Biological Safety Manual

The Biological Safety Manual is Reviewed and Updated Annually

By Environmental Health & Safety
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Overview

Pace University's Approach to Biosafety

Work involving biological materials typically involves agent specific strategies designed to manage the agent and agent associated risks. Researchers are often guided by pressures from funding sources, standards of practice, guidelines, communal intellect and their own knowledge base with no specific regulatory or authoritative doctrine to govern practice. To complicate matters further, biological research often involves the use of chemicals, radiological materials, lasers, animal model systems and physical hazards which must also be managed safely. There exists a need to position each individual scope of work within an overarching operational framework that is capable of anticipating, evaluating and managing the various aspects of the work being performed.

For biosafety in particular, this means developing internal policies coupled to effective working policies that are aimed at managing work associated risks efficiently. This also means developing a comprehensive understanding of each process, the inherent hazards, identifying roles and responsibilities, use of appropriate controls, training, surveillance, monitoring and following up on new material reviews and equipment or operational changes. These concepts serve as the basis for risk assessment and risk management and define our approach to biological safety at Pace University.

Biological Safety Program Goals

The Biological Safety Program goals include the following:

- Assure a safe environment exists for conducting cutting edge biological research
- Safeguard the health of members of the Pace community against exposure to biological agents or other materials used at the University
- Prevent agricultural or environmental damage from biological agents used, transferred or disposed of by the University
- Provide guidance and implement systems for biosafety controls
- Provide required biosafety training designed to supplement lab specific or task specific training
- Ensure compliance with applicable federal, state and local guidelines.

Reporting a Problem

Immediate police, fire, environmental or medical response

DIAL 777 FROM ANY PACE PHONE IN THE EVENT OF AN EMERGENCY OR PRESS THE SECURITY BUTTON ON YOUR PACE PHONE.

Security and Environmental Health & Safety (EH&S) Telephone Numbers:

New York City: B-Level, East Wing (Schimmel Entrance)	(212) 346 - 1800
Pleasantville: Goldstein Fitness Center Lobby	(914) 773 - 3400
Briarcliff: Dow Hall Lobby	(914) 923 - 2700
Graduate Center-White Plains: Lobby	(914) 422 - 4166

School of Law-White Plains: Preston Hall Lobby	(914) 422 - 4300
All Campuses: Environmental Health & Safety	(914) 923 - 2818

Medical Questions or Concerns?

Westchester Campuses
Goldstein Fitness Center, Room 125
861 Bedford Road
Pleasantville, New York 10570
Telephone: (914)773-3760

Or

New York City Campuses
41 Park Row, Suite 313
New York, 10038
Telephone: (212)346-1600

Accident Reporting

Illnesses and injuries must be reported to University officials by contacting Security at the above numbers or by dialing x777 from a campus telephone. The supervisor of an injured employee, the department head, or a designated individual within the department must complete all sections of the Accident Reporting Form within 24 hours after the injury is first reported. It is the responsibility of the Principal Investigator and laboratory supervisor to ensure all accidents and injuries are reported to University officials.

CHAPTER 1.0 INTRODUCTION

The Pace University Health and Safety Policy outlines safety responsibilities and training requirements to ensure individual and institutional compliance with relevant environmental health and safety laws, regulations, policies, and guidelines. This Biological Safety Manual provides recommendations for good laboratory practices for biological laboratories and is designed to serve as a useful resource and to assist laboratories in designing their own site-specific laboratory safety procedures to meet these requirements. While safety at Pace is everyone's responsibility, each community member has specific responsibilities and authorities as outlined in the health and safety policy.

1.1 Biosafety Requirements

This document outlines the minimum expectations for those conducting or participating in research at Pace University. It is the responsibility of the Principal Investigator to ensure that the lab is compliant with all federal, state and local guidelines and University policies. Pace University is committed to excellence in research and strives to maintain a safe living, learning and working environment for faculty, staff, students and other members of the Pace community. Principal investigators are required to notify EH&S of plans to conduct research with pathogens at biological safety level two (BSL-2) or higher. This includes but is not limited to microorganisms, cell lines, human materials, animals, plant materials and toxins. The Principal Investigator must certify the accuracy of the information on file with EH&S on an annual basis. EH&S must be notified if there are changes in research protocol, material usage, room changes or changes in staff to any BSL-2 or higher projects.

Investigators wishing to use animals in research must register with the Institutional Animal Care and Use Committee (IACUC). The IACUC is responsible for review and monitoring of animal used in research protocols. Review of proposed animal use includes an assessment of potential hazards specific to the proposed research and processes related to animal care and husbandry. The IACUC works closely with the staff veterinarian to consider the potential for zoonotic disease and other hazards related to the species involved. The review may also identify additional training requirements, preventative measures or special health precautions and/ monitoring. The contact for the New York IACUC is Dr. Nigel Yarlett and the contact for the Westchester IACUC is Dr. Joshua Schwartz. The IACUC must be notified if there are changes in research protocol, material usage, room changes or changes in staff.

The Biological Safety Officer role will currently be filled by the Director of Environmental Health & Safety. The Biological Safety Officer serves as a resource to the Pace community on matters of biological safety and is an ex-officio member of both IACUCs.
The Biosafety Officer should be consulted prior to:

- Initiating work with biohazardous material, an infectious agent or bio-nanomaterial
- Changing the scope or location of existing work
- Ordering/ Transferring infectious agents
- Arranging for visiting researchers to work in your laboratory

1.2 Scope

This document applies to members of the Pace University community administrators, faculty, staff, and students involved in the oversight, use, storage or disposal of biologically hazardous materials or animals in research. This manual defines policies and procedures for with conducting research at Biosafety Levels 1 and 2. This document provides information on registration, training, recommended work practices, safety equipment and facility design. However, it is the responsibility of the Principal Investigator (PI) to appropriately assess and mitigate the risks associated with individual research protocols. This manual does not include working in Biosafety Level 3 or 4 laboratories. Work involving Biosafety Level 4 (Risk Group 4) organisms is prohibited at Pace University.

Additional guidance is provided in Biosafety in Microbiological and Biomedical Laboratories, published by the Centers for Disease Control/ National Institutes of Health and commonly referred to as the BMBL.

The Pace University Biological Safety Level 2 Manual is maintained by the Department of Environmental Health & Safety (EH&S). This manual is designed to be used in concert with department and laboratory specific manuals and procedures that specifically address the scope of work of the individual lab. EH&S will serve as a technical resource to assist in compliance with applicable standards of practice or state and federal regulations. EH&S will support research efforts by consulting with laboratory personnel on matters pertaining to the environment, health and safety and will develop and provide training programs aimed at managing associated risks appropriately.

1.3 Responsibilities

The ultimate responsibility for health and safety within laboratories rests with each individual who works in the laboratory; however, it is the responsibility of the Principal Investigator, Faculty, and laboratory supervisor to ensure that employees (including visiting scientists, fellows, volunteers, temporary employees, and student employees) have received all appropriate training, and have been provided with all the necessary information to work safely in laboratories under their control. Principal investigators, Faculty, and Lab Supervisors have numerous resources at their disposal for helping to ensure a safe and healthy laboratory that is compliant with state and federal regulations.

1.3.1 Deans, Directors, and Departments Chairs

- Be familiar with and implement the University Health & Safety Policy within units under their control or designate a person in the department with the authority to carry out these requirements.
- Communicate and implement the University Health and Safety Policy and its requirements to faculty, staff (including temporary employees), visiting scholars, volunteers, and students working in laboratories within their units.
- Assist the EH&S with implementation of Safety Manuals.

- Ensure laboratory personnel develop and adhere to proper health and safety protocols.
- Direct individuals under their supervision, including but not limited to – Principal Investigators, supervisors, regular and temporary employees, visiting professors, and students employees - to obtain any required safety and health training before working with hazardous chemicals, biohazardous agents, radiation, and/or other physical/mechanical hazards found within their working or learning environments.
- Determine and ensure that safety needs and equipment for units/departments are met (e.g., engineering controls, training, protective equipment) and ensure corrective measures for noncompliance items identified in safety audits are corrected promptly.
- Encourage the formation of a college and/or department safety committee(s).
- Keep EH&S informed of plans for renovations or new laboratory construction projects.
- Ensure college and departmental procedures are established and communicated to identify and respond to potential accidents and emergency situations.
- Notify EH&S before a faculty member retires or leaves the University so proper laboratory decommissioning occurs. Establish college and departmental priorities, objectives, and targets for laboratory safety and health performance. Obtain assistance and guidance from EH&S when necessary.
- Encourage college and departmental laboratory participation in self-inspection process as a means to regularly check performance against regulatory requirements and identify opportunities for improvement.

1.3.2 Laboratory Directors and Safety Representatives

- Communicate existence and importance of University policies as they relate to health and safety to principal investigators, unit supervisors, and supervisory personnel having oversight of employees working with health hazards.
- Ensure that the biological safety needs for the unit or department are being met as they relate to training, protective equipment, and corrective actions on items of non-compliance.
- Report accidents, laboratory acquired illnesses, material losses and work site injuries initially with Security and then University Human Resource Services and the Department of Environmental Health and Safety.
- Develop and maintain adequate accident/ illness prevention and health and safety programs within colleges or units.
- Develop and maintain business continuity plans for units/ departments that specifically address individual roles and responsibilities for all personnel involved in response planning and implementation.
- Principal Investigators, Unit Supervisors, and Department Safety Representatives assist in implementing the University's health and safety policy, use of the Biosafety Manual and all other University safety practices.
- Communicate to employees and students information about health hazards in the workplace.

- Provide direction to supervised individuals regarding required safety training necessary prior to work involving biological hazards.
- Provide appropriate training resources.
- Develop practices and procedures that serve to protect employees and students.
- Maintain workplaces and equipment under your direction in a safe, well maintained manner.
- Identify and meet the safety needs for personnel they relate to appropriate engineering controls, training, personal protective equipment and corrective measures for non-compliant issues.
- Conduct periodic self-audits to identify operational gaps in work practices and or facilities.

1.3.3 Employees and Students

- Comply with policies and procedures outlined in this manual and all other university health and safety practices and programs.
- Attend all required health and safety training.
- Conduct activities involving the use of biological materials in a safe manner using information received through safety education or training, properly functioning safety equipment or devices, all recommended personal protective equipment and specific standard operating procedures as necessary for the work being done particularly those involving the use of carcinogenic or radioactive materials, select agents or recombinant DNA.
- Inform supervisor or instructor of any safety hazards in the workplace.
- Report accidents, laboratory acquired illnesses, material losses and work site injuries to supervisor or instructor.

1.3.4 Department of Environmental Health & Safety (EH&S)

- Coordinate the University biological safety program by enforcing applicable standards governing the use, storage, and disposal of hazardous biological substances, housekeeping, drinking water quality, and insect and rodent control.
- Consult with supervisors and administrators who have employees with concerns about working with biological materials.
- Interface with the University Health Care Unit (UHCU) on matters pertinent to biosafety.
- Develop and maintain programs that facilitate appropriate response to emergencies involving biohazards.
- Responsible for the implementation of policies and guidelines that are in-keeping with federal, state and local mandates.
- Provides guidance on all matters pertinent to biological safety and identifies operational and policy gaps.
- Provide guidance on achieving University and Departmental safety objectives by :
    - Evaluating and inspecting laboratory facilities prior to work with infectious agents and other biologically active materials.

    - Recommending and approving biosafety barriers, equipment, work practices, hazard communication and PPE.
    - Providing training on policies and guidelines as they relate to biological safety.
    - Investigating laboratory accidents and provides guidance on corrective and preventative actions to be implemented.
    - Ensuring that appropriate decontamination measures are taken following spills involving infectious materials.
    - Ensuring the appropriate disinfection of any apparatus requiring repair or servicing before it is handled by non-laboratory staff.
- Development of institutional plans to reduce laboratory acquired infections.
- Authorized to recommend discontinuation/ suspension of any research work involving biohazardous materials that creates an unreasonable risk to the health and safety of faculty, staff, students, or University environment.

1.3.5 University Health Care Unit

- Provide initial medical triage and first aid during exposure incidents and direct employees to appropriate medical consultation for any employee or student with questions or concerns related to hazards associated with exposure to a hazardous chemical or agent.
- Notify Environmental Health and Safety of employee or student concerns at their request.
- Work with Environmental Health and Safety to address and coordinate health services.

1.3.6 Office of the Dean of the Dyson College of Arts and Science

- Help plan and coordinate research.
- Represent the university in research matters as they relate to external agencies and sponsors.

1.3.7 Office of Sponsored Research & Economic Development

- Oversee the administration of sponsored programs at Pace University including sponsored research, instruction and extension.

1.3.8 Institutional Animal Care and Use Committee (IACUC)

- Provide guidance and oversees the animal care and use program.
- Ensure compliance with federal regulations, applicable laws, and policies.
- Has the authority to suspend any research in that the committee feels places the health and welfare of an animal at risk.

1.3.9 Institutional Review Board for Human Participants (IRB)

- Protect the rights and welfare of individuals who volunteer to participate in the research mission of the University.

1.3.10 Safety & Security

- Ensure that the university has an integrated approach to Safety, Health, and Risk Management across the campus.

Chapter 2.0 RISK ASSESSMENT and MANAGEMENT

The essential steps in the risk analysis and management process are outlined below:

2.1 Assessment

Risk assessment serves as the basis for developing and implementing safeguards to protect the health and safety of laboratory workers and the public from risks associated with working with hazardous materials. The term risk implies that there is a probability that injury or disease will occur. This probability increases with the number of hazardous activities or the number of related variables. Working with biological material may be hazardous given the specific material or agent. However, since research involving biological materials often involves the use of radiological and/ or chemical materials, it is imperative that the risk assessment strategy assume a holistic approach, one that accounts for contributing hazards from sources other than the biological that may further complicate the task of managing risks within the laboratory. The risk assessment process is designed to assist personnel in the proper selection of appropriate biosafety levels, training, procedural protocols, microbiological practices, safety equipment, and facilities to prevent occupationally acquired infections. It is essential that the risk assessment be performed prior to the start of "risky" activities. The initial assessment and determination of the acceptability of risks are necessary activities when judging the safe handling of potentially infectious organisms. An agent or procedure is considered safe when the risks associated with it are well managed. The risk assessment process must be mutable and must change as agent use, practices, employees or facilities change.

An effective risk assessment process adequately identifies characteristics of microorganisms as well as host and environmental factors that influence the potential for exposure and balances this against expensive or burdensome safeguards that may prove ineffective.

- Identify hazards and perform an initial risk assessment of laboratory hazards
- Determine the appropriate biosafety level and select additional precautions
- Evaluate integrity of equipment and the proficiencies of staff work practices
- Review risk assessments with a biosafety professional.

2.2 Management

Risk management is the systematic application of policies, practices and resources to the assessment and control of risk affecting human health and safety and the environment. Proper management of risks may involve the development of risk reduction options, program objectives and prioritization of issues and resources. Performance measures are developed and monitored in order to support performance evaluation. In the research environment this translates into adherence to University and departmental health and safety policies, developing standard operating procedures for high risk activities, use of safety and engineered sharps, use of engineering controls and periodic self-inspections.

2.3 Resources

The Material Safety Data Sheets for Infectious Substances developed by the Public Health Agency of Canada contains health hazard information such as infectious dose, viability (including decontamination), medical information, laboratory hazard, recommended precautions, handling information and spill procedures. The Control of Communicable Diseases Manual is an important reference for information on communicable diseases and provides detailed agent summaries including occurrence, reservoir, severity of illness, modes of transmission, susceptibility and methods of control. This manual specifically addresses risk assessment and management of work that poses a biological hazard. However investigators are encouraged to think "outside the box". Environmental Health & Safety is home to a number of programs and resources designed to assist the principal investigator in managing and identifying the risks associated with research.

2.4 Identifying Hazards and Performing the Initial Risk Assessment

Factors which need to be considered as part of the risk assessment process include the natural route of infection, other infectious routes that may manifest as a result of laboratory specific manipulation, the presence of a suitable host animal, reports of laboratory acquired infection, planned laboratory procedures, genetic manipulations which may extend the host range and prevailing conditions in the immediate geographic area. Depending on the characteristics of research undertaken, the nature of risk and the associated variables may be unknown or uncharacterized. In such cases, a conservative approach to risk assessment is recommended.

The principal investigator or laboratory director must consult with the university Biological Safety Officer to ensure that the laboratory is in compliance with established guidelines and regulations and to conduct a risk assessment to determine the proper work practices and containment requirements for work with biohazardous materials. The Principal Investigator is encouraged to consult EH&S and the Chemical Hygiene Plan, which provide guidance on managing additional risks faced in the laboratory. While it is impossible to achieve zero risk, the assessment process is aimed at identifying, minimizing and managing risks.

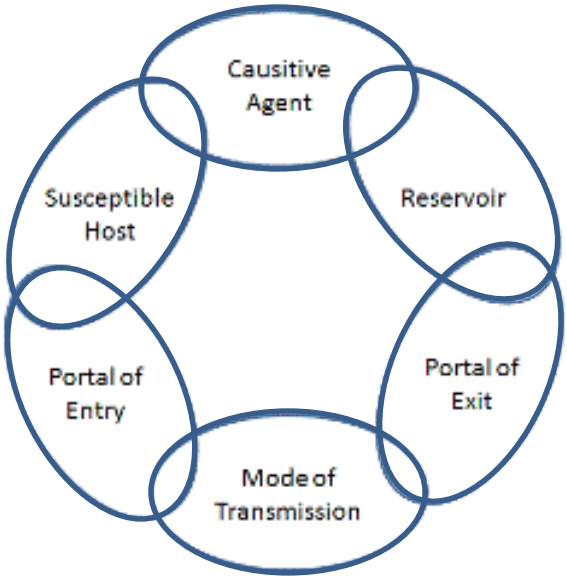
2.4.1 Human, Animal, and Plant Pathogens

The manipulation of human, animal and plant pathogens in the laboratory may pose a significant risk to laboratory personnel and the environment. In general, the risk posed by the agent is a factor of its risk group level (pathogenicity and niche), laboratory procedures and processes and immune status of laboratory staff (host-parasite interactions). The risk assessment must consider if the agent will be manipulated in a pure, highly concentrated form (as is the case for cultures), techniques used to study the agent that may energize the material leading to spills, splashes and the generation of infectious aerosols, sanitization and hygiene. Additionally, the risk assessment may be complicated by the use of animal models to study the pathogenic agents. Often the model itself may be a source of uncharacterized pathogenic organisms, allergens or a means of transmitting the agent via shedding or direct inoculation as a result of bites or scratches.

2.4.2 Understanding the Infectious Disease Process

The infectious disease process is defined as the interaction between the pathogenic microorganism, the environment, and the host. The process may be thought of as a circular chain with six links.

For an infectious disease to occur, each link in the chain must be connected. Missing links and/ or breaks in the chain interrupt the infectious disease process.



2.4.3 Factors to Consider When Evaluating Risk Posed by a Biological Agent

- ***Pathogenicity*** - the ability of an agent to cause disease.
- ***Virulence*** - severity or degree of pathogenicity
- ***Route of transmission*** - Historically, agents that can be transmitted via the aerosol route have caused the most laboratory acquired infections. Agents that exhibit greater aerosol potential, pose a higher risk of infection to personnel.
- ***Agent stability*** - An increased ability of the agent to survive in the environment, results in a higher probability of transmission. Consider whether factors such as desiccation, exposure to sunlight/ ultraviolet light or chemical disinfectants influence agent stability.
- ***Infectious dose*** - the infectious dose varies from organism to organism and can range from one to hundreds to millions of organisms or infectious units. The investigator must be conscious of the amount of agent needed to cause illness in a healthy individual. However, the investigator must also bear in mind that individuals with compromised immune systems demonstrate an increased susceptibility to infection at much lower doses.
- ***Concentration*** - Given that the risk of infection generally increases as the agent concentration increases, the investigator must consider if procedures such as amplification, sonication or centrifugation may affect the amount of agent or its transmissibility. Additionally, investigators must take into account the presentation of the material whether solid tissue or media, viscous blood or fluid.
- ***Origin*** - This may refer to a geographic location (foreign or domestic), host (human, plant, animal, zoonotic) or nature of the source (disease outbreak, clinical diagnostic specimen).
- ***Availability of data from animal studies*** - while data from animal models does not always correlate directly to agent action in human models, this information is quite valuable in the absence of human data.
- ***Availability of effective prophylaxis or therapeutic intervention*** - effective vaccines, if available, should be offered to laboratory personnel in advance of their handling infectious material. However, immunization must not substitute for engineering controls, proper practices and procedures or the use of personal

protective equipment (PPE). The availability of post-exposure prophylaxis should also be considered and discussed with personnel.

- ***Medical surveillance*** - medical surveillance is an important component of occupational medical support services and serves as a form of secondary protection. Effective surveillance programs help to identify exposures early, preventing further injury and expedite treatment.
- ***Experience and skill level of at - risk personnel*** - in this environment, it is essential that laboratory workers demonstrate proficiency in specific tasks prior to working with microorganisms. The investigator must develop tools which accurately assess employee aptitude and document that staff has demonstrated the skills necessary to work with biological materials.

2.4.4 Risk Group Classification of Infectious Agents

Several systems exist for the classification of human and animal infectious agents (e.g., NIH Guidelines, WHO, Canadian Biosafety); based on the relative hazards these agents may pose to healthy, immuno-competent individuals in the laboratory.

Classification of Infectious Microorganisms by Risk Group

Risk Group Classification	NIH Guidelines for Research involving Recombinant DNA Molecules 2002[2]	World Health Organization Laboratory Biosafety Manual 3rd Edition 2004[1]
Risk Group 1	Agents not associated with disease in healthy adult humans.	(No or low individual and community risk) A microorganism unlikely to cause human or animal disease.
Risk Group 2	Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are *often* available.	(Moderate individual risk; low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
Risk Group 3	Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).	(High individual risk; low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
Risk Group 4	Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).	(High individual and community risk)A pathogen that usually causes serious human or animal disease and can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive

Note: ***Classification systems do not address circumstances in which an individual may have increased susceptibility because of preexisting diseases, medications, compromised immunity, or pregnancy. Determination of additional risk due to immune status must be made in consultation with a health professional.***

Although classification systems differ, microorganisms are assigned to one of four risk groups based on the:

- Pathogenicity of the organism
- Mode of transmission and host range
- Availability of effective preventive measures and treatment (e.g., vaccines, antibiotics) and maintain adequate accident/ illness prevention and health and safety programs within colleges or units.

Note: ***The use of agents in Risk Groups 3 and 4 are not permitted at Pace University.***

Restricted animal pathogens defined as animal pathogens that are excluded from the United States by law or whose entry is restricted by United States Department of Agriculture administrative policy are also prohibited.

The NIH Guidelines contain a comprehensive list of risk group 2-4 agents. However, those agents not listed in Risk Groups 2, 3, and 4 are not automatically or implicitly classified in Risk Group 1; you must conduct a risk assessment on the known and potential properties of the agent, and consider the relationship to agents on the list. The risk group classification and the types of laboratory activities being conducted are used as a starting point to estimate the appropriate containment for working with a biohazardous agent and assignment to one of four biosafety levels (BSL1-4). The assigned biosafety level takes into consideration characteristics of the agent such as its infectivity, severity of any associated disease, transmissibility and the nature of the work being conducted. Generally, organisms of a particular risk group are handled at the corresponding biosafety level (e.g., RG2 at BSL2). The fundamental principle of biological safety is containment. A thorough understanding of containment includes knowledge of acceptable practices and techniques, components of primary barriers, protective clothing, mechanical devices, and secondary facility design. Each of these components contributes to decreased personal exposures, and laboratory and environmental contamination.

Bloodborne Pathogens and Standard/ Universal Precautions

Universal precautions require that all blood and body fluids be handled as if contaminated with HIV, HBV or other blood-borne pathogens. In the laboratory, this translates to the consistent use of standard microbiological practices, BSL2 facilities and BSL2 specific practices in addition to additional precautions identified by the risk assessment.

2.4.5 Recombinant DNA (rDNA)

Recombinant DNA organisms are typically constructed by introducing a small segment of DNA from a "donor" organism into a "recipient" organism. The genome of the resulting organism derived by a rDNA technique from these two "parents" is therefore most like that of the recipient organism. Since all but a small fraction of the genetic information in the modified organism is that of the recipient organism. The risk assessment of the new organism would rely heavily on the knowledge of its parental organism, as well as on an analysis of how the new organism appears to differ from the parent. Contact EH&S prior to beginning any rDNA work.

Properties of donor and recipient organisms

Properties of the "recipient" organism that should be taken into account include origin and classification, as well as genetic, pathogenic, physiological and ecological characteristics. Properties of the "donor" organism relate to the structure and function of the DNA sequences to be added. More information concerning the properties of the donor organism will be needed, when these DNA sequences are not fully characterized.

Recombinant DNA technique for deriving the organism

The relevant properties of the recipient organism and the donor DNA provide information on the properties specific to the modified organism. Description of the rDNA technique for deriving the organism provides important information on its anticipated properties. Component parts, for example, would include the donor nucleic acids, control elements, linking sequences, antibiotic-resistance genes, flanking regions etc.

Properties of the organism derived by rDNA techniques

The risk assessment must consider the extent to which the recipient's properties are altered by the introduced DNA. The first consideration should be the degree of expression of the introduced genetic material. The second would be the extent to which relevant properties of the recipient have been modified as a result of the genetic manipulation, including significant new or unexpected effects. Recombinant DNA techniques can be used to modify the genome of an organism, e.g. to delete a portion of a recipient genome. Compared to other kinds of manipulations, the use of a deletion technique would ordinarily connote lowered risk since a deletion typically makes smaller and more precisely defined changes, while also typically weakening the organism, and no new genetic information has been added to the parental organism. Deletions are also likely to mimic mutations that occur naturally in organisms. However, appropriate consideration should be given to the possibility of the expression of unanticipated functions particularly in the case of other types of modifications.

In summary, the risk assessment for the use of recombinant organisms should include the following considerations:

- **Formation** - the creation of a genetically-altered micro-organism through deliberate or accidental means.
- **Release** - the deliberate release or accidental escape of some of these microorganisms in the workplace and/or into the environment.
- **Proliferation** - the subsequent multiplication, genetic reconstruction, growth, transport, modification and die-off of these micro-organisms in the environment, including possible transfer of genetic material to other micro -organisms.
- **Establishment** - the establishment of these micro-organisms within an ecosystem niche, including possible colonization of humans or other biota.
- **Effect** - the subsequent occurrence of human or ecological effects due to interaction of the organism with some host or environmental factor.

2.4.6 Cell Lines

In considering the risk posed by the use of cell lines in research, one must consider the intrinsic properties of the cell culture as well as properties acquired as a result of genetic modification. Specifically, consideration should be given to the species, tissue or cell type and culture type and cell line status (primary, immortalized). Primary cells are obtained directly from fresh tissues. Immortalized cells are produced by isolating cells from tumors, mutating primary cells with mutagens or using viruses or rDNA to produce cells capable of continuous growth. Hybridoma cell lines are produced by fusing a primary cell line to continuous cell line. In general, the closer the genetic relationship of the cell line is to

humans, the greater the risk of its use. The following chart summarizes the risk assigned to intrinsic properties of cell cultures.

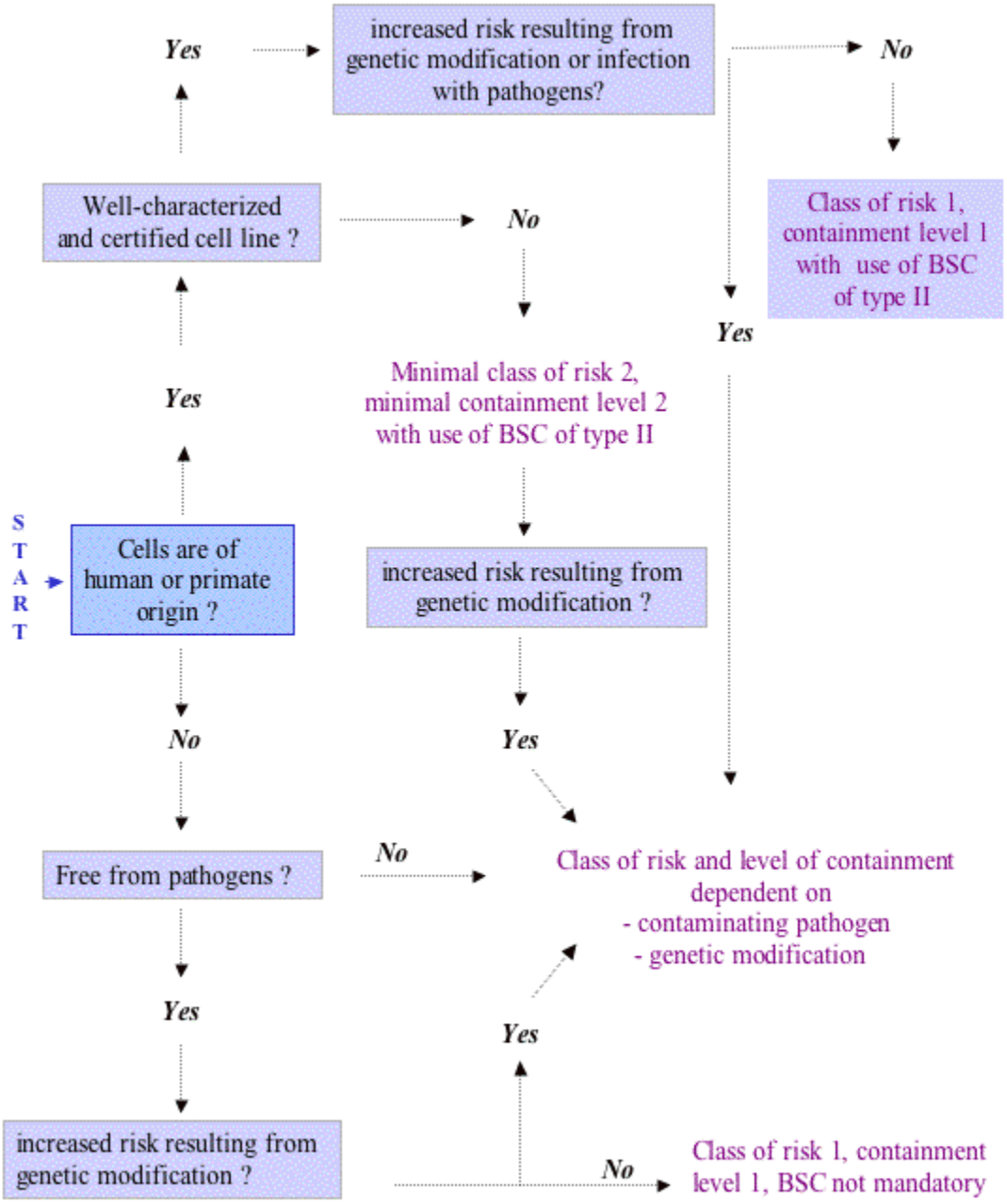
Intrinsic Properties of Cell Cultures and Associated Risk Level

Often, cells are deliberately infected with pathogens as part of the study design. The risk assessment must include the Risk Group categorization of the agent and the associated risk factors. Additionally, one must consider the presence of uncharacterized, adventitious contaminating biological agents within the cell line. These agents may include bacteria, fungi, viruses, prions, mycoplasma or parasites. The user should be aware that cell lines are generally not screened to rule out the presence of adventitious biological agents.
Finally, due to the nature of many cell lines, tumorigenic potential must also be considered in the risk assessment. Under certain circumstances, a cell line may be considered free of contaminating agents. These conditions are outlined below.

Conditions to be fulfilled in order to consider cells free of adventitious contaminating pathogens:

- Use of well-characterized cell lines or controlled cell sources for primary cells such as specified-pathogen- free (SPF) animals.
- In the absence of well-characterized cell lines or SPF, tests for detection of likely contaminating agents should be negative;
- The use of media sources free from contamination;
- The use of appropriate containment measures to reduce contaminations during sampling or subsequent manipulation of cells (re-feeding, washing steps).

The following flowchart summarizes key steps in the risk assessment of a cell line.



A culture collection, such as ATCC will generally recommend a minimum the containment level required for a given cell line based upon its risk assessment. For most cell lines the appropriate level of containment is Category 2. However, this may need to be increased to Category 3 depending upon the type of manipulations to be carried out and whether large culture volumes are envisaged. In order to receive Risk group 2 level materials from ATCC, the researcher is required to complete an application that includes an institution profile,

laboratory facility description and materials transfer agreement. The completed application must be reviewed and approved by EH&S. The following is a list of precautionary measures recommended for work with cell culture materials.

- Use good microbiological practices, especially those that are aimed at avoiding accidental contamination
- Treat each new culture that is manipulated for the first time in the laboratory facility as potentially infectious. The use of a biosafety cabinet of class type II is strongly recommended until the cells have been shown negative in sterility tests for bacteria (including mycoplasma) and fungi.
- Cell cultures from ill-defined sources should be handled under biosafety level 2 (BSL2) conditions. If there is a reasonable likelihood of adventitious agents of higher risk class, the cell line should be handled under the appropriate containment level until tests have proven safety;
- Clean up any culture fluid spills immediately;
- Work with one cell line at a time, disinfect the work surfaces between cell lines handling, aliquot growth medium so that the same vessel is not used for more than one cell line;
- Avoid pouring actions that are a potential source of cross-contamination;
- If necessary, carry out a quality control of cells demonstrating the absence of likely contaminating pathogens (e.g. PCR, reverse transcriptase detection, electron microscopy studies for observation of retrovirus-like particles, infectivity assays with sensitive cell cultures or indicator cell cultures).

2.5 Recognizing Routes of Exposure

Laboratory workers increase their risk for infection when they handle biohazardous or infectious agents. Although some procedures may entail high risk (e.g., grinding tissue samples, invasive animal surgery, drawing blood), laboratory workers can minimize the risk by utilizing the principles of biosafety presented throughout this document and supplementing with good work practices, engineering controls, safety equipment, and prudent use of personal protective equipment. Some common routes of exposure include:

- Exposure to mucous membranes
- Ingestion
- Occupational Inhalation
- Parenteral Injection

Exposures to mucous membranes of the mouth and nose commonly occur through the following practices:

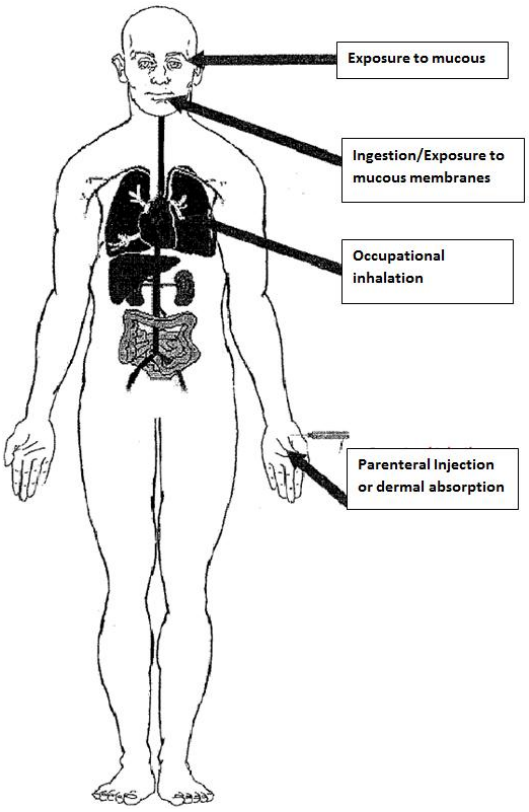
- Eating, drinking, smoking, applying cosmetics, etc. in the laboratory
- Transfer by contaminated hands or objects
- Lack of hand washing
- Ingestion often occurs as a result of
- Splashing of infectious material
- Mouth pipetting
- Lack of hand washing

Occupational Inhalation Exposure may occur through the following practices:

- Using aerosol-generating procedures such as vortexing, blending, sonicating, etc.
- Changing contaminated bedding from infected animals
- Blowing out pipettes

Parenteral Inoculation may result in the piercing of skin or mucous membranes by:

- Accidental inoculation with needles, sharp instruments, broken glass, etc.
- Cuts, scratches
- Animal bites



2.6 Recognizing Task/ Equipment Specific Hazards

The equipment discussed below are known to produce aerosols in the laboratory under normal operating conditions however, it is the responsibility of the Principal Investigator to identify any and all aerosol generating sources of equipment and encourage the use of techniques that minimize the release of aerosols and subsequent doses to laboratory staff.

Equipment

Centrifuge

Centrifuges are commonly found in microbiological laboratories. They provide a physical barrier between the worker and the bio-hazardous material being centrifuged.

Centrifuges are also a source of exposures to infectious aerosols and have been associated with hundreds of laboratory-acquired infections. Practices such as filling tubes, removing caps after centrifugation, removing supernatants, and re-suspending pellets can create aerosols. The most significant hazard, however, is created when a tube containing infectious material breaks during centrifugation. To minimize the risk of creating hazardous aerosols, equipment should be properly maintained and personnel trained on operating procedures. All centrifugation of biohazardous materials must use safety buckets or sealed centrifuge tubes in sealed rotors. If centrifuging infectious materials, the rotors should be opened in the BSC. Small centrifuges that are not equipped with safety cups may be operated in the Biological Safety cabinet. A log book should be maintained detailing operation records for centrifuges and rotors. Observe the following procedures when infectious and biohazardous materials are centrifuged:

- Use sealed tubes and safety buckets that seal with O-rings. Inspect all equipment for cracks and chips prior to use. Do not cap tubes with aluminum foil as the foil may rupture or detach during centrifugation.
- When possible, fill centrifuge tubes and rotors in the biological safety cabinet. Never overfill tubes. After filling and sealing, wipe tubes and rotors with a disinfectant to remove any external contamination.
- Always balance tubes, buckets, and rotors.
- After centrifugation, transport rotors to a biological safety cabinet to safely open rotors and remove tubes. This practice minimizes potential exposure to infectious material released from a broken tube. If a tube should break, turn off centrifuge and/or close lid, leave room, and contact Environmental Health & Safety (2-2818).
- When appropriate, use a vacuum system with in-line reservoirs and filters to remove supernatants from tubes. Avoid decanting or pouring off.
- Work in a biological safety cabinet when pellets are re-suspended. Use a swirling rotary motion rather than shaking or vortexing. Let aerosols settle before the tube is opened.
- To reduce the hazards associated with the escape of aerosols, small low-speed centrifuges may be placed in a biological safety cabinet.

Blenders, Sonicators, Homogenizers and Mixers

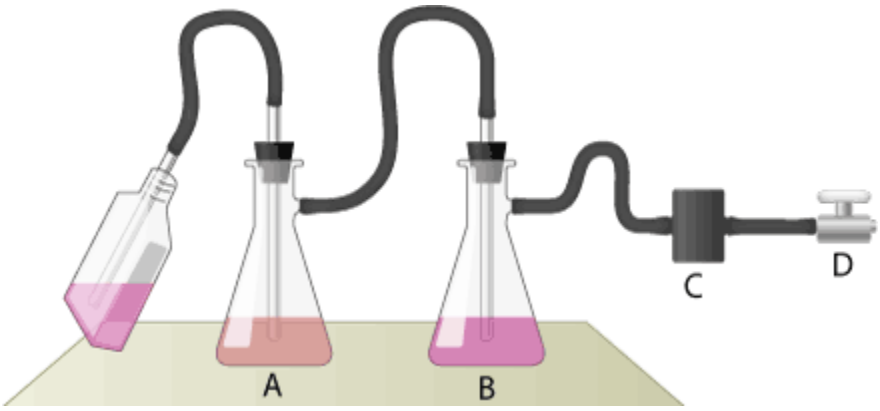
The use of blenders and related mixing equipment can generate considerable quantities of aerosols, and like centrifuges, can rapidly contaminate spaces and surfaces. Conduct any blending or mixing of biohazardous materials in a BSC. This includes the use of mortars and pestles. Safety blenders are preferred as they prevent leakage from the bottom of the blender jar, have a cooling jacket, and are able to withstand autoclaving.

Conventional blender jars have the potential for breakage, if used, test with a dye solution prior to use with infectious materials. If you must use glass jars, cover with a polypropylene container to prevent spraying of glass and contents should the jar break. During use, the top of the blender jar can be covered with a towel moistened with disinfectant. Allow the contents and aerosols in the jar to settle before the lid is opened. Many sonicators lack safety equipment and must be operated in a BSC. Stomacher style homogenizers are

available which use a plastic bag to contain the material and any resulting aerosols. The plastic bag should be filled and emptied in the BSC.

Vacuum Line Chemical Traps and Filters

The use of vacuum within the laboratory has the potential to generate aerosols, contaminate vacuum lines, pumps and the laboratory environment. The use of vacuum line traps and filters prevent infectious material from entering vacuum lines. Aspirate culture media or other fluids with a suction or aspirator flask (A) should be connected to an overflow collection flask (B) that contains a disinfectant. Couple the flasks to an inline hydrophobic filter followed with a HEPA filter (C) designed to protect the vacuum system (D). The HEPA filter must be inspected and replaced if clogged or if liquid makes contact with the filter.



Lyophilizers and Ampoules

Production of aerosols may occur when ampoules are loaded or removed from the lyophilizer unit. Use a biological safety cabinet to fill ampoules with suspensions of infectious agents or biohazardous materials. Attach a HEPA filter to the vacuum pump exhaust to remove infectious or hazardous agents. Decontaminate all surfaces of the unit after lyophilization. Ampoules that contain liquid or lyophilized material should be opened in a biological safety cabinet. Ampoules may be wrapped in a disinfectant-soaked towel, held upright, and snapped open at the neck. To reconstitute lyophilized samples, slowly add liquid to avoid creating aerosol particles from the dried material.

Ampoules used for freeze-drying of cultures, toxins or other biohazardous material must be made of Pyrex-type as they are less likely to implode during sealing under vacuum and are more resistant to breakage during handling or storage.

Microtome/ Cryostat

The use of microtomes and cryostats in the laboratory presents a laceration hazard in addition to generating potentially infectious aerosols. Tissues prepared via fixation or freeze-drying should be considered capable of causing infection and should be treated with care. Users involved in sectioning tissues of human origin must attend Bloodborne Pathogens Training. Use of equipment safety features such as auto-decontamination cycles, blade release, and retractable blades could reduce risks associated with use. Observe the following procedures when using microtomes/ cryostats:

- Always retrieve samples, change blades, dislodge blocks, or clean equipment with appropriate engineering controls (i.e. forceps, tweezers, dissecting probes, and small brushes
- Always keep hands away from blades.
- Use extreme caution when aligning blocks, the blocks may be close to the blades. If available, make sure block holder is in locked position when loading/aligning blocks.
- Use protectors/guards for knife-edges that may extend beyond microtome knife holder.
- Keep blocks wet when in the microtome to minimize airborne shavings during slicing.
- Wear appropriate PPE such as gloves, lab coat or gown, mask, safety glasses or goggles. Consider the use of surgical grade Kevlar gloves to provide additional protection from cuts and scrapes.
- Avoid freezing propellants that are under pressure as they may cause splattering or droplets of infectious materials.
- Decontaminate equipment on a regular schedule using an appropriate disinfectant.
- Consider trimmings and sections of tissue as contaminated and discard in the appropriate waste stream.
- Do not move or transport microtome with knife in position.
- Secure knives in containers when not in use.
- Do not leave motorized microtomes running unattended.

Miscellaneous Equipment

Ultra low freezers, liquid nitrogen, and dry ice chests as well as refrigerators should be periodically checked and cleaned out to remove any broken ampoules, tubes, plates, etc. that contain infectious or biohazardous materials, and subsequently decontaminated. Use rubber gloves and respiratory protection during this cleaning. All infectious or toxic material stored in refrigerators or deep freezers should be properly labeled. Security measures should be commensurate with the hazards. The degree of hazard represented by contaminated liquid nitrogen reservoirs will be largely dependent upon the infectious potential of the stored microorganisms, their stability in liquid nitrogen, and their ability to survive in the airborne state. Investigations suggest that storing tissue culture cell Lines in containers other than sealed glass ampoules might result in potential inter BSM contamination among cell lines stored in a common liquid nitrogen repository. Care must also be exercised in the use of membrane filters to obtain sterile filtrates of infectious materials. Because of the fragility of the membrane and other factors, such filtrates cannot be handled as noninfectious until culture or other tests have proved their sterility. Shaking machines should be examined carefully for potential breakage of flasks or other containers being shaken. Screw-capped durable plastic or heavy walled glass flasks should be used. These should be securely fastened to the shaker platform. An additional precaution would be to enclose the flask in a plastic bag with or without an absorbent material.

Cryogenic Liquids

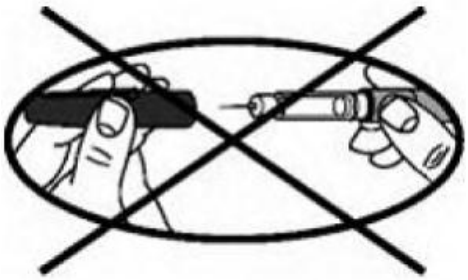
When working with cryogenic materials such as liquid nitrogen, you must wear appropriate PPE including face shields, splash goggles and heavy leather or other insulating protective gloves. These items must be worn during the transfer and normal handling of cryogenic fluids. Additionally, shirt sleeves should be rolled down and buttoned over glove cuffs, or a lab coat, should be worn in order to protect against liquid spraying or spilling inside the gloves. Trousers without cuffs should be worn. Avoid storing cryogenics in cold rooms, environmental chambers, and other areas with poor ventilation. If necessary, install an oxygen monitor/oxygen deficiency alarm and/or toxic gas monitor before working these materials in confined areas.

Sharps

Hypodermic Needles and Syringes

Users of hypodermic syringes and needles must comply with the applicable New York State Department of Health regulations, and are responsible for appropriate certification, procurement, storage, and distribution. Laboratories should minimize the use and handling of syringes and needles, and restrict the use of these sharps to procedures in which there are no alternative devices. Sharps injuries arise because of improper handling, recapping, and disposal of needles and other sharps. Engineering and work practice controls must serve as the primary means to minimize sharps injuries. Whenever possible, use engineered sharps systems to reduce of accidental exposure when working with biohazardous materials.

- When working with potentially infectious or other biohazardous agents wear gloves (to minimize, but not eliminate, the impact of accidental injection) and work in biosafety cabinet whenever possible.
- Lay cap on a horizontal surface
- Align needle and scoop cap onto needle
- Push against s solid object to snap close
- Cautiously handle and use syringes and needles to prevent accidental exposure through injection or the production of aerosols. Use needle locking syringes or disposable syringe-needle units in which the needle is an integral part of the syringe for injection or aspiration of infectious materials.
- Carefully fill the syringe to avoid or minimize the production of air bubbles, and expel all air, liquid, and bubbles into a towel or cotton pad moistened with disinfectant.
- Ensure that sharps disposal containers readily available in all areas where you may generate syringe and needle waste, and do not fill the containers more than ¾ prior to disposal.
- Do not recap, bend, shear, break or remove contaminated needles from the syringe following use or as a means of disposal. Dispose as a whole unit into a sharps disposal container.
- If it is necessary to recap a needle as part of a specific procedure or lack of available sharps disposal container, use a mechanical device (e.g. forceps) or a one-handed scoop technique.



Pipettes

- Use pipetting aids when pipetting infectious materials. Even with pipetting aids, pipettes should always be plugged with cotton. When possible, perform pipetting activities in a biosafety cabinet.

Note: ***Never suction or pipette by mouth.***

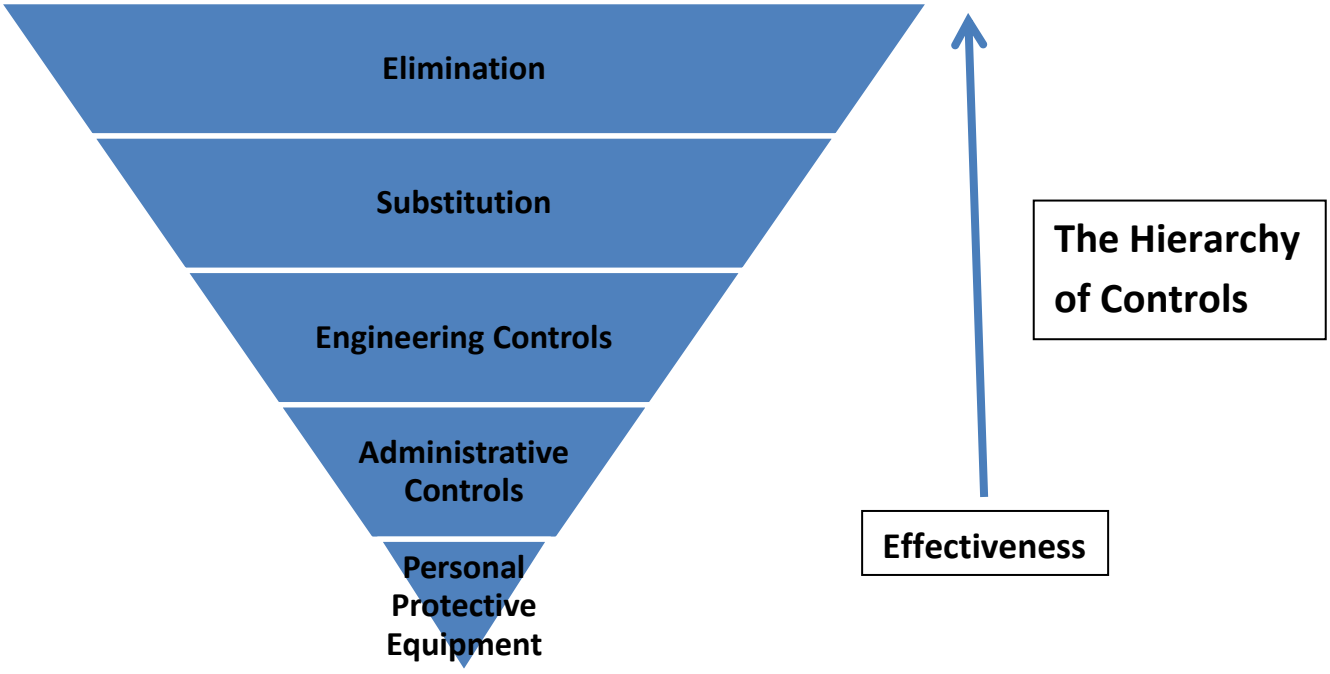
- Pipette toxic chemicals in a chemical fume hood.
- Do not forcefully expel infectious or toxic materials from a pipette. Discharge as close as possible to the fluid or agar level. To expel the last drop of liquid, touch the pipette end to the side of the container to break the surface tension.
- Avoid mixing infectious or toxic fluids by alternate suction and expulsion through a pipette, or by bubbling air from a pipette through the fluid.
- Place a disinfectant dampened towel or other absorbent material (e.g., plastic backed bench paper) on the work surface to catch stray droplets of infectious or toxic materials.
- Contaminated pipettes should be placed horizontally into a pan or tray containing enough suitable disinfectant (e.g., 1:10 dilution of household bleach) to completely immerse the pipette. These disinfectant trays should be placed within the biosafety cabinet to achieve maximum containment and minimize laboratory contamination.
- Avoid the use of vertical discard containers outside of the cabinet.
- After suitable contact time, excess disinfectant can be carefully poured down the sink. Disposable pipettes can be placed in rigid container (e.g., cardboard box) lined with a red biohazard bag, three or four layers of bags to minimize poke thru, or in a sharps disposal container. Reusable pipettes can first be rinsed in water and then autoclaved along with the pan.

CHAPTER 3.0 MANAGING LABORATORY HAZARDS

Managing the hazards associated with work in the laboratory environment effectively requires coordination of laboratory practice and technique, safety equipment, personal protective equipment, and facility design. This system of layering and redundancy may not always guarantee successful outcomes when managing risk, but may serve to minimize the potency and frequency of the risks involved. Certain experimental activities can impact the risks of working with biohazardous materials. For example, activities performed outside of a biosafety cabinet including blending, homogenizing, centrifuging, vigorous shaking, and opening tubes under pressure, can increase the risk for aerosol exposure, splashing, and splattering. Additionally, the risk factors with a specific agent increase as you increase the volume of material, incorporate sharps, or involve animals. One of the best ways to determine and establish suitable laboratory procedures is to perform a Hazard Assessment. A Hazard Assessment focuses on specific activities or job tasks as a way to identify hazards and implement mitigation strategies. Priority activities include those that represent higher risks, are most likely to occur, and may result in serious consequences. To perform a Hazard Assessment, one should ask the following questions:

- What can go wrong?
- How could it happen?
- What are the consequences?
- What are other contributing factors?

Conducting a Hazard Assessment allows the opportunity to remove the hazard with an assortment of controls. The hierarchy of controls and their descriptions can be found below.



Control	Example
Elimination	The job is redesigned or the substance is eliminated so as to remove the hazard. However, the alternative method should not lead to a less acceptable product or less effective process.
Substitution	Replace the material or process with a less hazardous one. For example, replace mercury thermometers with spirit thermometers.
Engineering controls	Install or use additional machinery such as local exhaust ventilation to control the risk. Separating the hazard from operators by methods such as enclosing or guarding dangerous items of machinery. For example, use guards on compression testing machines.
Administrative controls	Reduce the time the worker is exposed to the hazard. Prohibit the eating, drinking and smoking in laboratory areas. Provide training. Perform risk assessments. Increase safety awareness signage.
Personal Protective Clothing and Equipment	Only after all the previous measures have been tried and found to be ineffective in controlling the risks to a reasonably practicable level, then Personal Protective Clothing and Equipment must be used. If chosen, PPCE should be selected and fitted to the person who uses it. Workers must be trained in the function and limitation of each item of PPCE. For example, an operator should know how long the compressed supply in a self contained breathing apparatus will last. PPCE may be used as a temporary control measure until other alternatives are installed.

3.1 Administrative Controls

Training

Adequate training is essential to establishing and maintaining a safety culture in the laboratory. It is the responsibility of the Principal Investigator to define training objectives for laboratory staff and specify the skill set needed to meet the desired level of proficiency. Initial training must be based on a need assessment which defines tasks and details the steps needed to accomplish them. It must include problem solving and stress corrective and preventative actions which rely on thinking and reasoning approaches as opposed to sheer memorization. Training must be followed by documented evaluation and revised or repeated as needs change. Finally, the overall effectiveness of training is dependent on management buy-in and good communication. At minimum, laboratory staff must receive training in:

- The appropriate selection and use of personal protective equipment
- The appropriate use of laboratory equipment and instrumentation
- Hazard recognition in the laboratory (chemical, biological, radiological, electrical)
- Good microbiological technique
- Appropriate decontamination and disinfection procedures
- Proper handling of waste streams
- Accident/ exposure reporting
- Notification and emergency procedures

- Laboratory specific protocols and procedures
- Additional required training may include:
- Bloodborne Pathogen training
- Biosafety Level 2
- Shipping and Transport of Infectious Materials

Outside Vendor Training Programs
Principal Investigators and laboratory supervisors can provide training programs to their employees through con-tracts with outside training companies or product vendors. A number of vendors are willing to provide free training programs upon request. If using an outside company or vendor, be sure to ask for documentation including training content, date of training, copies of handouts, and the sign-in sheet. All of this documentation must be kept on file.

In-House Training Programs
In-house training can include department provided training, and training by Principal Investigators and laboratory supervisors. Training sessions can be stand-alone classes, on-the-job training, or short (15 minute) trainings incorporated as part of a laboratory group meeting. The key is to make sure the training is documented with a sign-in sheet.

Training Manuals and Booklets
Principal Investigators and laboratory supervisors can utilize training manuals, booklets, webpage downloads, etc., as part of an ongoing training program by simply having laboratory staff review the material, be given an opportunity to ask any questions, and sign off that they read and understood the material.

Standard Operating Procedures
Standard Operating Procedures (SOPs) are documents to follow for the proper safety precautions and response when using a certain biological protocol, or process. These should be generated for protocols involving infectious or pathogenic materials, carcinogens, acutely toxic, and highly hazardous materials. It is the responsibility of the principal investigator and laboratory supervisor to ensure written SOPs incorporating health and safety considerations are developed for work involving the use of hazardous chemicals in laboratories under their supervision and that PPE and engineering controls are adequate to prevent overexposure. Principal investigators and laboratory supervisors must ensure that personnel working in laboratories under their supervision have been trained on the applicable SOPs. SOPs can be stand-alone documents or supplemental information included as part of research notebooks, experiment documentation, or research proposals. The requirement for SOPs is to ensure a process is in place to document and addresses relevant health and safety issues as part of every experiment.
At a minimum, SOPs should include details such as:
- The agents or chemicals involved and their hazards
- Special hazards and circumstances
- Use of engineering controls (such as biological safety cabinets)
- Required PPE

- Spill response measures
- Decontamination procedures
- Description of how to perform the experiment or operation
- Standard Operating Procedures

It is the responsibility of Principal Investigators and laboratory supervisors to ensure that staff and students working in laboratories under their supervision have obtained the required health and safety training and have access to MSDS (and other sources of information) for all hazardous chemicals used in laboratories under their supervision. MSDS must be accessible at all times.

Signs and Labels

Signs and labels are used in identifying the hazards present within their laboratories and communicating this information to anyone who enters the lab. The supervisor or designee is responsible to ensure appropriate information is incorporated into a door sign. The sign lists the name of the Principal Investigator and the names of others who have responsibility for the room, along with corresponding contact numbers. Supervisors select the most important hazards in their lab area from a list of hazard types, and then rate the risk level as low, moderate, or high for each hazard. The sign indicates any limitations on access, warning messages, and emergency response information.

Signs must also be posted which indicate the location of fire extinguishers, eyewashes, safety showers, spill kits and first aid kits. Additionally, signs should indicate PPE requirements for work in the space. Biohazard labels should be posted on all equipment used to grow or store Risk Group 2 or higher organisms and infectious organisms or organisms containing recombinant DNA molecules. Signage used in the laboratory must inform personnel and visitors of safety policies or indicate hazards which might result in injury or death. These may be general directional, informational, life safety, hazard identification or system identification.

Labels

All containers (both hazardous and non-hazardous) MUST be labeled. Names must be written out in English. If a label is starting to fall off a container or is becoming degraded, then the container needs to be relabeled (using tape, permanent marker, EH&S Right-To-Know labels, etc.) or the material needs to be transferred to another properly labeled container.

Equipment that is potentially contaminated but destined for disposal or repair must be appropriately decontaminated prior to leaving the laboratory. A tag must be affixed to the equipment indicating that the item has been decontaminated, the date, disinfectant used and the name of the individual who performed the decontamination.

Laboratory procedures and work practices

Laboratory personnel should seek to utilize microbiological practices that are the most effective, but limit exposure to potentially infectious material. Consider the availability of

safer, alternative procedures or non-infectious or less infectious organisms that could be substituted, and yet provide the desired outcome. While there is a wealth of acceptable procedures that have been performed in the laboratory for many years, the inherent safety of an activity is not always implied from its long-term usage. Consider the example of mouth pipetting, commonly used for many years, which is now considered a high-risk practice.

General Good Laboratory Practices

- Outer street clothing (coats, hats, etc.) should be kept in an area where accidental contamination with infectious or other hazardous materials is unlikely to occur.
- Long hair, beards, and loose-flapping clothing are potentially dangerous when working near an open flame, biohazard materials that could be inadvertently spilled, or moving laboratory equipment. Tying back hair or employment of hairnets should be encouraged in all laboratories.
- Keep jewelry to a minimum. Do not wear dangling jewelry in the lab.
- Consideration must be given to whether a person should be permitted to work alone on a biohazardous laboratory operation. Emergency situations often necessitate actions by others if someone is contaminated in the incident, such as a spill, in order to prevent injury and avoid additional contamination away from the spill site.
- The PI must evaluate and set lab policy in this regard.
- Protection of the eyes is a matter which should be given high priority in every laboratory. Signs indicating "Eye Protection Required" should be prominently displayed in all areas where a hazardous exposure may exist. Infection can occur through the eyes if a pathogenic microorganism is splattered into the eye, and many chemicals commonly employed in the laboratory can cause serious damage if similarly deposited. Safety spectacles or goggles should be worn when necessary.
- Every laboratory that uses materials that are irritating to the eyes must have an eyewash fountain. These eyewash fountains must be ANSI approved.

Note: ***Contact lenses provide little or no practical protection to the eyes. In fact, foreign material present on the surface of the eye often becomes trapped beneath the contact lens, and similarly entrapped caustic chemicals, irritating vapors, and infectious agents cannot be readily washed from the eye without removal of the lenses. Supervisors and/or instructors are responsible for the enforcement of all regulations regarding the wearing of safety glasses, use of contact lenses, and the use of additional eye protection.***

Laboratory benchtops must be impervious to water and chemically and thermally resistant. Laboratory chairs must be covered with non-porous material that facilitates cleaning and decontamination with an appropriate disinfectant. Substitute plastic ware for glass ware wherever possible.

Note: ***In most cases laboratory glassware can be cleaned effectively by using detergents and water. In some cases it may be necessary to use strong chemicals for cleaning glassware. Strong acids should not be used unless necessary. In particular,***

Chromic acid should not be used due to its toxicity and disposal concerns. One product that may be substituted for Chromic acid is "Nochromix Reagent". The Fisher catalog describes this material as: "Nochromix Reagent. Inorganic oxidizer chemically cleans glassware, contains no metal ion, rinses freely—leaving no metal residue, making this product valuable for trace analysis, enzymology, and tissue culture work. It is mixed with sulfuric acid.

Standard Microbiological Work Practices

- The overall use of standard microbiological practices can minimize and even prevent exposure to biohazardous materials. Standard practices are based on the primary need to protect the worker, coworkers, community and environment while assuring product integrity.
- The principal investigator or laboratory director should limit or restrict access to the laboratory when experiments that involve infectious agents or biohazardous materials are conducted. Additionally, the principal investigator can impose special entry requirements, such as personal protective equipment or immunizations.
- Wash hands with soap and water after exposure to potentially infectious materials, after removing gloves and other personal protective equipment, after completion of any procedure in which biohazardous material is used, and before you leave the laboratory. If a sink with water and soap is not available or accessible, alcohol based hand sanitizers (e.g., gels or foams) can be substituted.
- Storage of food in refrigerators or freezers used for infectious materials, radioactive materials, or chemical carcinogens is strictly forbidden. Store and consume food outside the laboratory or work place.
- Use mechanical devices when pipetting. Mouth pipetting is expressly forbidden.
- Institute policies for the safe handling of sharps such as:
    - Securing unused hypodermic syringes and needles, and log their distribution
    - Utilizing one sharps item at a time. Don not leave sharps unattended
    - Having readily accessible sharps disposal containers close to work area
    - Incorporating engineered sharps injury protection systems (e.g., safer needles) when practical
    - Substituting plastic-ware for glass items whenever possible.
    - Use sharps only when no other alternatives are available
- Conduct procedures or activities that impart a significant amount of energy to material within a certified biological safety cabinet or other type of approved secondary containment. These activities are likely to produce aerosols, splashing, or splattering of infectious or biohazardous materials, and include procedures such as vortexing, grinding, blending, sonicating, centrifuging, and cutting or slicing of infectious or biohazardous materials.
- Decontaminate work surfaces at least once a day and after any spill of infectious or biohazardous materials. With a disinfectant that has been proven to be effective against the agent/ material used.
- Segregate biohazardous waste in red biohazard bags or sharp disposal containers, and dispose as regulated medical waste (see section on waste disposal for more

specific information). It is recommended that regulated medical waste be autoclaved to reduce the hazard of handling the waste.

- Use the universal biohazard warning symbol to indicate areas and equipment where infectious agents and biohazardous materials are handled and stored.
- Incorporate an insect and rodent control program to reduce any mechanical transmission of disease agents. Report any insect/ rodent intrusion to facility manager.
- Persons working with infectious material should avoid touching the face, eyes or nose with gloved or unwashed hands.
- The use of Kleenex rather than cloth handkerchiefs is recommended for personal hygiene in laboratories handling infectious materials.
- Gloves must be worn when working with an infectious agent. Gloves must also be worn when one anticipates hand contact with blood, potentially infectious materials, mucous membranes, or non-intact skin. Vinyl, latex, and nitrile single-use, disposable gloves should be replaced as soon as possible if contaminated, torn, punctured or damaged in any way. Never wash or decontaminate gloves for reuse.
- PIs should be aware of the possibility that employees may have allergies to latex which can be life-threatening to some individuals. When chemical hazards are also present more extensive consideration of the many available types of glove materials is necessary. Contact EHS if assistance is needed.
- Laboratory clothing should be routinely laundered at work. When clothing is overtly contaminated with infectious materials decontaminate by steam sterilization (autoclaving) or other proven effective means (e.g., soak in bleach solution) before laundering. Avoid laundering at home unless the clothing can first be decontaminated. Disposable clothing (coats, gowns, etc.) must be decontaminated by steam sterilization before discarding.

3.2 Engineering Controls

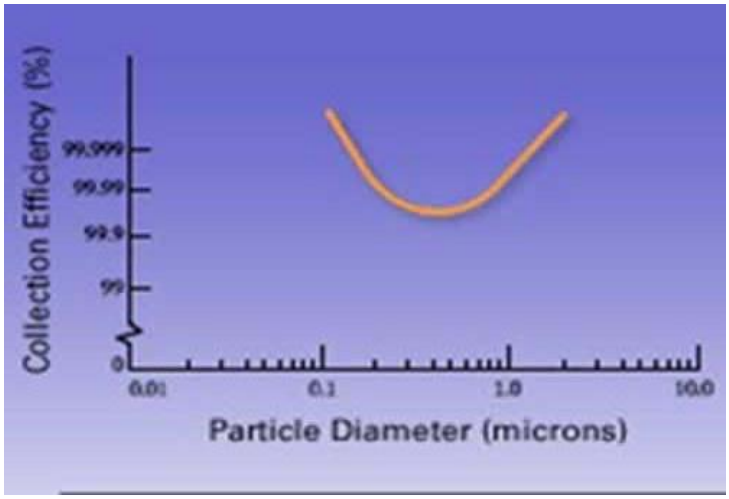
The release of infectious aerosol particles has been determined to be the leading cause of laboratory acquired infections. Many standard laboratory procedures impart enough energy to microbial suspensions to generate respirable aerosols (1-10 μm). Some of these particles are capable of remaining airborne for protracted periods and when inhaled can be retained deep within the lung. Larger droplets may settle out onto skin or mucous membranes of the upper respiratory tract as well as present a contamination hazard to surrounding surfaces, which serve as reservoirs for cross contamination. The assessment of the risks associated with aerosol generating equipment and the implementation of practices and procedures designed to mitigate these risks are essential to safe operation of the laboratory.

Biological Safety Cabinets (BSCs)

Biological safety cabinets (BSC) are primary devices intended to contain and minimize exposure when working with biohazardous materials. They are often, but incorrectly referred to as laminar flow hoods, tissue culture hoods, and biological fume hoods. When properly used biological safety cabinets protect laboratory personnel against exposure

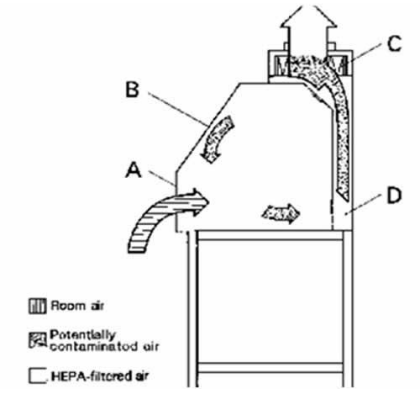
during experimental procedures (personnel protection), protect experimental materials from contamination (product protection), and protect the environment (environmental protection). A cabinet is recommended for manipulations of infectious agents that are likely to create aerosols (e.g., aspirating with a syringe, removing caps from tubes after centrifugation, vortexing of open tubes, sonication). Additionally, BSCs are used when manipulating human blood and body fluids, working with concentrated or large volumes of infectious agents, and maintaining aseptic conditions when working with cell and tissue cultures. BSCs are extremely effective and are an important containment device; however they are only one part of a comprehensive biosafety program and are not a substitute for careful work practices and good aseptic technique. Appropriate practices that minimize the production and escape of aerosols, and maximize protection from possible exposure to infectious material must be incorporated.

Biological safety cabinets utilize vertical laminar airflow (i.e., uniform air velocity in one direction along parallel flow lines) to achieve a barrier of protection against airborne contaminants such as microorganisms. HEPA filters (High Efficiency Particulate Air) inside the cabinet remove 99.97% of airborne particles that are 0.3um, and higher efficiencies (99.99%) with particles above and below 0.3um.



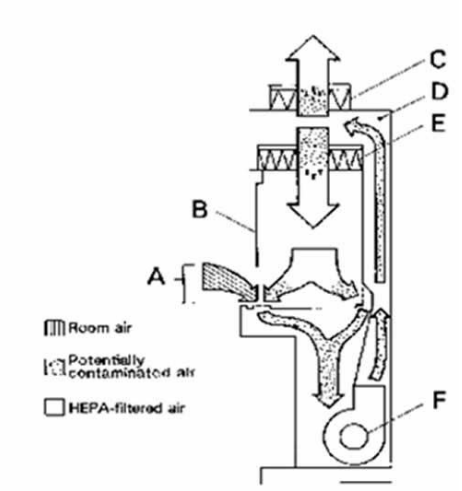
Classes of Biosafety Cabinets

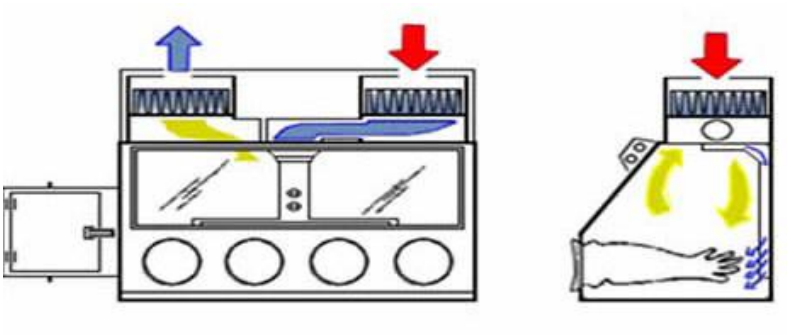
There are three different classes of biological safety cabinets.



Class I cabinets offer good protection for the operator and the environment, and are simple and economical to operate. Radioisotopes and some toxic chemicals can be used (if the cabinet is ducted to the outside), but HEPA filtered air is not provided over the work area. Thus, these cabinets do not protect your materials from contaminants introduced from the environment or the operator.

Class II cabinets are most commonly used on campus and can be used to manipulate low to moderate risk agents. Unlike class I cabinets, class II cabinets afford protection for the operator AND the work per-formed. The capacity to protect materials within the cabinet is pro-vided by the flow of HEPA-filtered air over the work surface. There are four subtypes of Class II cabinets based on the construction, inflow air velocities, and the exhaust systems.





Class III cabinets provide maximum protection to the environment, the worker, and the product, and are used with high-risk agents. These cabinets are gas-tight enclosures and the interior is accessed through a dunk tank or a double -door pass through box. Supply and exhaust air are HEPA-filtered

NOTE: ***Do not confuse other laminar flow devices or "clean air benches" with BSCs. Some laminar flow hoods direct HEPA filtered air horizontally across the work surface towards the operator and the open, laboratory environment. These hoods are not safety devices and must never be used with infectious, toxic, or sensitizing materials.***

Biological safety cabinets must be routinely inspected for proper airflow and filter integrity to ensure that they are providing protection to the worker and the environment. Certification must be performed when a BSC:

- Is first installed (damage or maladjustments can occur during shipment)
- annually thereafter the BSC should have a label indicating the date it was last tested
- moved to a new location, or
- when the HEPA filters are changed or other repairs are performed

Certification must be performed by a contractor who is trained to National Sanitation Foundation Standard No. 49. Some available contractors that can provide service include: TSS (866-536-5656) and ENV Services (800-292-5255).

The BSC should be located “deep” within the laboratory away from air currents produced by ventilation inlets, opening/closing of the laboratory door (s), and away from areas of heavy traffic. If possible, close laboratory doors, limit entry, egress, and walking traffic during operation. Air currents and movements create turbulence that can disrupt the protective “envelope” and laminar air flow within the cabinet. Other nearby laboratory equipment such as centrifuges, vacuum pumps, etc. can also affect the performance of the

BSC. Similarly, do not locate cabinets directly opposite each other or opposite a chemical fume hood, as laminar airflow will be hindered.

Observe the magnehelic gauge and note its relative position each time you operate the BSC (e.g., maintain a log). The magnehelic gauge measures the pressure drop across the HEPA filters, and thus indicates filter load and integrity. An increase or decrease in the pressure value may indicate clogging or leaking of the filter, respectively.

Chemical Fume Hoods

Fume hoods and other capture devices must be used for operations that might result in the release of toxic chemical vapors, fumes, or dusts. Bench top use of chemicals that present an inhalation hazard is not permitted. Fume hoods must be used when conducting new experiments with unknown consequences from reactions or when the potential for a fire exists.

Building & Grounds (B&G) coordinates annual testing and inspection of fume hoods on campus. After each inspection, an inspection sticker is affixed to the fume hood. If your fume hood does not have an inspection sticker or if the existing inspection sticker on your fume hood indicates a year or more has passed since the hood was last inspected, then contact B&G or EH&S. The fume hood inspection program at Pace consists of an initial comprehensive inspection followed by annual standardized inspections for all fume hoods on campus. This initial inspection will provide baseline information including, but not limited to, hood usage, type of hood, room and building information, as well as average face velocity measurements.

Follow-up inspections for proper use and face velocity (airflow) measurements will be performed on an annual basis or upon request by laboratory personnel. Upon completion of each inspection, hoods will be labeled with an inspection sticker indicating face velocity, date inspected, and initials of the inspector. Hoods will be labeled with a safe operating tips sign, and stickers with green arrows. The green arrows represent the sash position at which the hood was tested for optimum working height. All inspection information will be recorded and kept on file. Contact EH&S for more information.

EH&S strongly recommends laboratory personnel conduct a dry ice capture test and/or a chemwipe test with their fume hoods when using new materials for the first time or whenever substantial changes have been made to an experimental setup in a hood, such as the addition of more apparatus.

3.3 Personal Protective Equipment

Laboratory workers must utilize personal protective equipment (PPE) as necessary to reduce or eliminate exposures from biological, chemical, and radiation hazards. The correct usage of the appropriate PPE can also minimize contamination of experimental materials. PPE is designed to augment suitable engineering controls and work practices, not

substitute for them. Selecting the appropriate PPE is integral to the risk assessment process and may include items such as gowns, lab coats, gloves, shoe covers, boots, face shields, respirators, safety glasses or goggles. It is the responsibility of the PI, lab supervisor, or designee to perform the risk assessment for their space and train lab staff on task specific hazards. This training must include how PPE is obtained, stored and maintained for the space, how to properly use PPE, and a discussion of the limitations of PPE. The supervisor must also discuss general PPE use and safety practices including removal of PPE prior to leaving lab areas.

Clothing

Protective clothing such as laboratory coats or gowns is used to protect the user against biological or chemical spills, and should be worn when working in the laboratory. The specific hazard and the desired level of protection will dictate the type of clothing needed. For example, an ordinary laboratory coat may be adequate for work in a BSL2 laboratory, but a solid front or wrap around gown is recommended in BSL3 laboratories.

Coats and gowns come in disposable and reusable models, constructed from a variety of materials. If possible, garments should have knit cuffs at the wrist, and must be resistant to liquid penetration. Refrain from wearing any protective clothing outside the laboratory.

Eye/Face Protection

When there is a possibility of splashes, sprays, or splatter to the face and mucous membranes with infectious or other hazardous materials, eye protection and a mask are required. Some examples of suitable mucous membrane protection include safety glasses, chemical splash goggles, or surgeon's mask. A face shield may be used for additional mucous membrane protection, but it cannot be used alone for eye protection.

Respiratory Protection

The inhalation of infectious materials poses a significant hazard. Respiratory protection is mandatory when containment and engineering controls (e.g., biological safety cabinets, ventilation) are not available or achievable, or when activities generate potentially infectious aerosols (e.g., invasive procedures with infected animals, disruption of animal bedding). Respiratory equipment includes disposable N95s, half or full face respirators with cartridges, and PAPRs (Powered Air Purifying Respirators). EH&S is establishing a program for the use of respirators on campus. The program is designed for those University personnel who, during their normal duties are, or could be exposed to hazardous substances or atmospheres that may affect their health and safety. Individual employees, who require respiratory protection must contact EH&S for a medical clearance form, fit test, selection of appropriate equipment, and annual training. There may be

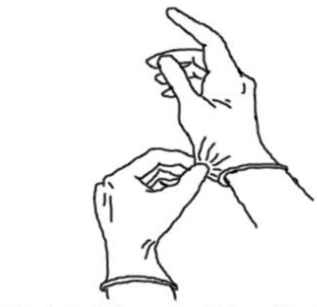
circumstances where voluntary usage of respiratory protection is acceptable. However, please consult with EH&S before use.

Gloves

Gloves protect the user from a variety of hazards including contact with infectious agents, contaminated surfaces or equipment, and animals. Employees must select a glove based on the particular tasks, as no one type of glove can adequately protect against every kind of hazard. Additionally, you should consider an alternative glove material (e.g., nitrile, vinyl) if you are sensitive to latex.

Disposable gloves (e.g., latex, nitrile, vinyl) offer little protection against needle sticks or animal bites, and so it is important to follow good microbiological practices and procedures to maintain an envelope of protection. Specialty gloves such as Kevlar or stainless steel mesh gloves can be worn during necropsy or surgery of infected animals to prevent accidental cuts from scalpels. Gloves should be long enough to cover the cuff or lower sleeve of laboratory clothing and protect exposed skin. Double gloving can provide additional protection. Remove disposable gloves and discard in biohazard waste containers when work with infectious or bio-hazardous material is completed. Do not wash or reuse disposable gloves. Heavy-duty latex and nitrile gloves can be decontaminated, washed, and reused if in good repair. Remove gloves when performing non-laboratory functions (e.g., answering the telephone, using the computer), or operating outside the laboratory (e.g., pushing elevator buttons, turning doorknobs). Always wash hands after removing gloves. Environmental Health & Safety can assist with proper glove selection.

Doffing Disposable Gloves Appropriately

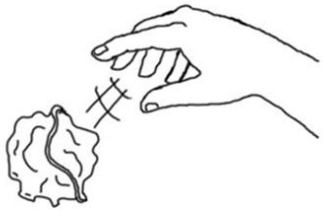


Step 1: Grab glove on outside next to wrist.

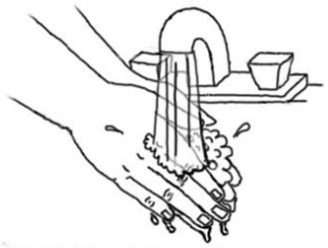
Step 2: Pull off inside-out.Place in gloved hand.

Step 3: Place fingers by wrist under glove.

Step 4: Push up inside-out and fold around glove in hand.



Step 5: Throw used gloves in proper disposal unit.



Step 6: Wash hands thoroughly.

Shoe Coverings

Open toed shoes and sandals are prohibited in the laboratory as these do not provide the appropriate level of protection against hazardous materials. In some instances, shoe covers are recommended to prevent the spread of contamination from one area to another. Additionally, shoe covers are a recommended PPE component when cleaning up large spills.

3.4 Decontamination

The decontamination process is required on a routine basis to protect laboratory workers and the general community from the inadvertent release of infectious agents and subsequent disease. Additionally, the integrity of microbiological experiments relies on the sterility of media and decontamination of equipment as standard operating practice. Decontamination encompasses treatments that reduce the number of microorganisms on contaminated items to an amount below which microbes can cause disease or contamination. It renders the material, whether an instrument, surface, or waste, safe for further handling. Decontamination includes disinfection, antisepsis, and sterilization.

- **Disinfection** utilizes antimicrobial materials to eliminate nearly all non-spore forming organisms on fomites or inanimate objects (e.g., equipment, work surfaces).
- **Antisepsis** is the application of an antimicrobial compound to the surfaces of living human or animal tissue.
- **Sterilization** destroys all microbial life, including spores, generally with steam or gas.

Chemical surface disinfection is the method used in the laboratory to inactivate and/or destroy microbes on surfaces. Many different chemical disinfectants are available. The most effective are, in many circumstances, the most toxic and corrosive as well.

Note: ***No one liquid disinfectant is equally effective against all organisms and under all physical and environmental conditions.***

The effectiveness of a disinfectant to kill or deactivate infectious agents will depend upon many factors, including:

- **Type of Agent/Microorganism-** Proteinaceous material, viruses, bacteria and fungi all display varying susceptibility to chemical agents. Spore-forming bacteria in particular are very resistant to most disinfectants, whereas vegetative stages of bacteria are most susceptible. In general, fungi display moderate resistance to disinfectants.
- **Degree of Contamination and Contact Time-** The degree of contamination affects the time required for disinfection, the amount of chemical required and other variables. For example, the greater the degree of contamination, the longer the contact time needed for action of the chemicals on the microorganisms to provide effective treatment.

- **Protein /Organic Content-** Protein containing material (blood, plasma, feces, tissue, etc.) absorbs and inactivates some chemical disinfectants. Halogens, i.e., chlorine, combine readily with proteins. Therefore, when protein containing materials are present in the waste, it may be more effective to absorb the waste and then disinfect the "cleaned" surface.
- **Type of Chemical-** Different chemicals have different modes of action and levels of activity. It is important to understand the mode of action in order to select the appropriate chemical. For example, household bleach is ineffective as a disinfectant in either acidic or basic conditions because the hypochlorous acid is no longer available to penetrate the cell wall.
- **Chemical Concentration/Quantity-** Most chemicals have a range of concentrations that are suitable for use for disinfection. In the development of standard operating procedures, it is important to choose the proper concentration and quantity of chemical that are best used for the disinfection of each standard waste load.
- **Other Considerations-** Other factors that should be considered in establishing standard operating procedures for chemical disinfection are the type of surface to be disinfected, and the presence of organic matter. The presence of organic matter (e.g., blood, animal feces) or hard water may reduce the effectiveness of many disinfectants like bleach, phenolics, or quaternary ammonium compounds. Finally, some disinfectants, such as bleach, may corrode metal surfaces.

Disinfectants

Alcohol- Ethyl and isopropyl alcohols, in concentrations of about 60% to 95%, are the most common alcohol disinfectants. They are effective against vegetative forms of bacteria, fungi, and lipid-containing viruses. Alcohols are relatively inexpensive, have low toxicity, and do not cause corrosion of surfaces. However, alcohols evaporate quickly and must be continually applied to achieve adequate disinfection, and are highly flammable. Alcohols are less effective against non-lipid viruses, and completely ineffective against bacterial spores and Mycobacterium tuberculosis (TB).

Chlorine Compounds- Chlorine-containing compounds are probably the most commonly used laboratory disinfectants for, bench tops, and floors, and spill cleanups as they are strong oxidizers and are highly corrosive. The most prevalent form, sodium hypochlorite (the form found in household bleach), contains 5.25 % available chlorine (50,000 ppm) and can be diluted 10 to 100-fold (5,000 ppm to 500 ppm) to produce an acceptable disinfectant solution. At these concentrations, sodium hypochlorite exhibits broad-spectrum activity against vegetative bacteria, fungi, lipid, and non-lipid viruses. Higher concentrations and extended contact time can be used to inactivate bacterial spores. The efficacy of hypochlorite as a disinfectant is reduced in the presence of organic materials, high pH, and exposure to light- only freshly prepared solutions should be used. Chlorine dioxide gas is used to sterilize medical and laboratory equipment, surfaces, rooms and tools. It is a very strong oxidizer and it effectively kills pathogenic microorganisms such as fungi, bacteria and viruses. It also pre-vents and removes bio film. As a disinfectant and

pesticide it is mainly used in liquid form. Chlorine dioxide is efficacious against protozoan parasites (Giardia) and spore forming bacteria.

Formalin- Formalin is 37% solution of formaldehyde in water. Dilution of formalin to 5% results in an effective disinfectant with good activity against vegetative bacteria, spores, and viruses. Formaldehyde is a human carcinogen and creates respiratory problems at low levels of concentration. Use only in a fume hood or other well-ventilated area.

Glutaraldehyde- Glutaraldehyde (2-5%) displays a broad spectrum of activity, including bacterial spores, and rapid kill. It is active in the presence of organic matter, noncorrosive toward metals, and more active than the chemically-related formaldehyde. One of the main uses has been the rapid, "cold" chemical sterilization of medical equipment that is sensitive to heat. However, because glutaraldehyde is toxic and damaging to the eyes, restrict its use to inside a fume hood and not on the open bench.

Hydrogen Peroxide- Hydrogen peroxide produces destructive hydroxyl free radicals and exhibits bactericidal, virucidal, tuberculocidal, sporicidal, and fungicidal properties. Higher concentrations (6- 25%) have promise as chemical sterilants. It can be easily broken down by heat or by the enzymes catalase and peroxidase to form the end products, oxy-gen and water. Vaporized forms of hydrogen peroxide are also used for biosafety cabinet and room decontaminations.

Iodophors- Iodophors are a complex of iodine and a carrier that provides sustained release and increased solubility of the iodine (70-150 mg/l available iodine). Iodophors are commonly used to decontaminate surfaces and equipment, are relatively nontoxic, and can be used as an antiseptic scrub. Although iodophors show a wide spectrum of antimicrobial and antiviral activity, they have variable effect on hepatitis B virus, and do not inactivate bacterial spores.

Phenol and Phenol derivatives Phenolic disinfectants (in concentrations of 0.5-5%) are used as preservatives and antibacterial agents in germicidal soaps and lotions. They are also used to disinfect various surfaces such as benches, walls, and floors. Phenolics inactivate vegetative bacteria including Mycobacterium tuberculosis, fungi, and lipid-containing viruses, but are not active against bacterial spores or non-lipid viruses. Halogen substitution or the addition of detergents enhances the efficacy of phenolics.

Quaternary ammonium compounds- Quaternary ammonium compounds (0.5-1.5%) are cationic agents that are relatively non-toxic and widely used as a general, non-specific disinfectant for walls, floors, and equipment. They are effective against many bacteria and lipid-containing viruses, but are not active against bacterial spores, non-lipid-containing viruses (e.g., hepatitis B), and Mycobacterium tuberculosis. Organic materials and salts found in water can inactivate quaternary ammonium compounds.

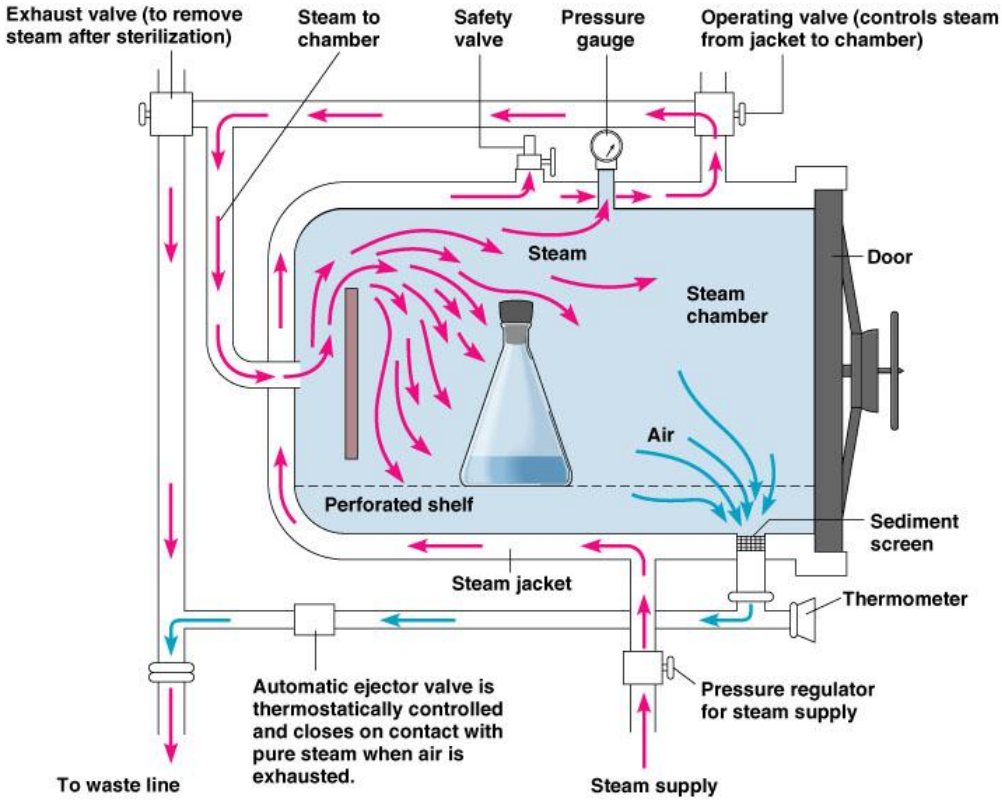
Sterilants

Heat- Sterilization by heat can be wet or dry. Moist heat, in the form of saturated steam, is inexpensive and results in effective and rapid heat transfer to a variety of materials. Steam sterilization, or autoclaving, uses steam in an insulated pressure chamber to achieve elevated pressures of at least 15 psi and temperatures of 121-132C for a prescribed time (see figure). There are two types of autoclaves; gravity displacement and pre-vacuum.

In the gravity displacement autoclave, steam enters the chamber and displaces the heavier air downward and out of the autoclave. The autoclave must be carefully loaded to eliminate air pockets or cold spots, which have a lower temperature than steam (containers in these air pockets will take longer to achieve adequate temperature). The pre-vacuum autoclave, as its name applies, uses a vacuum to remove heavier air from the chamber, and replaces it with lighter, saturated steam. However, this vacuum mode cannot be used with liquids. Heating under pressure, causes liquid materials to bubble or boil and may cause the bottles to break or explode if overfilled or improperly contained. This is sometimes referred to as a "hot-bottle explosion".

When autoclaving liquids:

- Use only vented closures - do not tightly seal bottles.
- Use glass bottles intended for autoclaving such as Type I borosilicate glass. Ordinary glass bottles are not designed for sterilization.
- Carefully remove hot bottles from the autoclave and do not allow the bottles to be jolted. Do not move bottles if boiling or bubbling are present. The bottles should be allowed to cool to the touch before attempting to move them from the sterilizer shelf or tray(s).



Note: ***Never autoclave flammable or other hazardous chemicals.***

Chemical, physical or biological indicators can be used to ensure that the correct temperature has been achieved and maintained for the specified amount of time needed to ensure sterilization. Chemical indicators, such as those used in autoclave tape, use a color change to indicate that the appropriate temperature and pressure have been reached. Biological indicators contain spores of the thermally resistant bacterium Geobacillus stearothermophillus. These spore strips are placed in a load, and are incubated after the autoclave cycle is completed. Growth of the spores and ensuing metabolism will cause a change in the color of a pH-sensitive chemical located in each strip, indicating that sterilization conditions were not achieved. Physical indicators often consist of an alloy designed to melt only after being subjected to 121°C or 249°F for 15 minutes. The change to the melted alloy is visible.

Dry Heat is used to treat materials that are impermeable to steam or could sustain damage from moisture. Dry heat sterilization, usually performed in a hot-air oven, is less efficient and requires higher temperatures and longer exposure times. To effectively kill all types of microbial cells, the temperature of dry heat in an oven needs to be 160-180°C (320-356°F) for two to four hours.

GAS

Paraformaldehyde/Formaldehyde- Paraformaldehyde/formaldehyde will inactivate vegetative bacteria, fungi, lipid and non-lipid viruses and bacterial spores when vaporized by heat, and is commonly used to decontaminate large containment equipment such as biological safety cabinets as well as entire laboratories. These substances are highly irritating, toxic, and suspected carcinogens. Extreme care must be taken when handling and using these substances. They should not be used in the laboratory on the open bench to decontaminate any equipment.

Vaporized Hydrogen Peroxide- Vaporized Hydrogen Peroxide will inactivate vegetative bacteria, fungi, lipid and non-lipid viruses and bacterial spores when vaporized by heat, and is commonly used to decontaminate large containment equipment such as biological safety cabinets as well as entire laboratories. The procedure commonly uses an aqueous solution of 30% hydrogen peroxide which is heated and transported by a carrier gas. The process generates peroxide vapor concentrations in excess of 3000 ppm. These substances are highly irritating, to eyes, mucous membranes and skin. Bleaching of hair and skin can occur. Overexposure can result in systemic poisoning. Extreme care must be taken when handling and using this substance. It must not be used by untrained individuals or in "leaky" systems.

RADIATION

Ultraviolet Radiation- Microorganisms are very susceptible to ultraviolet light of wavelength 254 nm. Ultraviolet light is commonly used to reduce the number of unprotected, surface, and airborne microorganisms, although it has limited power to penetrate dust, dirt, etc. The effectiveness of ultraviolet light depends on the intensity, which decreases by the square of the distance from the lamp, and with time. The intensity

is also affected by the accumulation of dust on the UV lamp, and the growth stage of the organism (dividing organisms are more susceptible than those in a dormant state). The effective life spans of the lamps are relatively short and expensive to replace. The UV light should be periodically checked with a flux meter to ensure that the energy output (40 uW/cm^2) is adequate to kill micro-organisms. It is important to remember that the use and misuse of UV lamps are an occupational hazard that carries risks for eye and skin injury, even after the radiation output has dropped below biocidal levels.

Note: ***You must wear the appropriate PPE and follow manufacturer's instructions.***

Waste Handling and Disposal

Appropriate disposal of Regulated Medical Waste (RMW) is everyone's responsibility, from the laboratory worker who generates the waste to the hauler who transports that waste to its final destination. Proper management of regulated medical waste reduces the level of concerns with respect to public health and environmental hazards associated with improper disposal.

In New York State, the Department of Health (DOH) defines biohazardous or regulated medical waste (RMW) as "waste which is generated in the diagnosis, treatment or immunization of human beings or animals, in research pertaining thereto, or in production and testing of biological". This includes:

- **Cultures and stocks of agents infectious to humans** (including human, primate, and mammalian cell lines), associated biologicals (e.g., serums, vaccines, antigens, toxins), and culture dishes and devices used to transfer, inoculate or mix cultures (e.g., Petri dishes, vials, filtration devices, flasks, inoculation loops, disposable gloves).
- **Human pathological wastes** including tissue, organs, and body parts, and specimens of body fluids and their containers. This does not include urine or fecal material.
- **Human blood and blood products** including serum, plasma or materials saturated with human blood. Excludes feminine hygiene products.
- **Sharps** such as syringes and needles, razor blades, scalpels, blood vials, Pasteur pipettes, etc. Also includes broken or unbroken glass (culture tubes, flasks, and beakers), glass slides, or coverslips that have been in contact with infectious material.
- **Animal wastes** including carcasses, body parts, body fluids, blood, or bedding originating from animals known to be contaminated with (zoonotic organisms) or intentionally inoculated with infectious agents. Excludes preserved animals used for educational purposes.

Note: ***Biohazardous wastes must not be mixed with chemical or radioactive waste, or with other laboratory trash.***

Cultures and other solid wastes- Place cultures and stocks of infectious agents, other biologicals, and non-sharps items contaminated

with biohazardous materials into red bags that have the biohazard symbol or the word "BIOHAZARD". Use double bags if necessary to prevent leakage.

Sharps- Collect all sharps items in approved rigid, leak-proof, and puncture-resistant containers that are prominently labeled with a universal biohazard sign and the word "BIOHAZARD". To prevent contamination and potential injury, dispose of needles and syringes directly into a sharps container without any further manipulation (e.g., NO clipping, bending, breaking, shearing, or recapping). Devices that clip off the needle are prohibited. Dispose of the sharps container when ¾ full.

Note: ***Food or other containers (e.g., empty coffee cans, chemical containers) are NOT appropriate for use as sharps containers.***

Pathological Wastes- Pathological waste is defined as animal carcasses, body parts, body fluids, animal blood-soaked materials, bedding, and associated containers, can be infectious or noninfectious. Small animal carcasses contaminated with infectious agents (pathological waste) should be packaged in double red biohazard bags and refrigerated or frozen until they can be transported.

Non-contaminated carcasses must be placed in double black bags.
Contaminated bedding in should be place in double red biohazard bags and then in an approved labeled container for treatment or disposal.

Drain Disposal- Liquid wastes that contain infectious agents, cell culture waste, blood, or other bodily fluids, must be chemically treated with bleach (e.g., 1:10 final dilution of bleach) or autoclaved (steam sterilized) prior to disposal to a sanitary sewer. Do not discharge large volumes of blood or fecal matter in the sanitary sewer as this may plug the drain and may place maintenance personnel at risk.

Segregation and Packaging
RMW must be segregated into the proper waste category, and into a properly labeled containment system at the point of generation. Biohazardous waste must be packaged, contained, and located in a way that protects and pre-vents its accidental release to the environment at any time. The principal investigator or designated supervisor of the laboratory is responsible for ensuring that staff properly identify, segregate, package, store and dispose of Regulated Medical Waste (RMW) appropriately.

CHAPTER 4.0 DETERMINING THE APPROPRIATE BIOSAFETY LEVEL

Biosafety Levels

There are four biosafety levels for activities involving microorganisms. The levels are designated in ascending order, by degree of protection provided to personnel, environment and surrounding community. Each biosafety level incorporates a set of standard microbiological practices and special practices aimed at addressing agent risks, enhancing worker safety and environmental protection. A thorough understanding of the agent, laboratory procedures and safety equipment, and associated hazards will assist you in selecting the appropriate biosafety level and precautions. However, certain circumstances such as changes in the health status or condition of an employee, preexisting diseases, immune deficiency, increased age, medications, or pregnancy can increase the risks of an individual for infection and affect the progression of disease. Evaluation of such host factors and analysis of the risk posed by different tasks can help you to manage potential exposure to biohazardous materials. The availability of immunizations and pre and post exposure surveillance and prophylaxis should also be considered. Examples of risk management include immunizations (e.g., hepatitis B, rabies), and pre and post exposure surveillance. e.g., physicals, work place evaluations, prophylaxis).

Biosafety Level 4

Biosafety Level 4 is used when working with dangerous and exotic agents who pose a high risk of life threatening disease, agents with an aerosol transmission route or agents having an unknown route of transmission. Agents that are antigenically similar or identical to BSL-4 agents are also classed in this category until sufficient data are obtained to confirm or re-designate the biosafety level. Individuals working in a BSL-4 environment must have specific training on the handling of extremely infectious materials and must understand the primary and secondary containment functions of standard practices, special practices, equipment, and laboratory design characteristics. These individuals must be supervised by staff competent in the handling of agents and containment.

Note: *Biosafety Level 4 work is prohibited at Pace University and as such, this information has been omitted from the table.*

Table1. Biosafety Levels

Complete descriptions of Biosafety Levels can be found in the
Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults	Standard Microbiological Practices	None required	Open bench top sink required

2	Associated with human disease, hazard: percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practices plus: Limited access Biohazard warning signs "Sharps" precautions Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers: Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials. PPEs: laboratory coats, gloves, face protection as needed	BSL-1 plus: Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practices plus: Controlled access Decontamination of all waste Decontamination of lab clothing before laundering Baseline serum	Primary barriers: Class I or II BSCs or other physical containment devices used for all open manipulations of agents; PPE: protective lab clothing, gloves, respiratory protection as needed	BSL-2 plus: Physical separation from access corridors, Self-closing, double-door access, Exhausted air not recirculated, Negative airflow into laboratory

Complete descriptions of Biosafety Levels can be found in the
Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition

4.1 Biosafety Level 1

Biosafety Level 1 is recommended for work that involves well characterized agents that are not known to cause disease in healthy adults and present a minimal hazard to laboratory personnel and the environment. Standard microbiological practices are utilized and work is often conducted on open benchtops. Personnel receive laboratory and procedure specific training and must be appropriately supervised.

Special Practices

- A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present.
- An effective, integrated pest management program is required.
- The laboratory supervisor must ensure that personnel receive the appropriate training regarding their duties, exposure prevention and exposure evaluation.
- Annual training is required to facilitate updates, additional training, or in the event of procedural or policy changes.
- Individuals must be provided with information regarding immune competence and conditions which may predispose them to infection. These individuals are encouraged to self-identify to The UHCU for appropriate counseling and guidance.

- The use of protective laboratory coats, gowns or uniforms are recommended to prevent contamination of personal clothing.
- Protective eyewear such as chemical splash goggles, safety glasses or a face shield should be worn when conducting procedures that may create splashes.
- Gloves must be worn when working with hazardous materials. Glove selection should be based on an appropriate risk assessment.
- Gloves should be changed when contaminated, if glove integrity has been compromised or when otherwise necessary.
- Plastic-ware must be substituted for glassware whenever practicable.
- Sharps such as needles and scalpels must be placed in a sharps container or other suitable hard walled for disposal.
- Procedures should be performed in a manner that minimizes the production of aerosols.
- Decontaminate surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
- Decontaminate all cultures, stocks and other potentially infectious materials using an effective method prior to disposal.

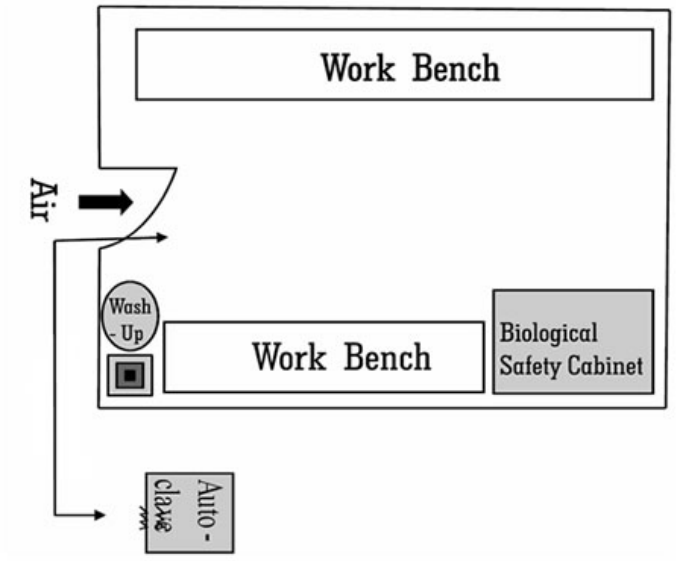
4.2 Biosafety Level 2

Biosafety Level 2 (BSL2) practices incorporate practices for Biosafety Level 1. Biosafety Level 2 work generally involves agents that pose a moderate hazard to individuals or the environment. Procedures that may create infectious aerosols or splashes are conducted in a Biological Safety cabinet (BSC) or other containment device. Personnel working in a BSL 2 laboratory also have specific training in the handling of pathogenic agents and are supervised by individuals who also demonstrate competency in the handling of infectious agents and associated procedures. Biosecurity is a major concern for the BSL2 laboratory due to the nature of the agents in use. Access to the laboratory is restricted to approved individuals when work with agent (s) is being conducted.

Special Practices

- All persons entering the laboratory must be advised of the potential hazards and meet specific entry or exit requirements.
- Laboratory personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the lab.
- A laboratory specific biosafety manual must be prepared and adopted. This manual must be readily available and accessible.
- The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL2 agents.
- Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
- Laboratory equipment should be routinely decontaminated, as well as after spills, splashes or other potential contamination.
- Equipment must be decontaminated before repair, maintenance or removal from the laboratory.

- Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
- Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures outlined in the laboratory's biological safety manual. These incidents must also be reported to the laboratory supervisor.
- Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.
- Animals and plants not directly associated with the work being performed are not permitted in the laboratory.
- All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment devices.
- Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worm while working with hazardous materials.
- Personal protective clothing must be removed before leaving the laboratory for non-laboratory areas such as cafeterias, libraries, and administrative offices.
- Eye and face protection must be when conducting procedures that pose a risk of splashes or sprays of infectious or otherwise hazardous material.
- Gloves must be worn to protect hands from contamination or exposure to hazardous materials. Gloves must not be worn outside the laboratory. Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.
- An eyewash station must be readily available.
- A validated method for decontaminating all laboratory wastes should be available in the facility.



Shaded components indicate minimum physical safety requirements. Additional safety equipment may be required depending on specific risks presented.

4.3 Biosafety Level 3

Biosafety Level 3 (BSL3) incorporates both BSL1 and BSL2 precautions. Work at BSL3 generally involves agents that may cause serious or potentially lethal disease via the inhalation route of exposure. Personnel working in the BSL-3 laboratory will receive training specific to the handling of pathogenic and potentially lethal agents and must be supervised by scientists that demonstrate competency in handling infectious agents and associated procedures. Procedures involving the manipulation of infectious materials must be conducted within certified BSCs, other approved containment devices or by personnel wearing the appropriate personal protective equipment. Biosecurity is a major concern for the BSL3 laboratory due to the nature of the agents in use. Access to the laboratory is restricted to approved individuals. Additionally, BSL3 work must receive EH&S pre-approval and is predicated upon a thorough risk assessment and contingent of proper engineering controls in the space. Each BSL3 laboratory must develop and maintain a Biosafety Level 3 manual that is specific to the laboratory. Laboratory specific procedures and practices will be developed in order to appropriately manage the hazards of working at Biosafety Level 3. Currently no BSL3 work is conducted at the University.

4.4 Animal Biosafety Levels

Laboratories engaged in animal research involving infected animals or non-infected animals that may serve as host species to zoonotic agents, present special challenges for risk assessment and management. Generally, the selected biosafety level with complementary practices and procedures should reflect established practices for working with infectious agents in vivo and in vitro.

Animal Biosafety Levels

Animal facilities must be physically separated from other activities including animal production and quarantine and clinical laboratories in order to minimize the risk of cross contamination. Animals not directly involved in animal research should not be brought into the laboratory. Control of arthropod vectors is of particular concern in animal facilities. If exposure to arthropods is a requirement of the study being conducted or if the agent under study can be transmitted via an arthropod vector, interior work areas must be mesh screened. Perimeter joints and openings must be sealed and additional control measures must be implemented to prevent arthropod entry and propagation.

As with other biosafety levels, access to the animal facility must be restricted. Personnel must have general safety training as well as specific training in animal facility procedures and the appropriate engineering controls, such as Class II BSC, must be present to manage aerosols and splashes.

4.5 Clinical / Diagnostic Laboratories

Clinical laboratories generally receive requests for analysis of a variety samples types with equally ambiguous histories. Typically, the infectious nature of the sample is unknown and specimens are often submitted with a broad request for microbiological examination for multiple agents.

It is the responsibility of the Laboratory Director or PI to establish written standard procedures in the laboratory that specifically address the issue of the infective hazard posed by clinical/diagnostic specimen and control access to clinical/diagnostic areas of the laboratory.

Generally, the initial processing of clinical/ diagnostic specimen and serological isolates can be done at biological safety level 2 and requires the use of standard precautions unless there is information which suggests the presence of an agent which may be transmissible via an aerosol route. Procedures that may cause spraying, splashing, splattering of droplets or the generation of aerosols must be performed in a BSC. Recommendations of practices specific to clinical laboratories can be obtained from the Clinical Laboratory Standards Institute.

4.6 Biosecurity

Recent federal regulations mandate increased security measures in order to protect biological pathogens and toxins from theft, loss or misuse. These legislations require institutions engaged in microbiological research or teaching to notify the U.S Department of Health and Human Services (DHHS) or the Department of Agriculture (USDA) of the possession of select agents. The regulations also allow for increased supervision of material and include a mechanism for restricting access to these materials to legitimized uses.

At the operational level, appropriate security measures must be implemented in order to protect public health from potential misuse of biological research materials as agents of terrorism. Facility, institutional security plans and emergency response procedures must be developed and standardized and must include notification of coordinating or appropriate agencies such as law enforcement, CDC, NIH, DHHS and Department of Homeland Security. Additionally, preventing access to laboratory or clinical areas by unauthorized individuals, maintaining records and inventories of agents of interest, development of procedures that prevent the removal of microbiological materials from laboratories and clinical settings and guarding access to electronic data are necessary to an effective biosecurity plan.

Chapter 5.0 - Selecting Additional Precautions

5.1 Eyewashes and Safety Showers

Plumbed emergency eyewashes should be activated weekly to verify proper operation by laboratory personnel and showers inspected and tested annually by Buildings & Grounds. Regular activation (weekly flushing) ensures the units are operating properly, helps to keep the units free of clutter, and helps prevent the growth of bacteria within the plumbing lines, which can cause eye infections. It is the responsibility of laboratory personnel to activate (flush) units on a regular basis. It is recommended to allow the water to run for at least 3 minutes. EH&S strongly encourages laboratories to post an Eyewash Testing LOG/ sign near the eye-wash to keep track and document that weekly activation is occurring.

Due to the flow requirements outlined in the ANSI standard, hand held bottles do not qualify as approved eye-washes. Hand held eyewash bottles are acceptable to use in conjunction with an emergency eyewash, such as sink mounted or portable units.

Laboratories are responsible for ensuring that access to eyewashes and emergency showers are kept free of clutter and ensuring the eyewash nozzle dust covers are kept in place. If nozzle dust covers are not kept on the eye-wash nozzles, dust or other particles can clog the nozzles and result in poor or no water flow. This can also result in dust or other particles being forced into the eyes when the eyewash is used.

If you discover your emergency shower or eyewash is not functioning properly, then contact your Building Coordinator to request a ticket to have the unit repaired.

5.2 Occupational Assessments

The Department of Environmental Health and the University Health Care Unit are committed to providing consultative services to assist Pace University in fostering a safe and healthy campus environment. EH&S responds to requests for assessment of potential safety hazards, possible instances of exposure, and suitability of protective equipment. The following is a list of programs:

Exposure Assessments

- *Personal Protective Equipment* - Environmental Health and Safety has developed a PPE training program and provides consultative services to departments in order to meet the employee protection needs and OSHA requirements. The EH&S program provides employees with the appropriate protective equipment and training that meets the OSHA PPE standard.
- Reproductive Hazard Assessment
- *Respiratory Protection* - The Respiratory Protection program is in development for University personnel who, during their normal duties, are or could be exposed to hazardous substances or atmospheres that may affect their well-being or their health, or that may otherwise be detrimental to their safety. The program will cover controls, fit, selection, and function of respiratory protection equipment and for the training of those employees who must use respirators and for their supervisors.

Chapter 6.0 - Evaluating the Integrity of Equipment and the Proficiencies of Staff Work Practices

6.1 Training Records

Training records must be evaluated annually by Supervisors/PIs to ensure that personnel have received the appropriate safety and task specific training.

6.2 Self-Inspection

The purpose of the self-inspection is to identify and possibly avoid breaches in containment and to check and verify the appropriate functioning of safety systems. The following is a list of items should be regularly inspected:

- Walls and ceilings - examine for cracks or openings, evidence of water leakage, cracking or flaking of epoxy sealant
- Eyewashes and safety showers-check for functioning. Ensure that access is not blocked
- Fire extinguishers-inspected monthly
- Class II Biological Safety Cabinets-inspected annually
- Accuracy of signage, verification of correct point of contact information
- Emergency procedures and phone numbers
- Appropriate spill kits
- First Aid kit supplies

6.3 Housekeeping

It is the responsibility of the PI and those working in the laboratory to ensure the personal safety of individuals charged with performing housekeeping duties for the university. This requires that biohazardous agents and any materials coming into contact with these agents be handled in a manner that precludes subsequent exposure of housekeeping staff. Housekeeping refers to the activities of lab personnel to maintain the general condition and appearance of a laboratory and includes:

- Keeping all areas of the lab free of clutter, trash, extraneous equipment, and unused chemical containers. Areas within the lab that should be addressed include benches, hoods, refrigerators, cabinets, chemical storage cabinets, sinks, trash cans, etc.
- Cleaning up all chemicals spills immediately, regardless if the chemical is hazardous or not. When cleaning up a chemical spill, look for any splashes that may have resulted on nearby equipment, cabinets, doors, and counter tops. For more information on cleaning up spills, see the Chemical Spill Procedures section.
- Keeping areas around emergency equipment clean and free of clutter. This includes items such as eye-wash/emergency showers, electric power panels, fire extinguishers, and spill cleanup supplies.
- Keeping a minimum of three feet of clearance (as required by fire codes) between benches and equipment. Exits must be clear of obstacles and tripping hazards such as bottles, boxes, equipment, electric cords, etc.

- When storing items overhead, keep heavier and bulkier items closer to the floor. New York State (NYS) Building Code prohibits the storage of combustible material (such as paper, boxes, plastics, etc.) within two feet of the ceiling in un-sprinklered rooms and within 18 of the crown of a sprinkler head in sprinklered rooms.

BSM APPENDICES

- APPENDIX A: RISK GROUP 2 (RG2) - BACTERIAL AGENTS INCLUDING CHLAMYDIA
- APPENDIX B: RISK GROUP 2 (RG2) - FUNGAL AGENTS
- APPENDIX C: RISK GROUP 2 (RG2) - PARASITIC AGENTS
- APPENDIX D: RISK GROUP 2 (RG2) - VIRUSES
- APPENDIX E: WHAT TO DO IN THE EVENT OF AN EXPOSURE
- APPENDIX F: COMOPSITION OF A BASIC BIOLOGICAL MATERIAL SPILL KIT
- APPENDIX G: WHAT TO DO IN THE EVENT OF A BIOHARDOUS MATERIAL SPILL
- APPENDIX H: SPILL OF A BIOHARDOUS RADIOACTIVE MATERIAL
- APPENDIX I: VACCINE DECLINATION FORM
- APPENDIX J: SHARPS INJURY LOG FORM
- APPENDIX K: ADDITIONAL BIOLOGICAL SAFETY RESOURCES
- APPENDIX L: BIOSAFETY LEVEL 2 CHECKLIST

Appendix A - Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia

- *Acinetobacter baumannii* (formerly *Acinetobacter calcoaceticus*)
- *Actinobacillus*
- *Actinomyces pyogenes* (formerly *Corynebacterium pyogenes*)
- *Aeromonas hydrophila*
- *Amycolata autotrophica*
- *Archanobacterium haemolyticum* (formerly *Corynebacterium haemolyticum*)
- *Arizona hinshawii* - all serotypes
- *Bacillus anthracis*
- *Bartonella henselae, B. quintana, B. vinsonii*
- *Bordetella including B. pertussis*
- *Borrelia recurrentis, B. burgdorferi*
- *Burkholderia* (formerly *Pseudomonas* species) except those listed in Appendix B-III-A (RG3))
- *Campylobacter coli, C. fetus, C. jejuni*
- *Chlamydia psittaci, C. trachomatis, C. pneumoniae*
- *Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani*
- *Corynebacterium diphtheriae, C. pseudotuberculosis, C. renale*
- *Dermatophilus congolensis*
- *Edwardsiella tarda*
- *Erysipelothrix rhusiopathiae*
- *Escherichia coli* - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including *E. coli* O157:H7
- *Haemophilus ducreyi, H. influenzae*
- *Helicobacter pylori*
- *Klebsiella* - all species except *K. oxytoca* (RG1)
- *Legionella including L. pneumophila*
- *Leptospira interrogans* - all serotypes
- *Listeria*
- *Moraxella*
- *Mycobacterium* (except those listed in Appendix B-III-A (RG3)) including *M. avium complex, M. asiaticum, M. bovis* BCG vaccine strain, *M. chelonei, M. fortuitum, M. kansasii, M. leprae, M. malmoense, M. marinum, M. paratuberculosis, M. scrofulaceum, M. simiae, M. szulgai, M. ulcerans, M. xenopi*
- *Mycoplasma*, except *M. mycoides* and *M. agalactiae* which are restricted animal pathogens
- *Neisseria gonorrhoeae, N. meningitidis*
- *Nocardia asteroides, N. brasiliensis, N. otitidiscaviarum, N. transvalensis*
- *Rhodococcus equi*
- *Salmonella* including *S. arizonae, S. cholerasuis, S. enteritidis, S. gallinarumpullorum,*
- *S. meleagridis, S. paratyphi, A, B, C, S. typhi, S. typhimurium*
- *Shigella* including *S. boydii, S. dysenteriae, type 1, S. flexneri, S. sonnei*

- *Sphaerophorus necrophorus*
- *Staphylococcus aureus*
- *Streptobacillus moniliformis*
- *Streptococcus* including *S. pneumoniae, S. pyogenes*
- *Treponema pallidum, T. carateum*
- *Vibrio cholerae, V. parahemolyticus, V. vulnificus*
- *Yersinia enterocolitica*

Appendix B - Risk Group 2 (RG2) - Fungal Agents

- *Blastomyces dermatitidis*
- *Cladosporium bantianum, C. (Xylohypha) trichoides*
- *Cryptococcus neoformans*
- *Dactylaria galopava (Ochroconis gallopavum)*
- *Epidermophyton*
- *Exophiala (Wangiella) dermatitidis*
- *Fonsecaea pedrosoi*
- *Microsporum*
- *Paracoccidioides braziliensis*
- *Penicillium marneffei*
- *Sporothrix schenckii*
- *Trichophyton*

Appendix C - Risk Group 2 (RG2) - Parasitic Agents

- *Ancylostoma* human hookworms including *A. duodenale, A. ceylanicum*
- *Ascaris* including *Ascaris lumbricoides suum*
- *Babesia* including *B. divergens, B. microti*
- *Brugia filaria* worms including *B. malayi, B. timori*
- *Coccidia*
- *Cryptosporidium* including *C. parvum*
- *Cysticercus cellulosae (*hydatid cyst, larva of *T. solium)*
- *Echinococcus* including *E. granulosis, E. multilocularis, E. vogeli*
- *Entamoeba histolytica*
- *Enterobius*
- *Fasciola* including *F. gigantica, F. hepatica*
- *Giardia* including *G. lamblia*
- *Heterophyes*
- *Hymenolepis* including *H. diminuta, H. nana*
- *Isospora*
- *Leishmania* including *L. braziliensis, L. donovani, L. ethiopia, L. major, L. mexicana,*
- *L. peruvania, L. tropica*
- *Loa loa filaria* worms
- *Microsporidium*
- *Naegleria fowleri*
- *Necator* human hookworms including *N. americanus*
- *Onchocerca filaria* worms including, *O. volvulus*
- *Plasmodium* including simian species, *P. cynomologi, P. falciparum, P. malariae, P. ovale, P. vivax*
- *Sarcocystis* including *S. sui hominis*
- *Schistosoma* including *S. haematobium, S. intercalatum, S. japonicum, S. mansoni,*
- *S. mekongi*
- *Strongyloides* including *S. stercoralis*
- *Taenia solium*
- *Toxocara* including *T. canis*
- *Toxoplasma* including *T. gondii*
- *Trichinella spiralis*
- *Trypanosoma* including *T. brucei brucei, T. brucei gambiense, T. brucei rhodesiense,*
- *T. cruzi*
- *Wuchereria bancrofti filaria* worms

Appendix D - Risk Group 2 (RG2) – Viruses

- Adenoviruses, human - all types
    - Alphaviruses (Togaviruses) - Group A Arboviruses
    - Eastern equine encephalomyelitis virus
    - Venezuelan equine encephalomyelitis vaccine strain TC-83
    - Western equine encephalomyelitis virus
- Arenaviruses
    - Lymphocytic choriomeningitis virus (non-neurotropic strains)
    - Tacaribe virus complex
    - Other viruses as listed in the reference source (see Section V-C, *Footnotes and References of Sections I through IV*)
- Bunyaviruses
    - Bunyamwera virus
    - Rift Valley fever virus vaccine strain MP-12
    - Other viruses as listed in the reference source (see Section V-C, *Footnotes and References of Sections I through IV*)
- Caliciviruses
- Coronaviruses
- Flaviviruses (Togaviruses) - Group B Arboviruses
    - Dengue virus serotypes 1, 2, 3, and 4
    - Yellow fever virus vaccine strain 17D
    - Other viruses as listed in the reference source (see Section V-C, *Footnotes and References of Sections I through IV*)
- Hepatitis A, B, C, D, and E viruses
- Herpesviruses - except Herpesvirus simiae (Monkey B virus) (see Appendix B-IV-D, *Risk Group 4 (RG4) - Viral Agents*)
    - Cytomegalovirus
    - Epstein Barr virus
    - *Herpes simplex* types 1 and 2
    - *Herpes zoster*
    - Human herpes virus types 6 and 7
- Orthomyxoviruses
    - Influenza viruses types A, B, and C
    - Other tick-borne orthomyxoviruses as listed in the reference source (see Section V-C, *Footnotes and References of Sections I through IV*)
- Papovaviruses
    - All human papilloma viruses
- Paramyxoviruses
    - Newcastle disease virus
    - Measles virus
    - Mumps virus
    - Parainfluenza viruses types 1, 2, 3, and 4
    - Respiratory syncytial virus
- Parvoviruses

    - Human parvovirus (B19)
    - Picornaviruses
    - Coxsackie viruses types A and B
    - Echoviruses - all types
    - Polioviruses - all types, wild and attenuated
    - Rhinoviruses - all types
- Poxviruses - all types except Monkey Pox virus (see Appendix B-III-D, *Risk Group 3 (RG3) - Viruses and Prions*) and restricted poxviruses including Alastrim, Smallpox, and Whitepox (see Section V-L, *Footnotes and References of Sections I through IV*)
- Reoviruses - all types including Coltivirus, human Rotavirus, and Orbivirus (Colorado tick fever virus)
- Rhabdoviruses
    - Rabies virus - all strains
    - Vesicular stomatitis virus - laboratory adapted strains including VSV-Indiana, San Juan, and Glasgow
- Togaviruses (see Alphaviruses and Flaviviruses)
    - Rubivirus (rubella)

Appendix E - What to Do in the Event of an Exposure

An exposure is defined as specific contact (eye, mouth, other mucous membrane, non-intact skin, percutaneous or aerosol) to potentially infectious material that results from the performance of an employee's duties.

Percutaneous Injury (cuts & needle sticks)

In the event of a percutaneous injury involving human blood or other body fluids, immediate action should be taken as follows:

1. Wash the site liberally with soap and water (without scrubbing) for approximately 15 minutes.
2. Encouraged bleeding for puncture wounds by applying pressure under running water.
3. Do not suck the site.
4. Report the incident immediately to your supervisor.
5. Report the details of your exposure event in a security report and sharps injury reporting form (Appendix J).
6. Seek medical evaluation at the Emergency Room or by a personal physician. If evaluation and care are provided by a personal physician, contact HR or the UHCU on the next business day.

Mucous Membrane Exposure

In the event of an exposure to the mucus membrane involving human blood or other body fluids, immediate action should be taken as follows:

1. Flush the area (without scrubbing) for approximately 15 minutes.
2. Report the incident immediately to your supervisor.
3. Report the details of your exposure event in a security report and by completing an accident reporting form (Appendix J).
4. Seek medical evaluation at the Emergency Room or by a personal physician. If evaluation and care are provided by a personal physician, contact HR or the UHCU on the next business day.

Appendix F – Composition of a Basic Biological Material Spill Kit

Microbiological and biomedical research laboratories should prepare and maintain a biological spill kit. A spill kit is an essential safety item for labs working with microbiological agents classified at Biosafety Level 2 or higher and for groups working with large volumes (> 1 liter) of Biosafety Level 1 material. A basic spill kit should include:

- Concentrated household bleach
- A spray bottle for making fresh 10% bleach solutions
- Forceps, autoclavable broom and dust pan, forceps, tongs or other mechanical device for handling sharps
- Paper towels or other suitable absorbent
- Biohazard autoclave bags for the collection of contaminated spill clean-up items
- Utility gloves and medical examination gloves
- Face protection (eye wear and mask, or full face shield)

Appendix G - What to do in the Event of a Biohazardous Material Spill

At Biosafety Level 2 (BSL2)

1. Avoid inhaling possibly airborne material, while quickly leaving the room. Notify others to leave. Close the door, and post with a warning sign.
2. Remove contaminated clothing, turning exposed areas inward, and place in a biohazard bag.
3. Wash all exposed skin with soap and water.
4. Immediately inform your supervisor and Environmental Health & Safety by calling 777 for Security at any time or 914-923-2818 for EH&S during business hours and report the event.
5. Allow aerosols to disperse for at least 30 minutes before reentering the laboratory.
6. Assemble clean-up materials (disinfectant, paper towels, red biohazard bags, sharps disposal container, and forceps).
7. Put on protective clothing (lab coat, mucous membrane protection, N95 or surgical mask, utility gloves, and booties if necessary). The use of an N95 respirator requires an individual to be registered within the University respiratory protection program.
8. Cover the area with disinfectant-soaked towels, and then carefully pour disinfectant around the spill. Make certain that the disinfectant chosen will inactivate the biohazardous or infectious materials.
9. Avoid enlarging the contaminated area. Use more concentrated disinfectant as it is diluted by the spill.
10. Allow at least 15- 20 minutes contact time.
11. Pick up any sharp objects with forceps and discard in a sharps disposal container.
12. Soak up the disinfectant and spill using mechanical means, such as an autoclavable broom and dustpan, since there may be sharps under the paper towels, and place the materials into a sharps disposal container. Smaller pieces of glass maybe collected with cotton or paper towels held with forceps. If no sharps were involved in the spill discard the materials into an autoclave bag.
13. Wipe surrounding areas (where the spill may have splashed) with disinfectant.
14. Soak up the disinfectant and spill, and place the materials into a biohazard bag.
15. Spray the area with 10% household bleach solution or other suitable disinfectant and allow to air-dry (or wipe down with disinfectant-soaked towels after a 10-minute contact time). Place all contaminated paper towels and any contaminated protective clothing into a biohazard bag and autoclave.
16. Note: Bleach solutions are not to be used on metal surfaces as corrosion may result.
17. If bleach must be used, perform a final wipe of affected surface with alcohol to remove residues.
18. Remove PPE and wash hands and exposed skin areas with antiseptic soap and water.

Appendix H - Spill of a Biohazardous Radioactive Material

A biohazard spill involving radioactive material requires response procedures that combine the techniques used when addressing these hazards separately. Use procedures that protect you from the radiological hazard while you disinfect the biological material. Before any clean up, consider the type of radionuclide, characteristics of the microorganism, and the volume of the spill. Contact EH&S (923-2818) and Security (777) for assistance with clean-up procedures.

General Guidelines for Personal Contamination

- Avoid inhaling airborne material. Quickly leaving the area or room and notify others to leave. Close the door and post a - DO NOT ENTER - warning sign.
- Remove contaminated clothing, turning exposed areas inward, and place in a biohazard bag or radioactive waste container labeled with both radioactive materials AND biohazard labels.
- Monitor exposed personnel for radioactive contamination with a survey meter and note locations where contamination has been found.
- Gently wash all exposed skin with soap and water, following it with a three-minute water rinse. Do not use bushes or abrade the skin as this will allow entry of radioactive and/or bio materials into the body. Continue to monitor radioactive contamination levels and stop washing when levels do not continue to decrease or when all of the contamination is removed.
- Immediately inform your supervisor and Security/Environmental Health & Safety by calling 777 (or 914-923-2818) to report the event.

General Guidelines for Cleanup

1. Allow aerosols to disperse for at least 30 minutes before reentering the laboratory.
2. Assemble cleanup materials (disinfectant, autoclave bags/containers, forceps, towel, sponges, and radiation survey meter). Label autoclave waste bags and containers with radioactive and biohazard labels.
3. Put on protective clothing (gown, surgical mask/ N95, gloves, and shoe covers).
4. Cover the area with disinfectant-soaked towels and carefully pour disinfectant around the spill. Use more concentrated disinfectant since it will be diluted by the spill. Allow at least 15-20 minutes contact time.
5. Avoid enlarging the contaminated area if possible. Monitor radioactive contamination levels as cleanup progresses. Place all contaminated items in an autoclave bag/container.
6. DO NOT use bleach solutions on iodinated material as radioactive iodine gas may be released. Instead, use an alternative disinfectant such as an iodophor or phenolic (consult appendix on disinfectants).
7. Handle any sharp objects with forceps. Wipe surrounding areas where the spill may have splashed with disinfectant.

8. Soak up the disinfectant with towels and place in the autoclave bags/containers, along with all contaminated protective clothing and other contaminated cleanup items.
9. Protective clothing must also be biologically decontaminated prior to disposal as radioactive waste.
10. Continue cleanup and monitoring of radioactive contamination until levels stop decreasing or when all of the contamination is removed.

Post Spill Cleanup Procedure

1. Wash hands and exposed skin areas with soap and water. Monitor personnel and spill area for residual radioactive contamination.
2. If skin contamination is found, repeat decontamination procedures under the direction of EH&S. Medical assistance from The UHCU Health Center may be required.
3. The Radiation Safety Officer will provide direction if the spill area has residual fixed contamination.
4. DO NOT autoclave the waste bags/containers until approval is received from EH&S.
5. If waste cannot be autoclaved, add additional disinfectant to ensure complete biological decontamination of all the materials.

Appendix I - Hepatitis B Vaccine Declination Form

(Completion of this form is mandatory for employees that are not receiving the hepatitis b vaccine)

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Name: _____ (Print employee name)

Signed: _____ (employee signature)

Date: _____

Appendix J - Sharps Injury Log Form

Please complete a log for each employee exposure incident involving a sharp and return to EH&S

Institution: _____ Department: _____

Address: _____City:_____ State: __ Zip Code: _____

Date filled out: _____ By: _____ Phone #:_____

Date of injury: _____ Time of injury: _____ ***Optional***: Sex: ☐ Male ☐ Female, Age____

Description of the exposure incident:

_____

_____

Job Classification:
☐ MD
☐ Nurse
☐ Medical Assistant
☐ Housekeeper/Laundry
☐ Student
☐ Other

Department/Location:
☐ Patient room
☐ Clinical laboratory
☐ Medical clinic
☐ Service/utility area
☐ Restroom
☐ Other

Body Part: (check all that apply)
☐ Finger ☐ Hand
☐ Face ☐ Head
☐ Torso ☐ Arm
☐ Leg
☐ Other_____

Procedure:
☐ Drawing blood
☐ Cutting
☐ Injection, through skin
☐ Other_____

Identify Sharp Involved:
Type: _____ Brand: _____ Model: _____
e.g. 18g needle/ABC Medical/"no stick" syringe

Did the device being used have engineered sharps injury protection?
☐ Yes ☐ No ☐ Don't know
Was the protective mechanism activated?
☐ Yes-fully ☐ Yes-partially ☐ No
Did the exposure incident occur?
☐ Before ☐ During ☐ After activation

Did the exposure incident occur?
☐ During use of sharp O While disassembling
☐ Between steps of a multi-step procedure
☐ After use and before disposal of sharp
☐ While putting sharp into disposal container
☐ Sharp in inappropriate place (table, trash, etc.)
☐ Other

Exposed Employee: If sharp had no engineered sharps injury protection, do you have an opinion that such a mechanism could have prevented the injury? ☐ Yes ☐ No

Explain:_____

Exposed Employee: Do you have an opinion that any other engineering, administrative or work practice control could have prevented the injury? ☐ Yes ☐ No

Explain:_____

Appendix K - ADDITIONAL BIOLOGICAL SAFETY RESOURCES

- NIH Guidelines for Research Involving Recombinant DNA (rDNA) work - http://oba.od.nih.gov/oba/rac/Guidelines/APPENDIX_B.htm#_Toc7238341
- CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition- http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf
- American Biological Association Risk Group Classification of Agents http://www.absa.org/resriskgroup.html
- Health Canada Biosafety MSDS http://www.phac-aspc.gc.ca/msds-ftss/index-eng.php
- Center for Disease Control & Prevention (CDC) http://www.cdc.gov/
- CDC – Biosafety Links http://www.cdc.gov/od/ohs/biosfty/biosfty.htm
- NIH (National Institutes of Health) Office of Biotechnology Activities (NIH OBA) http://www4.od.nih.gov/oba/
- NIH National Advisory Board for Biosecurity (Dual Use Research) http://www.biosecurityboard.gov/Framework%20for%20transmittal%200807_Sept07.pdf
- US Army Research Institute of Infectious Disease (USAMRID) http://www.usamriid.army.mil/
- NIH / CDC Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm
- Dept. of Transportation – Shipping Infectious Substances http://hazmat.dot.gov/training/Transporting_Infectious_Substances_Safely.pdf

Appendix L - Biosafety Level 2 Checklist

PACE UNIVERSITY

Biosafety Level 2 Checklist (BSL-2)

Reference: CDC BMBL/ 5th Edition, NIH Guidelines, Sep 09

Building & Room:	**Inspector:**
P.I.:	**Inspection Date:**
Laboratory Contact:	**Phone Extension:**
PI Signature:	**Inspector Signature:**

Biosafety Level 2	**Yes**	**No**	**N/A**	**Comments (additional space on p.2)**
A. Standard/Special Microbiological Practices				
1. Does the Principal Investigator (PI) establish and enforce policies that control access to the lab?	☐	☐	☐	
a. Are lab doors self- closing and have locks in accordance with university policies?	☐	☐	☐	
b. Are all people entering the lab advised of the hazards and meet specific entry/exit requirements?	☐	☐	☐	
2. Do personnel wash hands after working with potentially hazardous materials and **before leaving** the lab?	☐	☐	☐	
a. Does the lab have a hand washing sink? It should be located near the exit door.	☐	☐	☐	
3. Is eating, drinking, storing food, applying cosmetics, etc., permitted in the lab?	☐	☐	☐	**Food must be stored outside the lab area**
4. Is mouth pipetting prohibited? Are mechanical pipetting devices used instead?	☐	☐	☐	
5. Are policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware developed and implemented?	☐	☐	☐	**If possible, safety-engineered needles (i.e., self-retracting) that reduce risk of injury should be adopted.**
a. Are needles bent, sheared, broken, recapped, removed from disposable syringes or otherwise manipulated by hand before disposal?	☐	☐	☐	
b. Are used needles and syringes carefully placed in conveniently located puncture-resistant sharps containers?	☐	☐	☐	
c. Are non-disposable sharps placed in a hard -walled container for transport to processing areas for decontamination?	☐	☐	☐	
d. Is broken glass removed with brush and dustpan, tongs, or forceps?	☐	☐	☐	
e. Is plastic ware substituted for glassware whenever possible?	☐	☐	☐	**Plastic aspirating pipets should be used in place of glass Pasteur pipets.**
6. Are procedures carefully performed to minimize the creation of aerosols or splashes of infectious materials and waste?	☐	☐	☐	
a. Are all aerosol generating procedures conducted in a Biosafety Cabinet or other appropriate physical containment devices?	☐	☐	☐	
7. Are work surfaces decontaminated after completion of work and after any spill or splash of potentially infectious material with an appropriate disinfectant?	☐	☐	☐	**Disinfectant used:**
a. Is lab equipment routinely decontaminated? As well as after spills, splashes, or other potential contamination.	☐	☐	☐	
b. Is the lab designed so that it can be easily cleaned and decontaminated? Carpets and rugs not permitted.	☐	☐	☐	
c. Are lab furniture (chairs, tables, etc.) appropriate for loading and use? Are spaces accessible for cleaning? Are bench tops impervious to water and resistant to chemicals?	☐	☐	☐	
d. Are chairs used in lab work are covered with non-porous material that can be easily cleaned/decontaminated with disinfectant?	☐	☐	☐	

Biosafety Level 2	**Yes**	**No**	**N/A**	**Comments (additional space on p.2)**
8. Are all infectious materials decontaminated before disposal using an effective method?	☐	☐	☐	
a. Are potentially infectious materials placed in a durable, leak proof container during collection, handling, processing, storage, or transport?	☐	☐	☐	
b. Are all waste dry materials placed in containerized red biohazard bags which are kept closed when not in use?	☐	☐	☐	
c. Is fluid medical waste inactivated by adding chlorine bleach to a final concentration of 10% bleach, mixed thoroughly, held for 30 minutes (minimum), and discarded in the sanitary sewer	☐	☐	☐	
9. Is a sign incorporating the universal biohazard symbol posted at the entrance to the lab? Does signage include Biosafety level, PI name, phone numbers and required procedures for entering and exiting lab?	☐	☐	☐	
10. Have you had any issues with insect or rodent control?	☐	☐	☐	
11. Does PI ensure that lab personnel receive appropriate training regarding their duties, precautions to prevent exposures and exposure evaluation procedures?	☐	☐	☐	
a. Are initial and refresher trainings documented?	☐	☐	☐	
b. Are all lab personnel and particularly women of childbearing age provided info regarding immune competence and conditions that may predispose them to infection? **(Individuals having these conditions are encouraged to self-identify to their medical service provider for appropriate counseling and guidance).**	☐	☐	☐	
B. Special Practices				
1. Are all persons authorized to enter the lab advised of potential hazards; are lab personnel provided medical surveillance and offered appropriate immunizations (i.e., Hepatitis B) for agents handled in the lab?	☐	☐	☐	
2. Are Laboratory specific **biosafety** manual/Standard Operating Procedures (SOP) prepared and adopted as policy? Is it available and accessible?	☐	☐	☐	
3. Does the PI ensure that lab personnel demonstrate proficiency with standard and specialized BSL-2 microbiological practices before working with these agents?	☐	☐	☐	
a. If both high hazard and low hazard experiments are conducted in your lab, are those areas in your lab reserved for experiments of lesser biohazard potential carefully demarcated from higher biohazard areas?	☐	☐	☐	
4. Are personnel routinely decontaminating lab equipment, or when the equipment requires repair, maintenance, or removal from the lab?	☐	☐	☐	
If spills occur, are staff properly trained and equipped to work with infectious material?	☐	☐	☐	
4. If a laboratory exposure should occur, are there written procedures or emergency information available and accessible in the laboratory? a. All such incidents must be reported to the PI. PI must also report incidents immediately to Security (x777) and the Biosafety Office (x2-2818). b. Medical evaluation, surveillance, and treatment should be provided when required and appropriate records maintained.	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	**Incidents that may result in exposure to infectious materials must be immediately evaluated and treated.**
5. Are animals and plants not associated with the work being performed permitted in the lab?	☐	☐	☐	
C. Safety Equipment (Primary Barriers)				
1. Are Biosafety cabinet (Class II), certified annually, and other containment devices or PPE used when: a. Potential for aerosols or splashes exists? These may include centrifuging, grinding, blending, inoculating animals intranasally, harvesting infected tissues, etc. b. High concentrations/titers or large volumes of agents are used? These may be centrifuged outside the BSC using sealed rotor heads or centrifuge safety cups.	☐ ☐	☐ ☐	☐ ☐	
2. Are lab coats/gowns/smocks/ worn when in lab, and removed prior to leaving lab (i.e., before leaving for cafeteria, library, and administrative offices)? Dispose or launder protective clothing appropriately (lab coats must not be taken home).	☐	☐	☐	
3. Are eye and face protection (goggles, mask, face shield or other splatter guard) used for work outside biosafety cabinet that may generate splashes or sprays?	☐	☐	☐	

Biosafety Level 2	**Yes**	**No**	**N/A**	**Comments (additional space on p.2)**
4. Are gloves worn to protect hands from exposure to agents? Glove selection should be based on risk assessment. Disposable gloves must not be washed or reused. Gloves must be removed and disposed as biohazardous waste prior to leaving lab. Alternatives to latex should be available.	☐	☐	☐	
5. Are eye, face, and respiratory protection used in rooms containing infected animals as determined by risk assessment?	☐	☐	☐	
D. Laboratory Facilities (Secondary Barriers)				
1. Do the lab windows open to exterior? If a lab does have such windows, they must be fitted with screens or a sign posted that states "Windows must remain closed."	☐	☐	☐	
2. Is the BSC installed properly to avoid room air fluctuations that might impede proper functioning of the cabinet?	☐	☐	☐	
3. Are vacuum lines protected with liquid disinfectant traps?	☐	☐	☐	
4. Are vacuum lines protected with HEPA (High Efficiency Particulate Air) filters?	☐	☐	☐	
5. Is the eyewash station readily available? Portable eye wash bottle may be used for initial response if eyewash station is not immediately available.	☐	☐	☐	
6. HEPA filtered exhaust air from a Class II BSC can be safely recirculated if cabinet is tested and certified annually. Contact EH&s for more information on vendors. Has the hood(s) been recertified in the last 12 months?	☐	☐	☐	**BSC Certification Date:**

Personnel Training	**Yes**	**No**	**N/A**	**Comments**
Documented lab safety training (i.e., Safety refresher training conducted within the last year, with sign-in sheet available?)	☐	☐	☐	
Documented biological safety training (required **bi-annually** if working with BSL-2 materials)?	☐	☐	☐	
Documented bloodborne pathogens training (required **annually** if working with human cell lines, tissue, blood, or other human-derived materials)?	☐	☐	☐	

Additional Comments:

Click here to enter text.

Record of Changes

The initial version of this plan was developed by Brian Anderson, MPH (Director of Environmental Health and Safety) in March of 2012. Annual review activity and edits are noted in the below table.

Date	Description of Activity (Edit/Review)	Page #	Change made by
7-11-12	**Initial draft and review completed**	**All**	**Brian Anderson**