing	ABSL-1 equipment primary barriers: • containment equipment appropriate for species: PPE: laboratory coats, gloves, face and respiratory protection as needed	ABSL-1 facility plus: • autoclave available • handwashing sink available in the animal room

ABSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	ABSL-2 practices plus: • controlled access • decontamination of clothing before laundering • cages decontaminated before bedding removed • disinfectant foot bath as needed	ABSL-2 equipment plus: • containment equipment for housing animals and cage dumping activities • Class I or II biosafety cabinets available for manipulative procedures (inoculation, necropsy) that may create infectious aerosols. PPE: appropriate respiratory protection	ABSL-2 facility plus: • physical separation from access corridors • self-closing, double door access • sealed penetrators • sealed windows • autoclave available in facility
4	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission	ABSL-3 practices plus: • entrances through change room where personal clothing is removed and laboratory clothing is put on; shower on exiting • all wastes are decontaminated before removal from facility	ABSL-3 equipment plus: • maximun containment equipment (i.e.Class III biosafety cabinet or partial containment equipment in combination with full body, air supplied positive-pressure personnel suit) used for all procedures and activities	ABSL-3 facility plus: • separate building or isolated zone • dedicated supply/exhaust, vacuum and decontamination systems • other requirements outlined in the complete description of ABL-4
Summarized from Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, 2009.				

- For work with hazardous drugs or other toxic chemicals in animals, see the SOP for Work with Toxic Chemicals in Animals. Contact Occupational Hygiene and Safety (919-684-5996) for assistance.
- For work with radioactive materials in animals, use Radiation Safety's Animal Care and Use Protocol Wizard online or contact the Radiation Safety Division (919-684-2194) for questions about SOP development.

Safe Use of Anesthetic Gases:

Many anesthetic gases are used at Duke University for performing animal surgeries. These gases can present a risk for potential exposure to the lab personnel performing the surgeries. Anesthetics of concern include ether, nitrous oxide, and halogenated agents (e.g. halothane, isoflurane, methoxyflurane). Some of these halogenated anesthetics have been linked to adverse health effects in exposed workers, such as reproductive and neurological effects. Emphasis must be placed on protecting personnel from exposure by adequately "capturing" the waste gas being generated. This may be accomplished by several methods depending on the method of delivery of the gas:

For enclosed chambers (e.g. Bell jar)-

- Perform work in a fume hood so when lid is removed, gases are captured by hood.
- Evacuate chamber via building vacuum system prior to removing lid.
- Make sure the chamber lid is tight-fitting.
- Remove chamber lid only when animal is being placed into or removed.

For anesthetic gas machines and vaporizers-

- Verify that proper filtration canisters are installed.
- Maintain filter canisters according to manufacturer's specifications.
- Choose an appropriate sized face-piece to ensure most efficient waste gas recovery.
- Maintain anesthesia machines and vaporizers according to manufacturer's instructions and in accordance with the Animal Care and Use Program's Policy on General Inhalational Anesthesia Machine/Vaporizer/Waste Gas Maintenance and Calibration.

Lab personnel who are concerned with possible exposure to anesthetic gases may contact the Occupational Hygiene & Safety division of OESO at 919-684-5996 to request an exposure risk evaluation.

REFERENCES

Guide for the Care and Use of Laboratory Animals
NIH Guidelines for Research Involving Recombinant DNA
Biosafety in Microbiological and Biomedical Laboratories

Laboratory Safety Manual

Section 6
Fire Safety

INTRODUCTION

PURPOSE

Both flammable and combustible materials are commonplace in most Duke Laboratories. For this reason, all laboratory employees should be aware of the risks in their work spaces and understand how to respond appropriately should a fire occur. Employees who take the time to familiarize themselves with the location of safety devices (i.e., fire extinguishers, pull alarms, safety showers, fire blankets, etc.) and proper route of egress before an accident occurs are more likely to respond to an emergency situation in a calm and efficient manner.

Duke employees are encouraged to implement the RACE acronym in the case of a fire. RACE is defined as the following:

Remove all individuals from the affected area

Activate the pull alarm and dial 911

Close all doors and windows

Extinguish the fire

OESO Fire Safety Division uses the recommendations contained in the National Fire Protection Association (NFPA) Codes as minimum guidelines to acceptable practices. A number of the NFPA Codes have been incorporated into the Occupational Safety and Health Act (OSHA) Standards and the North Carolina State Building Code. Questions regarding the applicability of specific NFPA Codes should be directed to the OESO Fire Safety Division (919-684-5609).

The basic standards for the storage and use of flammable and combustible liquids applicable to laboratory operations listed here are by no means comprehensive but represent those cited most frequently during laboratory audits and building inspections.

Defining Flammable and Combustible Materials

Combustible Liquids

The National Fire Protection Association (NFPA) and North Carolina Building Code (Fire Code) define combustible liquids as any liquid having a flash point at or above 100°F. Combustible liquids are divided into subclasses as follows:

Class	Flashpoint (Closed Cup)
II	At or above 100 but below 140°F.
IIIA	At or above 140 but below 200°F.
IIIB	At or above 200°F.

Flammable Liquids

The National Fire Protection Association and North Carolina Building Code define flammable liquids as any liquid having a flash point below 100°F and having a vapor pressure exceeding 2068.6 mm Hg (40 psia) at 100°F. Flammable liquids are also known as Class I liquids and are divided into subclasses as follows:

Class	Flashpoint (Closed Cup)	Boiling Point
IA	Below 73°F.	Below 100°F.
IB	Below 73°F.	100°F or above.
IC	73-99°F.	

List of Flammable Liquids by NFPA Classification

The following list of flammable and combustible liquids was developed to assist users in the proper classification and storage of flammable and combustible liquids in the laboratory. This information is meant to be an illustrative list of common flammable and combustible liquids. If you are unsure of the material classification of materials you are working with, contact Duke OESO Fire Safety Division (919-684-5609).

Class IA Flammable Liquids (Flash point at or below 73 F, boiling point at or below 100 F)		
1-1 Dichloroethylene	Ethyl Chloride	Pentane
Acetaldehyde	Isopentane	Petroleum Ether
Collodion	Isopropyl Chloride	Propylene Oxide
Ethylamine	Methyl Ethyl Ether	
Ethyl Ether	Methyl Formate	

Class IB Flammable Liquids (Flash point below 73 F, boiling point at or below 100 F)		
Acetone	Gasoline	Octane
Benzene	Hexane	Propyl Acetate
Butyl Alcohol	Methyl Acetate	Isopropyl Acetate
Carbon Disulfide	Methyl Alcohol	Isopropyl Alcohol
1,2-Dichloroethylene	Methylcyclohexan	Toluene
Ethyl Acetate	Methyl Ethyl Ketone	Butyl Acetate
Ethyl Alcohol	Methyl Propyl Ketone	
Ethyl Benzene	VM&P Naphtha	

Class IC Flammable Liquids (Flash point at or below 73 F, boiling point at or below 100 F)		
Amyl Acetate	Isopropanol	Styrene (Monomer)
Amyl Alcohol	Methyl Alcohol	Turpentine
Butyl	Methyl Isobutyl Ketone	Xylene
Dibutyl Ether	Naptha	
Isoamyyyl Acetate	Propyl Alcohol	

Class II Combustible Liquids (Flash point at or above 100 F, and below 140 F)		
Acetic Acid	Hydrazine	Methyl Lactate
Camphor Oil	Kerosene	Mineral Spirits
Cellosolve Acetate	Naptha (coal tar)	Varsol
Cyclohexane	Naptha (high flash)	
Fuel Oil #1, 2, 4 & 5	Methyl Cellosolve	

Class III A Combustible Liquids (Flash point at or above 140 F, and below 200 F)		
Aniline	Formic Acid	Isophorone
Butyl Cellosolve	Furfural	Nitrobenzene
Carbolic Acid	Furfuryl Alcohol	Phenol
Cyclohexanol	Naphthalenes	Pine Oil

Class III B Combustible Liquids (Flash point at or above 140 F, and below 200 F)

Cellosolve Solvent	Formalin	Picric Acid
Ethylene Glycol	Glycerin	

In keeping with the United Nations' Globally Harmonized System for Classification and Labeling of Chemicals (GHS), The Occupational Safety and Health Administration defines Flammable Liquids in 4 categories:

Category	Criteria
1	Flash point <23 °C (73.4 °F) and initial boiling point ≤35 °C (95 °F).
2	Flash point <23 °C (73.4 °F) and initial boiling point >35 °C (95 °F).
3	Flash point ≥23 °C (73.4 °F) and ≤60 °C (140 °F).
4	Flash point >60 °C (140 °F) and ≤93 °C (199.4 °F).

Flammable Solids

OSHA defines flammable solids as powdered, granular, or pasty chemicals which are dangerous if they can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly, or which may cause or contribute to fire through friction. Flammable solids include materials which, in contact with water, emit flammable gases.

Flammable Gas

OSHA defines a flammable gas as a gas having a flammable range with air at a temperature of 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi).

National Fire Protection Association (NFPA) System for Classification of Hazards

The NFPA diamond is a symbol used to identify the hazards associated with a given chemical to rescue workers. Frequently this symbol is found on the sides of buildings where chemicals are stored and on chemical containers. Below are shown the various hazards symbolized by the diamond and the numerical code which indicates the severity of the hazard. Class IA & IB flammable liquids have an NFPA Fire Hazard rating of 4. Class IC flammable liquids are rated as 3. Combustible liquids are rated as 1, or 2.

In this labeling system, the number 4 is associated with higher hazards, and the numbers 1 and 0 with lower hazards. (This is the opposite order from the GHS Hazard Categories.)

HEALTH HAZARD
4 — Deadly
3 — Extreme Danger
2 — Hazardous
1 — Slightly Hazardous

FIRE HAZARD
Flash Points:
4 — Below 73° F
3 — Below 100° F
2 — Above 100 F°, Not Exceeding 200° F
1 — Above 200° F
0 — Will not burn

SPECIFIC HAZARD
Oxidizer OX
Acid ACID
Alkali ALK
Corrosive CORR
Use NO WATER
Radioactive

REACTIVITY
4 — May detonate
3 — Shock and heat may detonate
2 — Violent chemical change
1 — Unstable if heated
0 — Stable

Globally Harmonized System (GHS) Classification and Labeling

The OSHA Hazard Communication Standard, based on the United Nations' Globally Harmonized System for Classification and Labeling of Chemicals (GHS), requires labeling using signal words, hazard statements, pictograms, and precautionary statements. Some of the required label elements for flammable liquids are shown below:

	Category 1	Category 2	Category 3	Category 4
Pictogram				***(None)***
Signal Word	**Danger**	**Danger**	**Warning**	**Warning**
Hazard Statement	**Extremely flammable liquid and vapor**	**Highly flammable liquid and vapor**	**Flammable liquid and vapor**	**Combustible liquid**

In this labeling system, the number 1 is associated with higher hazards, and the number 4 with lower hazards. (This the opposite order from the NFPA ratings.)

SAFE STORAGE AND HANDLING OF FLAMMABLE CHEMICALS

The laboratory's chemical hygiene plan should contain written standard operating procedures for those chemicals that pose a fire risk in the laboratory. Safety data sheets (SDSs) are available from the manufacturer or through OESO's website. OESO may be consulted on safety practices for particular chemicals.

Safe storage and handling practices for flammable chemicals are detailed below. See also the Hazardous Materials Policy in the University Safety Manual, Section 3 - Chemical Safety in this Laboratory Safety Manual, and the SOP for Flammable Materials.

Storage:

Flammable chemicals must be stored in appropriate areas within the laboratory and away from any potentially incompatible materials.

Storage of Flammable Liquids in Flammable Storage Cabinets

The total stored volume of flammable liquids in approved storage cabinets shall not exceed 20 gallons per one hundred square feet with a maximum of 10 gallons per one hundred square feet being Class I liquid, as defined by the North Carolina Fire Code. All storage cabinets for flammable liquids shall meet NFPA 30 requirements. Not more than 60 gallons of flammable liquids may be stored in any single storage cabinet.

Storage of Flammable Liquids Outside of Flammable Storage Cabinets

The total capacity of flammable liquids not currently in use outside an approved storage cabinet shall not exceed 10 gallons per laboratory A laboratory is defined as a room, or suite of rooms, separated from adjacent areas by walls and doors having at least a one hour fire rating. In regards to flammable liquid storage only, OESO Fire Safety does not limit or define the square footage of a laboratory. A Fire Safety Specialist may provide further guidance to the laboratory if the 10 gallon storage limit is exceeded. Chemical containers that are not actively being used must not be stored in the work area of chemical fume hoods. Too much clutter can disrupt air-flow patterns and potentially compromise worker protection.

Storage of Flammable Liquids in Refrigerators and Freezers

Class I flammable liquids as defined by the North Carolina Fire Code shall not be stored in unapproved or residential-type refrigerators. Storage of flammable liquids in well-sealed containers is permissible in listed flammable storage refrigerators labeled to indicate that they are approved for storing flammable liquids. See Supplement C "Storage of Flammable Chemicals in Refrigerators**"** for additional information.

Per enforcement directive from the City of Durham Fire Marshal, all laboratory refrigerators and freezers must be labeled to indicate whether or not they are suitable for storing flammable liquids.

Refrigerators and freezers utilized throughout the University, Hospital, and Medical Center generally fall within the following three categories:

1. Those designed to store flammable liquids with all electrical equipment that meets Class I, Division I requirements.

2. Those that have been modified by a licensed electrician to meet the Class I, Division I requirements.

3. Those "residential-type" refrigerators that cannot be utilized to store flammable liquids, but are used to store other chemicals or laboratory reagents.

Those refrigerators and freezers which fall into either category 1 or 2 will require a blue and white label which states that the device is approved for flammable storage. Those which fall into category 3 will require a red and white label be affixed which states that the appliance is not approved for flammable storage.

To request aid in identifying the category in which an appliance falls, contact the OESO Fire Safety Division at 919-684-5609.

Handling and Use:

Purchases of flammable chemicals should be kept to a minimum.

All sources of ignition (e.g., Bunsen burners, hot plates, and electrical equipment) must be eliminated from areas in which flammable or combustible chemicals are used.

Use the chemical fume hood to capture vapors when appreciable quantities of flammable substances are being used.

Keep containers of flammable chemicals closed at all times when not in use.

Classes of Fires

Class A fires are those which involve ordinary combustible materials such as wood, paper or cloth. These fires should be extinguished by using a dry chemical extinguisher. Water is effective in extinguishing these type fires, however, water extinguishers are rarely found in the Medical Center.

Class B fires are those which involve flammable liquids, gases, oil, paint and greases. Either dry chemical or carbon dioxide extinguishers should be used to extinguish these type fires. Note: flammable liquids may re-ignite after being extinguished. **DO NOT USE WATER!**

Class C fires are those which involve electricity. Either dry chemical or carbon dioxide extinguishers should be used to extinguish these type fires. **DO NOT USE WATER!**

Class D fires are those which involve combustible metals such as magnesium or sodium. Water can react with sodium and other alkali metals explosively, therefore **DO NOT USE WATER!** Also understand that CO2 extinguishers are unlikely to be able to contain a Class D fire.

Fire Extinguishers

There are three basic types of portable fire extinguishers found throughout the Medical Center and University. These include dry chemical, carbon dioxide and halotron extinguishers. These devices are to be used to extinguish small or beginning fires. Any employee wishing to operate an extinguisher should contact the OESO Fire Safety Division at 919-684-5609.

CO 2 Fire Extinguishers

The carbon dioxide extinguisher is rated to extinguish Class B and C fires. The carbon dioxide is in the extinguisher as a liquid under pressure, and is discharged as a gas. Extinguishing is accomplished by removing the oxygen from the fire. Carbon dioxide is a “clean” agent which will evaporate and leave no residue.

Dry Chemical Extinguishers

Dry chemical extinguishers are intended for use on Class A, B or C fires. Best results are obtained by attacking the near edge of the fire and progressing forward, moving the nozzle rapidly with a side-to-side sweeping motion. Discharge should be continued after flames are extinguished (especially on Class A fires) to prevent possible re-ignition.

Halotron Extinguishers

Halotron is a clean fire extinguishing agent which is a safe and environmentally acceptable replacement for halon 1211. Halotron, which is discharged as a liquid which rapidly evaporates, will be used throughout many patient care areas.

Class D Fire Extinguishers

These types of fire extinguishers are rarely used in the Medical Center and University. Laboratories using potentially flammable metals should contact the Fire Safety Division at 919-684-5609 for information about getting a Class D extinguisher. Extinguishers for Class D fires must match the type of metal that is burning. Usually a list of metals for which the extinguisher is appropriate is shown on the extinguisher’s labeling. *Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards* recommends the use of Met-L-X or Met-L-Kyl extinguishers.

All employees should be familiar with the location of extinguishers in his or her work area. In order to operate an extinguisher appropriately, one must implement the PASS acronym which stands for:

P—Pull the pin
A—Aim the nozzle at the base of a fire
S—Squeeze the handle
S—Sweep the base of the fire

Fire Drills

Fire drills are conducted in all University, Hospital and Medical Center buildings by OESO Fire Safety on a routine basis. If your laboratory hasn't participated in a complete evacuation drill in the past year, contact Fire Safety at 919-684-5609 to schedule a drill in your area.

Site-Specific Fire Plan

Your Site-Specific Fire Plan (SSFP) consists of two parts. Part I contains information specific to your work area. To access this document, click on the link below and select your organization and your specific work area. Print this document, have the manager/supervisor sign it, and store it in your work area as the cover page for Part II of the SSFP.
Note: The prefix on the document title is your fire zone.

Part I: http://www.safety.duke.edu/fire-life-safety/site-specific-fire-plans

Part II: Contains generic information that applies to all Duke Facilities. Print this document and store it in your work area with Part I of the SSFP.

Duke Hospital, Duke Eye Center, Radiology, MRI, Children's Health Center:
http://www.safety.duke.edu/sites/default/files/Site-Specific%20Fire%20Plan%20Part%20II%20-%20Duke%20Hospital.pdf

Cancer Center:
http://www.safety.duke.edu/sites/default/files/Site-Specific%20Fire%20Plan%20Part%20II%20Cancer%20Center.pdf

Duke Clinic:
http://www.safety.duke.edu/sites/default/files/Site-Specific%20Fire%20Plan%20Part%20II%20Duke%20Clinic.pdf

University Buildings/Medical Center Buildings:
http://www.safety.duke.edu/sites/default/files/Site-Specific%20Fire%20Plan%20Part%20II%20-%20MedCenter-Campus.pdf

Duke Medicine Pavilion:
http://www.safety.duke.edu/sites/default/files/SiteSpecificFirePlanPart%20II-DukeMedicinePavilion.pdf

If your department/work area is located in more than one fire zone, be sure to print a copy of Part I and Part II for each zone. You will not need to return a copy of the signature page of the SSFP to OESO Fire Safety Division - signatures are to be retained by the department/work area. If you need assistance in locating your SSFP, please contact OESO Fire Safety Division (919-684-5609)

REFERENCES

Occupational Safety and Health Standards, Fire Protection; 29 CFR 1910 Subpart L
North Carolina Building Code, Volume V, Fire Prevention
National Fire Protection Association (NFPA) Standards