THE UNIVERSITY OF RHODE ISLAND



Biosafety Manual

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1.0 INTRODUCTION TO BIOSAFETY

1.1 Background

Work with microorganisms, cells, and tissues comprise a wide variety of routine activities in biomedical research and biotechnology laboratories. These activities include current and expanding technologies, such as development of new products from cells and tissues for therapeutic use, isolation and identification of genes, and genetic manipulation of cells, tissues, microorganisms, plants, and animals. However, these routine activities do present underestimated health hazards for laboratory staff, placing them at increased risk for infections from bacteria, fungi, viruses, viral vectors, recombinant deoxyribonucleic acid (rDNA), and biological organisms containing rDNA.

Biosafety can be simply defined as a group of practices and procedures designed to provide a safe working environment for individuals who work with these potentially hazardous biological materials. The primary goal of biosafety is to reduce or eliminate exposures to these materials through the use of containment. The term containment refers to safe methods for managing potentially infectious materials in laboratory environments. Containment includes not only good microbiological techniques and safety equipment (primary containment), but also the design and operation of the laboratory facility (secondary containment).

Biosafety guidelines for research laboratories have been developed by two government agencies, the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). In addition, specific guidance for teaching laboratories has been developed by the American Society of Microbiology. These guidelines provide the foundation for this manual and the safe operating procedures (SOPs). They are designed to protect laboratory personnel and individuals in the surrounding community and are described in the following documents:

- National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines): (<u>https://osp.od.nih.gov/biotechnology/nih-guidelines/</u>).
- Biosafety in Microbiological and Biomedical Laboratories (BMBL), which is published jointly by the CDC and the NIH: (<u>http://www.cdc.gov/biosafety/publications/bmbl5/index.htm</u>); the most recent edition was published in 2009.
- American Society of Microbiology Guidelines for Biosafety in Teaching Laboratories (<u>https://www.asm.org/getattachment/3c1eb38c-84d7-472f-aa9b-5d695985df21/ASM-Biosafety-Guidelines.pdf</u>).

These three publications classify biological agents into four distinct risk groups (RGs) and the procedures and practices for working with biological agents into four distinct biosafety levels. Each of these levels is matched with progressively restrictive practices and laboratory design features that have been developed to reduce health risks from exposures to potentially hazardous biological agents. These levels are further discussed in Section 2.

1.2 Regulations

Federal, state, and local agencies have developed regulations for protecting laboratory workers and the general public from potential health hazards associated with the use of biological agents in laboratories. Some of these regulations, such as those from the U.S. Occupational Safety and Health Administration (OSHA), have the force of law while those from NIH and CDC are recommended guidelines. However, as part of the grant application process, many federal and private granting agencies require applicants to certify that they adhere to both the suggested federal guidelines and the federally mandated requirements. It is URI Institutional Biosafety Committee (IBC) policy that all laboratories comply with these Regulations and Guidelines.

Federal

Laboratory workers who come in contact with human blood or other human bodily fluids are at increased risk for exposures to and infections from certain bloodborne pathogens (BBP), such as human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). The OSHA Bloodborne Pathogens Standard (29 Code of Federal Regulations [CFR] 1910.1030) was designed to eliminate or minimize occupational exposures to blood and other bodily fluids and the risks for developing the infectious diseases associated with them. All laboratories that work with human cells, human blood, human tissues, and certain, specific human body fluids must adhere to the OSHA BBP Standard:

(http://www.osha.gov/SLTC/bloodbornepathogens/standards.html.

A requirement of the OSHA BBP Standard is that employers must prepare an Exposure Control Plan designed to eliminate or minimize employee exposures to BBP. The URI Exposure Control Plan for Researchers is located as **Appendix A.**

Universal Precautions is a key element of a BBP program and must be implemented at all times when working in the Biosafety Level 2 (BL2) laboratories. Universal Precautions involves treating all samples as potentially infectious. For example, blood from any source, even HIV-seronegative control donors, should be handled as potentially infectious. Training in Universal Precautions techniques is given at the time of orientation and on an annual basis. For more information regarding OSHA BBP training, refer to URI Environmental Health and Safety (EH&S) Office: <u>http://web.uri.edu/ehs/</u>

Safe practices for studies involving the use of rDNA (e.g., viral vectors, bacterial plasmids) are governed by the *NIH Guidelines*

(<u>https://osp.od.nih.gov/biotechnology/nih-guidelines/</u>). While the NIH Guidelines is a guidance document, all research at URI, regardless of funding source, must to comply with this document. Furthermore for projects that are NIH funded, compliance with the NIH Guidelines is a requirement listed as a Term and Condition in the NIH Grants Policy Statement.

State of Rhode Island

The State of Rhode Island regulates the management of biohazardous waste through the Regulated Medical Waste Regulations (Regulation DEM-OWM-MW-1-2009, amended July, 2010). The principal issues deal with what constitutes biological waste and how to dispose of it properly. Overall, the State statutes agree with the NIH and CDC definition of biological waste.

1.3 Institutional Biosafety Committee

The NIH places the responsibility for implementing its Guidelines in the hands of the URI Institutional Biosafety Committee (IBC). In compliance with the NIH Guidelines, the URI IBC includes representatives from the general public as part of its Committee membership. All research involving the use of rDNA and infectious microorganisms, including bloodborne pathogens, and human and nonhuman primate materials must be registered with the IBC. Additional information can be found on the URI Office of Research Integrity website.

The primary responsibilities of the IBC are to:

- Promote the best practices for the safe handling and disposal of potentially hazardous and infectious biological materials.
- Ensure compliance with all relevant federal, state, and local regulations for work with biohazardous materials.

The functions of the IBC are as follows:

- Recommend appropriate biosafety-related policies and procedures for management of potentially hazardous biological materials.
- Serve as a resource for technical information for biological risk assessment and reduction of exposures to biohazards.
- Keep current on regulations pertaining to the use of potentially biohazardous materials.
- Assist investigators in identifying technical resources and relevant information related to biosafety.

1.4 Responsibilities of the Principal Investigator and Laboratory Staff

Principal Investigator

Principal Investigators (PIs) are responsible for implementation of the applicable biosafety procedures and practices in their laboratories. They must ensure that the appropriate equipment and facilities are available for laboratory staff members and are used properly. They must also arrange for appropriate employee training regarding the safe use of potentially hazardous biological agents and require that individuals handling BBPs receive the annual training mandated by OSHA. Each PI must be aware of the potential adverse health effects of the biological materials used in his or her laboratory, the appropriate biosafety level, and any other pertinent factors that will ensure the safety of laboratory staff members and the surrounding community.

In addition to the responsibilities of the PI identified above, when research involves the use of rDNA, the PI agrees to abide by the NIH Guidelines. Under the NIH Guidelines, the PI has a number of specific responsibilities. In particular, the PI must (among other tasks):

- Ensure that no research is conducted with biological materials prior to approval by the institution's IBC.
- Report any significant problems, violations of the NIH Guidelines, or any research-related accidents, illnesses, or potential exposures to the URI EHS and the URI IBC.
- Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents. This instruction should be specific to the agents and materials used in the research project.
- Make available to all laboratory staff protocols that describe the potential biohazards and the precautions to be taken with the agents to be used.

Additional responsibilities of the PI who work with rDNA are located in the NIH Guidelines (<u>https://osp.od.nih.gov/biotechnology/nih-guidelines/</u>). Failure to comply with the NIH Guidelines by one PI could affect all NIH-funded projects at URI; therefore, compliance is absolutely mandatory.

Laboratory Staff

Laboratory staff members are responsible for following URI health and safety policies and the procedures and instructions from their PIs and URI EH&S. They need to comply with NIH, CDC and OSHA regulations, use safe laboratory practices, and inform the PI, laboratory supervisor, or EHS regarding any potentially hazardous situations or conditions.

2.0 PRINCIPLES OF BIOSAFETY

The BMBL classifies work with biological agents into four distinct biosafety levels (BLs) that have increasingly restrictive practices and facilities. Each BL designation is based on the potential health risks for individuals handling the biological materials. The four BLs generally correspond to NIH Risk Groups (RGs), which classify organisms into four RGs according to their relative pathogenicity for healthy adult humans. BLs and RGs are summarized in Table 2.1.

Table 2.1Biosafety Level Classifications for Biological Agents					
Biosafety Level	Risk Group	Examples			
BL1	Individual risk: LOW Community risk: LOW	Escherichia coli Adeno-associated viruses			
BL2	Individual risk: MODERATE Community risk: LOW	Streptococcus Staphylococcus Hepatitis B and C viruses Adenoviruses Most retroviruses and lentiviruses			
BL3	Individual risk: HIGH Community risk: MODERATE	Tuberculosis West Nile virus			
BL4	Individual risk: HIGH Community risk: HIGH	Ebola virus			

2.1 Biosafety Levels 1 and 2

The majority of laboratory work at URI involves the use of BL1 and BL2 containment and procedures. BL1 is applicable to work involving well-characterized agents not known to consistently cause disease in healthy adult humans; these agents present minimal potential health hazards to laboratory personnel and the surrounding community (i.e., RG1 organisms). BL2 is recommended for work involving agents that present moderate potential health hazards to laboratory personnel and the surrounding community (i.e., RG2 organisms). BL2 includes all of the practices and procedures of BL1 and then builds upon these guidelines. Table 2.2 provides a brief summary of the biosafety level criteria for BL1 and BL2.

Biosafety			Safety Equipment	Facilities
Level	Agents	Practices	(Primary Barriers)	(Secondary Barriers)
BL1	Not known to consistently cause disease in healthy adults	Standard Microbiological Practices	Personal Protective Equipment (PPE) includes laboratory coats; gloves; eye protection as needed	Open bench top sink required
BL2	Associated with human disease. Potential hazards from percutaneous injury, ingestion, and mucous membrane exposure.	 BL1 practices plus: Limited access Biohazard signs PPE Sharps precautions Biosafety manual that defines any biological waste decontamination policies 	 Primary barriers include Class I or II biosafety cabinets or other physical containment devices for all manipulations of agents that cause splashes or aerosols of infectious materials. PPE includes laboratory coats; gloves; face protection as needed 	BL1 plus: • Autoclave available

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2.2 Hazard Analysis / Risk Assessment

Each research project must be evaluated by the PI through a risk assessment to determine which practices and procedures are required when working with biological materials to determine the optimal practices, equipment, and facilities to be used to ensure safety. The proposed risk assessment is then presented to the IBC for final review and approval.

In some cases, a risk assessment may conclude that standard BL2 procedures and work practices, along with additional safe guards, are required. For example, additional safe guards might be required when there is insufficient information available about the agents in question and/or about worker safety when using these agents.

At a minimum, the risk assessment should include the following:

- Pathogenicity of the biological material and infectious dose
- Consideration of the outcome of an exposure
- Natural route of exposure
- Other routes of exposure (parenteral, airborne, ingestion, etc.)
- Stability of biological material in the environment
- Concentration of biological material and amount to be manipulated
- Presence of a suitable host
- Information available from animal studies and reports of laboratory-acquired infections or clinical reports
- How the biological material will be used (concentration, sonication, aerosolization, centrifugation, etc.)
- Any genetic manipulation of the organism that may extend the host range of the agent or alter the agent's sensitivity to known, effective treatment regimens
- Local availability of effective prophylaxis or therapeutic interventions

2.3 Limited Information

There are situations when the information is insufficient to perform a risk assessment. For these situations, the following conservative approach should be used:

- Universal precautions should always be followed, and barrier protections applied (e.g., gloves, gowns, eye protection), regardless of the origin of the samples.
- Biosafety level 2 should be the minimum requirement for the handling of specimens.

3.0 SAFE OPERATING PROCEDURES

Table 2.2 provides general recommendations for appropriate laboratory practices, safety equipment and facilities based on biosafety level. More detailed requirements and guidance for working with biological materials are outlined in the Safe Operating Procedures (SOPs). These SOPs are generally applicable to all laboratories. However, PIs should consider specific laboratory processes and tailor or create new SOPs for their specific laboratory.

3.1 Standard and Special Microbiological Practices for BL1 and BL2 Laboratories

Standard microbiological practices must be followed in accordance with the <u>Biosafety in</u> <u>Microbiological and Biomedical Laboratories</u>, 5th Ed</u>. URI expects that all research be conducted according to this document. The URI Standard and Special Microbiological Practices SOP is located as **Appendix B**.

3.2 Safe Use of Biological Safety Cabinets

Biological safety cabinets (BSCs) provide a primary level of containment for working safely with potentially hazardous biological materials. When combined with good microbiological practices, BSCs can protect both laboratory personnel and the environment. Although many may think that the principle function of BSCs is to protect cells and cultures from contamination by bacteria and fungi, **their primary purpose is to protect the laboratory workers from exposures to potentially infectious agents.** Implementation of the procedures outlined in the SOP will ensure optimal operation of a BSC and a safe working environment for the user. The URI Safe Use of Biosafety Cabinets SOP is located as **Appendix C.**

BSCs are required to be tested and certified annually by technicians accredited by the National Sanitation Foundation (NSF). Additionally, BSCs shall be certified when they are first installed and whenever they are serviced or moved, even to a nearby laboratory, because the HEPA filters may be dislodged from their proper fitting during these moves. Please contact the <u>URI EH&S office</u> for information regarding BSC certifications.

3.3 Centrifuge Safety

The centrifuge safety SOP describes safe handling and maintenance of centrifuges and procedures for responding to spills and leaks within centrifuges. The URI Safe Use of Centrifuges SOP is located as **Appendix D.**

3.4 Avoiding the Production of Biological Aerosols

Generation of biological aerosols through the use of centrifuges, mixing operations (e.g., sonication, homogenization) can result in laboratory-acquired infections. Refer to the SOP for techniques to minimize the risk of generating aerosols. The URI Avoiding the Production of Biological Aerosols SOP is located as **Appendix E.**

3.5 Transporting Cell Cultures, Research/Clinical Specimens or Biohazardous Materials

This SOP describes proper procedures for transporting materials between laboratories within the same building. The URI Transporting Biohazardous Materials SOP is located as **Appendix F.**

3.6 Sharps Handling and Disposal

Some of the most serious accidents in biological research laboratories are those caused by puncture wounds or through skin (percutaneous exposures). All objects that can puncture skin are designated as sharps and require special disposal treatment. Examples of sharps include hypodermic needles, glass Pasteur pipettes, microscope slides and coverslips, razor blades, and suture needles. For more information on Sharps Handling and Disposal, refer to the SOP. The URI Sharps Handling and Disposal SOP is located as **Appendix G.**

3.7 Managing RI Regulated Medical Waste (Biohazardous Waste)

Regulated medical waste may be disposed of in two ways: designated biological waste box or chemical disinfection. Appropriate disinfection procedures will be chosen and utilized in accordance with both the PI and URI EH&S in order to ensure adequate decontamination of biological wastes. For more information, refer to the SOP. The URI Managing Biohazardous Waste SOP is located as **Appendix H.**

3.8 Disinfectants for Biohazardous Materials

Disinfection and decontamination are terms that are often used interchangeably, but they each have specific definitions. Disinfection is a chemical or physical treatment that destroys most biological agents, except spores. Decontamination refers to a chemical or physical treatment that destroys most biological agents to a low level, but not necessarily zero. A number of disinfectants are commonly used in laboratory settings, particularly to wipe down surfaces to remove infectious agents. For more information, refer to the SOP. The URI Disinfectants for Biohazards Materials SOP is located as **Appendix I.**

3.9 Biohazard Spill Management Plan

The Biohazard Spill Management Plan describes recommended procedures for the management of small spills of blood, bodily fluids, or other potentially infectious materials. If a large volume of a biological material spills or if equipment (centrifuge/homogenizer/biosafety cabinet) malfunctions while processing biological materials, contact <u>URI EH&S</u> for immediate consultation to implement appropriate measures to contain the spill. The URI Biohazard Spill Management Plan SOP is located as **Appendix J.**

4.0 IMMUNIZATIONS AND MEDICAL RESTRICTIONS

Certain biological materials require personnel who work with them to receive immunizations and/or have medical restrictions.

Under the OSHA BBP Standard, a hepatitis B vaccine is recommended for all employees working with human blood, body fluids, tissues, or other potentially infectious materials. Those employees declining vaccination will be asked to sign the OSHA waiver indicating that hepatitis B vaccine has been offered and refused. Any questions should be directed to Environmental Health and Safety.

4.1 Pregnancy

Several infectious agents are known to affect embryonic development. Women of childbearing age should be aware of the risks associated with studies using these agents. Men or women who live with women of childbearing age should also know of the risks and should be especially careful not to bring infectious agents home on clothing or other laboratory materials.

For an infectious agent to affect embryonic development, the infectious agent must be transmitted to the child. In some cases, transmission is via the blood through the placenta. Examples of organism that are known to have some adverse effects on human embryo and fetal development include rubella virus, herpes simplex virus, and varicella virus.

Should you become or wish to become pregnant, it is wise to inform your obstetrician and gynecologist of any infectious agents and any chemicals you may encounter in your work. Women who are pregnant or become pregnant are encouraged to inform their supervisors or PIs and discuss exposure issues regarding associated risks of research being conducted and pregnancy, including infectious agents and chemical exposures and encounters, and encounters. Radiation exposure can also cause fetal damage. If concerned about radiation exposure, contact the <u>URI</u> Radiation Safety Office.

4.2 Other Medical Restrictions

Restrictions or recommendations will be made on an individual basis after discussion with either an occupational medicine practitioner or your personal physician.

Examples of some conditions that might warrant special precautions are HIV infection, immunosuppressive conditions, or drug therapy that suppresses the immune system.

5.0 LABORATORY SAFETY TRAINING INFORMATION

General laboratory safety information, including biological safety training is provided for all URI laboratory staff by URI EH&S. Laboratory staff including PIs, are required to take this training annually. Lack of compliance with the training requirement will prevent new research from being approved by the IBC. Introductory training is provided through scheduled in-person trainings. Refresher training is provided in online format on CITIprogram.org. The URI EH&S office will also conduct training for specific groups upon request.

6.0 SHIPPING AND RECEIVING PROCEDURES FOR BIOLOGICAL SPECIMENS

Import, export, and interstate transport of biological materials are subject to requirements and laws from several federal agencies. The U.S. Public Health Service (PHS), U.S. Department of Transportation (DOT), U.S. Department of Agriculture (USDA), and U.S. Postal Service, regulate transport of hazardous materials by rail, air, vessel, and public highway. The guidelines and regulations of the International Air Transport Association (IATA) and International Civil Aviation Organization also apply when shipping substances by air. Import/Export Permit requirements are regulated by the Bureau of Customs; the Department of Commerce, CDC, and USDA require permits for certain agents.

The PHS defines etiological agents as viable microorganisms that cause disease in humans; infectious substances are those substances that contain etiologic agents. This terminology is used by the DOT and IATA. Diagnostic specimens are anything that the shipper reasonably believes to contain an infectious substance. Diagnostic and infectious specimens are regulated by the USDA, U.S. Food and Drug Administration (FDA), PHS, and IATA. Biological product means a product prepared in accordance with regulations that govern the manufacture of vaccines, reagents, or all viruses, serums, toxins, etc. intended for use in the diagnosis, treatment, or prevention of diseases in humans or animals. Biological products are regulated by the USDA, FDA, PHS, DOT, and IATA.

Laboratory staff may receive awareness level training from the URI EH&S office for the shipment of hazardous materials. Individuals packaging specimens/hazardous materials for shipment must also receive function-specific training. The training is required every two years or when there is change in the regulations. For assistance regarding training and other requirements necessary for the legal shipping of hazardous materials, please contact the <u>URI EH&S office</u>.

The required type of packaging, labeling, and documentation depend on the biohazardous material being shipped, how it is being shipped, and where it is being shipped. Specific packaging requirements for various biological agents should be reviewed by the PI to ensure compliance with all regulatory requirements. Please be aware that anyone who ships restricted items improperly and without authorization may be subjected to fines and/or incarceration.

7.0 GENERAL LABORATORY SAFETY AND BIOLOGICAL SAFETY INSPECTIONS

Various federal, state, and local regulations require laboratory inspections are to be conducted at least on an annual basis for all BL2 laboratories and higher and at least once every two years for BL1 laboratories. Laboratory inspections are typically scheduled beforehand to ensure the visit to the laboratory does not create a disruption; however, the URI EH&S office reserves the right to perform unannounced inspections. The surveyor will review any non-compliant conditions observed, and make recommendations for improvement. An unannounced site visit may occur any time after 30 days to make certain that all conditions are corrected.

8.0 WORKING WITH LABORATORY ANIMALS

Working with animals in a laboratory setting can present risks from infections and injuries to all personnel. Those personnel working with laboratory animals must be aware of the potential risks and implement measures to prevent injury or illnesses related to laboratory animal use.

Prior to commencing any work **IN ANIMALS** that utilize RG2 pathogens, it is **mandatory** that all Investigators contact the Attending Veterinarian (AV) to report the pathogen name(s) and the animal facility requested for such use to ensure the University can safely accommodate this research.

The URI Office of Research Integrity manages the Research Occupational Health Program. Prior to working with animals, all faculty, staff and students who work with animals must complete training and be medically cleared. For more information, see:

http://www.uri.edu/research-admin/office-of-research-integrity

All use and handling of animals at URI must be conducted safely, humanely, and in compliance with all institutional and federal regulations. Any unsafe or hazardous behavior or work conditions regarding the use of animals must be reported to the AV or the IACUC.

9.0 APPENDIX

- Appendix A Exposure Control Plan for Researchers
- Appendix B Standard and Special Microbiological Practices SOP
- Appendix C Safe Use of Biosafety Cabinets SOP
- Appendix D Safe Use of Centrifuges SOP
- Appendix E Avoiding the Production of Biological Aerosols SOP
- Appendix F Transporting Biohazardous Materials SOP
- Appendix G Sharps Handling and Disposal SOP
- Appendix H Managing Biohazardous Waste SOP
- Appendix I Disinfectants for Biohazardous Materials SOP
- Appendix J Biohazard Spill Management Plan SOP
- Appendix K Centrifuge Safety Poster
- Appendix L OSHA Definitions
- Appendix M Exposure Determination
- Appendix N Universal Biohazard Symbol
- Appendix O Equipment Decontamination Label
- Appendix Q Guidance on the Use of Human Primates
- Appendix R ABSL Determination Matrix
- Appendix S Zoonotic Agents of Concern
- Appendix T Hand Care SOP for Researchers



Appendix A Bloodborne Pathogens Exposure Control Plan for Researchers



Department of Public Safety Environmental Health and Safety Laboratory Safety Program

> http://web.uri.edu/publicsafety/ Approved: August 2015



Appendix A

Bloodborne Pathogens

Exposure Control Plan for Researchers

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EXPOSURE CONTROL PLAN FOR RESEARCHERS

Section I

Purpose of the Exposure Control Plan

A. The purpose of the Exposure Control Plan is to minimize the occupational exposure of employees to blood or other potentially infectious materials (OPIM), as required by OSHA 29 CFR 1910.1030, the Bloodborne Pathogens Standard.

A copy of the OSHA Standard is available on-line at:

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_i d=10051.

- B. Occupational exposure is defined as "reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties."
- C. Other potentially infectious materials are defined as (1) The following human body fluids: semen, vaginal fluids, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or Hepatitis B virus-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV; (4) Human cell cultures.
- D. All at-risk employees who may have occupational exposure are expected to follow the guidelines established in this policy. Compliance is mandatory.

Section II

University Responsibility and Employee Inclusion in the Plan

- A. The Department of Public Safety's Environmental Health and Safety (EHS) division is responsible for implementing the Exposure Control Plan (ECP), maintaining the Sharps Injury Log, reviewing and updating the ECP at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure, and as necessary, to reflect new or revised employee positions with occupational exposure.
- B. All University of Rhode Island employees who, by the nature of their job-required tasks, have occupational exposure to blood or other potentially infectious materials (OPIM) shall be included in this plan.

All at risk employees who have occupational exposure shall receive bloodborne pathogens training within 10 days of initial job assignment. Employees will also be offered the HBV vaccine within 10 days of initial job assignment.

C. Graduate students and Post docs are considered employees of the University and are covered under the Bloodborne Pathogens Standard. Undergraduate students performing tasks that put them at risk as part of their learning experience are not covered by this Standard. However, it is the responsibility of the educator to advise students of the risks involved, and teach them how to perform all tasks and procedures safely. Undergraduates who work in labs where there is occupational exposure are strongly encouraged to attend annual Bloodborne Pathogens and Biosafety training.

Supervisors (including Department Heads and Managers) will perform an exposure determination for each job classification within their administrative division to identify at risk personnel. The determination will be done without regard for the use of personal protective equipment.

- C. Employees who have occupational exposure and are included in the program shall attend an EHS Bloodborne Pathogens + Biosafety class within 10 days of being assigned to their positions. Employees who start work after the semester begins shall take the CITI online Bloodborne Pathogens training within 10 days of assignment, and take the EHS class Bloodborne Pathogens + Biosafety class when next offered. Faculty and staff who take CITI Certification training should contract EHS directly to schedule the HBV series.
- D. Supervisors will re-evaluate positions on a regular basis to identify changes in job responsibilities, and to identify those individuals who might need to be included in the plan as a consequence of those changes. Supervisors will immediately advise EHS when employees become eligible for inclusion to assure compliance with all provisions of the regulation.

- E. All required training, personal protective equipment, supplies, engineering controls, record keeping, as well as any testing necessary for compliance with the standard shall be supplied at no cost to the employee.
- F. When the potential for occupational exposure exists, students, faculty and staff shall utilize the methods described in the plan to minimize occupational exposure.

Preventive measures that should be considered include, but are not limited to:

Engineering Controls

- Enclosed containers
- Mechanical pipetting devices
- Splash shields
- Sharps disposal containers
- Secondary leak-proof containers for transport of materials for autoclaving
- Biological safety cabinets
 See Appendix C: Safe Use of Biosafety Cabinets SOP

Administrative Controls

- Safe work practices
- Work place policies
- Written Standard Operating Procedures

Personal Protective Equipment (PPE)

- Gloves
- Safety goggles
- Lab coats
- Impervious aprons
- G. Research utilizing blood or other potentially infectious materials must be approved by the Institutional Biosafety Committee (IBC) before work can begin or samples used in the lab. This policy also includes preliminary research done to determine if a project is viable.

If research involves human subjects, the project must also be reviewed and approved by the Institutional Review Board.

- H. Exposure control plans must be reviewed periodically and updates made to reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens. Review allows for the investigation of commercially available and safer medical devices that are designed to eliminate or minimize occupational exposure.
- I. At the time of review, employers are required to solicit employee input to help

evaluate and select effective engineering and work practice controls. Employee input and suggestions must be documented.

Section III

See Appendix M: Exposure Determination

KINGSTON CAMPUS

Research laboratory job classifications in which *some employees* are covered:

1. The Research Office:

Director of Research Integrity, Veterinarian, Technicians

Potential exposure to research involving human materials.

- College of Pharmacy: Professor, Associate Professor, Assistant Professor, Lecturer, Graduate Assistant. Analysis of blood and OPIM, research using materials of human origin including cell cultures.
- Department of Cell & Molecular Biology: Professor, Associate Professor, Assistant Professor, Lecturer, Graduate Assistant. Analysis of blood and OPIM including cell cultures.
- Department of Nutrition and Food Sciences: Professor, Associate Professor, Assistant Professor, Lecturer, Graduate Assistant. Finger sticks, analysis of blood and OPIM.
- 5. Kinesiology Department:

Professor, Associate Professor, Assistant Professor, Lecturer, Graduate Assistant. Venipuncture, finger sticks and analysis of blood.

6. Department of Chemistry:

Professor, Associate Professor, Assistant Professor, Lecturer, Graduate Assistant. Analysis of blood and OPIM, research using materials of human origin including cell cultures.

7. Department of Physics:

Professor, Associate Professor, Assistant Professor, Lecturer, Graduate Assistant. Analysis of blood and OPIM, research using materials of human origin including cell cultures.

8. Department of Public Safety, EHS division:

Coordinator of Hazardous Materials and Chemical Waste, Chemical Hygiene Officer, and other personnel designated by the Director.

Pick up and transportation of medical waste, access to and inspection of areas where blood and OPIM are stored or used.

- College of Engineering: Professor, Associate Professor, Assistant Professor, Lecturer, Graduate Assistant. Chemical analysis of blood for inorganic materials (metals), analysis of water samples, manipulation of human body fluids or equipment contaminated with human body fluids.
- 10. Center for Vector-Borne Disease: Professor, Graduate Assistant, Post-doctoral fellow, Research Assistant,

Research Associate Analysis of blood and OPIM, work with bloodborne pathogens.

 Rhode Island State Crime Lab: Director, Criminalist I, II, III, Principal Clerk Stenographer. Admitting evidence, analysis of blood and OPIM.

PROVIDENCE CAMPUS (Feinstein College of Continuing Education – CCE)

- Department of Cell & Molecular Biology: Professor, Associate Professor, Assistant Professor, Lecturer, Graduate Assistant. Analysis of blood and OPIM including cell cultures.
- Clinical Laboratory Science (Biotechnology Program) Professor, Associate Professor, Assistant Professor, Lecturer, Graduate Assistant, Lab Manager Human cell cultures
- Clinical Laboratory Science (Cytopathology Program) Human blood and other potentially infectious materials.

Section IV Methods of Compliance

It is the responsibility of each supervisor (including Deans, Directors, Department Heads, Principal Investigators and Managers, etc.) to ensure that persons under their supervision work in a safe and healthy environment. Immediate supervisors will advise employees of the potential hazards of their assigned duties and make them aware of the measures outlined below to protect themselves against accidental exposure.

Universal Precautions shall be observed to prevent contact with blood and other potentially infectious materials. All human blood, body fluids and cell cultures shall be treated as if they are known to be infectious for HBV, HCV, HIV and other bloodborne pathogens even though they might not be. Gloves will be worn when handling blood or other potentially infectious materials.

A. Engineering Controls

Engineering controls are used to eliminate the hazard and minimize employee exposure to bloodborne pathogens. Engineering controls include, but are not limited to the following:

- Biosafety cabinets
- Hand washing stations
- Sharps disposal containers
- Safe sharps devices
- Enclosed transport containers

- Safety centrifuge cups
 See Appendix D: Safe Use of Centrifuges SOP; Appendix K: Centrifuge Safety
 Poster
- B. Personal Protective Equipment (PPE)

Personal Protective Equipment shall be worn to create a physical barrier between the lab worker and the hazard.

- 1. When there is the possibility of occupational exposure, properly fitted personal protective equipment shall be provided to the employee at no cost.
- 2. Supervisors are responsible for training employees in the safe use of PPE.
- 3. When there is risk of occupational exposure, supervisors are responsible for assuring that their employees use appropriate personal protective equipment.

Laboratory PPE includes, but is not limited to, the following:

- Gloves
- Gowns
- Lab coats
- Impervious aprons
- Face shields or masks
- Eye protection
- 4. Masks in combination with eye protection, such as goggles or glasses with solid side shields, or chin-length face shields shall be worn whenever splashes, spray, splatter, or droplets of blood or OPIM may be generated.
- 5. Barrier lab coats shall be provided when there is the risk of occupational exposure.
- 6. Personal protective equipment shall be repaired or replaced by the employer as needed to maintain its effectiveness.
- C. Administrative Controls

Administrative controls are used to help manage the risk of working with infectious materials and include, but are not limited to the following:

- Safe work practices
- Written Standard Operating Procedures (SOPs)
- Policies (institutional and lab)
- Training
- Licenses and permits

Safe Work Practices

These are controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g. prohibiting recapping of needles using a two-handed technique).

- 1. If using needles to manipulate blood or other potentially infectious materials, this must be indicated on your IBC Protocol Review Form.
- 2. Contaminated needles and other sharps shall not be bent, sheared or broken. Recapping or removing needles is prohibited unless there is no alternative or such action is required by a specific procedure. If recapping or removing a needle from a syringe is required, justification must be included on the IBC form and the procedure approved prior to implementation. Recapping or removal must be accomplished using a one-handed technique, alone or in combination with a mechanical device. See **Appendix G: Sharps Handling and Disposal SOP.**
- 3. Sharps disposal containers labeled with the international biohazard symbol (available from laboratory supply vendors) must be available at the work site.
- 4. Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be puncture resistant, labeled with the universal biohazard symbol and filled with an appropriate tuberculocidal solution.
- 5. Eating, drinking, smoking, applying cosmetics or lip balm and handling contact lenses is prohibited in work areas where there is a reasonable likelihood of occupational exposure. Hand cream is not considered a "cosmetic" and is permitted. However, some petroleum-based hand creams can adversely affect glove integrity. See **Appendix B: Standard and Special Microbiological Practices.**
- 6. Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or bench tops where blood or other potentially infectious materials are present.
- 7. All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering and generation of aerosols or droplets of these substances. See **Appendix E: Avoiding the Production of Biological Aerosols SOP.**
- 8. Mouth pipetting is prohibited.
- 9. Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage,

transport or shipping.

- 10. Labels that incorporate the universal "Biohazard Symbol" shall be used to identify areas where blood or other potentially infectious materials are used and shall be purchased by the user (available from lab supply vendors).
- 11. Equipment which may become contaminated with blood or other potentially infectious materials shall be decontaminated prior to servicing. See **Appendix O: Equipment Decontamination Label**. If complete decontamination cannot be accomplished, a readily observable label shall be attached to the equipment identifying the areas that are still contaminated.

D. Personal Hygiene

- 1. Hand washing facilities or effective portable decontamination materials shall be readily available in areas where exposure to blood or other potentially infectious materials is likely to occur.
- 2. Employees shall wash their hands after removing gloves and/or other personal protective equipment, and before leaving the work area.
- 3. Following contact with blood or other potentially infectious materials, employees shall wash the affected areas with soap and water, or flush mucous membranes with water immediately or as soon as feasible.
- 4. If a garment is penetrated by blood or other potentially infectious material, the garment shall be removed immediately or as soon as feasible. Spot decontaminate soiled lab coats with an effective agent such as 70% ethanol.
- 5. All personal protective equipment shall be removed prior to leaving the work area. Gloves and lab coats are not to be worn in public areas such as hallways or elevators.
- 6. Reusable personal protective equipment, if contaminated, shall be decontaminated and inspected prior to reuse.

Section V

Housekeeping

It is the responsibility of supervisors to ensure that the worksites under their control are maintained in a clean and sanitary condition. They are also responsible for ensuring that work areas have appropriate written schedules for cleaning and method(s) for decontaminating based upon the type of surface to be cleaned, the type of matter or contaminant present, and tasks or procedures being performed. These written schedules

shall become part of the lab's biosafety manual.

All equipment and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials, and at the end of each 7-hour shift. See **Appendix I: Disinfectants for Biohazardous Materials SOP.**

A. Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

An appropriate disinfectant is defined as one that is approved by the U.S. Environmental Protection Agency (EPA) for the intended use, and mixed to the appropriate strength, or a solution of household bleach diluted 1:10 with water. The disinfectant must be properly labeled, readily available at the work site, made up fresh for use and afforded adequate contact time to accomplish the goal. EPA recommends 10 minutes of contact time for 10% bleach. Bleach is highly corrosive to stainless steel and surfaces must be wiped 4-5 times with clear water to remove all trace of residue and prevent corrosion. Commercial disinfectant products such as Wescodyne are also suitable.

- B. Protective coverings, such as plastic wrap, aluminum foil, and imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated, or at the end of the work shift if they may have become contaminated during the shift. If these coverings are compromised causing contamination of a work surface, surfaces must be decontaminated with an appropriate disinfectant such as 10% bleach or a hospital-approved disinfectant. Sufficient contact time must be allowed for complete decontamination.
- C. Bins, pails, cans, and similar receptacles intended for reuse, which have a reasonable likelihood of becoming contaminated with blood or other potentially infectious materials, shall be inspected for contamination each time before being put into service and decontaminated after each use.
- D. Broken glassware which may be contaminated with human blood or body fluids shall not be picked up directly with the hands. Handle using mechanical means, such as a brush and dustpan, tongs or forceps. Contaminated broken glassware shall be placed in a puncture resistant container, autoclaved and disposed in the lab's "Broken Lab Glassware" box.
- E. Broken contaminated glass or plastic ware shall not be picked up by hand even if gloves are worn. Use tongs or a dustpan and broom instead.

F. Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires persons to reach by hand into the containers until after decontamination has been completed and documented.

Section VI

Rhode Island Regulated Medical Waste (Regulation DEM-OWM-MW-1-2009)

http://www.dem.ri.gov/pubs/regs/regs/waste/medwaste10.pdf

This policy has been established to ensure safe disposal of the University's infectious waste. See **Appendix H: Managing Biohazardous Waste SOP.**

Infectious waste must be properly identified, segregated from the solid waste stream and deposited in specially designated Biohazard Waste boxes provided by EHS. The biohazardous waste pickup schedule is posted on the EHS web site.

Regulated Medical Waste is any waste generated in the diagnosis (including testing and laboratory analysis), treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals, or in the development of pharmaceuticals. Regulated medical wastes mixed with non-hazardous solid wastes shall be considered regulated medical wastes.

This policy governs all University activities involving any of the types of biological waste listed below:

- A. <u>Cultures and Stocks</u>: Cultures and stocks of infectious agents and associated biologicals including: cultures from medical and pathology laboratories; cultures and stocks of infectious agents from research laboratories; wastes from the production of biologicals; discarded live and attenuated viruses; and culture dishes and devices used to transfer, inoculate and mix cultures.
- B. <u>Pathological Wastes</u>: Human pathological wastes, including tissues, organs, and body parts that are removed during surgery or other medical procedures.
- C. Human Blood, Body Fluids and Blood Products:
 - 1. Liquid waste human blood or body fluids;
 - 2. Blood products;
 - 3. Items saturated and/or dripping with human blood or body fluids;
 - 5. Items that are saturated and/or dripping with human blood or body fluids;

including, but not limited to, serum, plasma, and other blood components, and their containers (e.g. blood bags and blood vials) and body fluids as described in Section I, C of the regulation;

- 5. Specimens of body fluids and their containers;
- 6. Human cell cultures

D. <u>Sharps</u>:

- 1. Sharps that have been used in animal or human care or treatment, including sharps generated in research laboratories, including, but not limited to, hypodermic needles, syringes with or without the attached needle, Pasteur pipettes, microscope slides, scalpel blades, blood vials, and needles with attached tubing, glass carpules, and glass culture dishes regardless of presence of infectious agents. Also included are other types of broken or unbroken glassware that have been used in animal or human care or treatment, and used microscope slides and cover slips. Disposable syringes and needles are considered medical waste after one use.
- 2. Sharps must be segregated and disposed of in leak-proof, rigid, puncture-resistant, shatterproof containers (sharps containers are available from lab supply vendors). If contaminated with infectious agents, sharps must be rendered non-infectious by autoclaving or chemical disinfection. Sharps containers must be disposed in Biohazard Waste. If a Biohazard Waste box is not available, call EHS to arrange pickup when a sharps container is full.
- E. <u>Animal Waste:</u> Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research, including production of biologicals, or testing of pharmaceuticals. See Section VII, H, 2 below.
- F. <u>Unused sharps</u>: Unused, discarded sharps, as defined in Section VI, A, d, of the regulation.
- G. <u>Spill/Cleanup Material</u>: Any material collected during or resulting from the cleanup of a spill of regulated medical waste.
- H. <u>Mixtures</u>: Any waste which is a mixture of regulated medical waste and some other type of waste which is neither radioactive nor a hazardous waste of a type other than regulated medical waste.

Section VII

Rhode Island Regulated Medical Waste Disposal Procedures

In the lab, dry infectious waste shall be collected in red bags provided by EHS. The bags

are labeled with the international biohazard symbol and used to line cardboard biohazard waste disposal boxes. Smaller bags can be purchased from laboratory supply vendors for step-on cans and bench top collection. Bags must be closed at the end of each day unless contained in a step-on receptacle.

- A. Free-draining blood, blood products and biotechnology effluents shall be stored in securely sealed leak-proof containers and deactivated with bleach prior to sink disposal.
- B. Sharp objects such as disposable serological pipettes that could cause a breach in the containment bag are prohibited from disposal in biohazard waste boxes.

Disinfected disposable serological pipettes shall be collected in a glassware disposal box that is lined with a plastic bag. A plain cardboard shipping box lined with a clear plastic bag can also be used for collection. When the box is full, seal the bag, tape the box and carry out to the Dumpster for disposal. Custodial staff has been instructed not to handle this waste. Do not dispose red biohazard waste bags to the Dumpster.

- C. Biohazard waste boxes shall be labeled with the investigator's name.
- D. Equipment and work areas where infectious materials, including cell cultures, are used must be identified with a universal biohazard label. These are available from lab supply vendors.
- E. URI Petri plate policy: plastic culture plates may be collected and autoclaved in clear autoclave bags (no biohazard symbol) that are marked with autoclave tape. When the tape is black-striped and the contents have melted and fused and are no longer recognizable, the bag may be disposed as solid waste in the Dumpster. Clear autoclave bags are available from lab supply vendors.

Section VIII

Hepatitis B Vaccination and Post-Exposure Evaluation

- A. OSHA requires new employees to complete Bloodborne Pathogens training within 10 days of initial assignment. Environmental Health and Safety (EHS) offers Bloodborne Pathogens training classes for researchers at the beginning of each semester and periodically throughout the semester. Employees who are unable to attend one of those classes can still meet the 10 day training requirement by completing online CITI Bloodborne Pathogens training within 10 days and attending an EHS Bloodborne Pathogens and Biosafety class at the first possible opportunity.
- B. Employees who take the CITI online training at first assignment shall contact EHS (401-874-7019) for information on the Hepatitis B vaccination. The safety, benefits, efficacy, methods of administration and availability of the vaccine will all be described at that

time.

- 1. Hepatitis B vaccinations will be arranged by EHS through an outside vendor, in compliance with current U.S. Public Health Service recommendations.
- 2. Employees who initially decline Hepatitis B vaccination, but at a later date, while still covered under the standard, decide to accept the vaccination, shall be given the vaccine series in a timely manner.
- 3. Covered employees who decline the Hepatitis B vaccination when offered, shall sign the Hepatitis B Decline Form.
- 4. If a routine booster dose(s) of Hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available to all covered employees.
- B. Post-exposure evaluation and follow-up

Following an exposure incident, the wound shall be cleaned with soap and warm water and/or eyes or other mucous membranes flushed with water for 15 minutes.

After first aid has been administered, the employee shall:

1. Report the exposure incident to the supervisor, (manager, department head or dean) and complete a URI Incident/Injury Report form (USP14-A). To expedite this process, forms are available online at:

http://web.uri.edu/hr/files/URI InjuryReport USP-14A.pdf

- Seek medical attention at South County Hospital, 100 Kenyon Ave., Wakefield, or at another qualified medical facility. Students who have paid the insurance fee to URI Health Services go first to Health Services. Depending on the nature of the exposure, they may be transported to South County Hospital for post-exposure evaluation and follow-up which shall include the following:
 - a. Documentation of the route(s) of exposure and circumstances under which the exposure incident occurred;
 - b. Identify and document the source individual if applicable, unless the employer can establish that identification is infeasible or prohibited by state or local law;
 - c. Obtain consent and make arrangements to have the source individual tested as soon as possible to determine HIV, HCV, and HBV infectivity; document that

the source individual's test results were conveyed to the employee's health care provider;

- d. If the source individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed;
- e. Results of the source individual's testing shall be made available to the exposed employee and the employee shall be informed of laws regulating the disclosure of the identity and infectious status of the source individual;
- e. The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained;
- f. If the employee consents to baseline blood collection but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible;
- g. Post exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service, will be offered to the exposed employee;
- h. Counseling of the exposed worker will cover symptomotology, risk of disease transmission and behavior modification recommended for at-risk individuals;
- i. Exposed employees are encouraged to report illness symptoms consistent with HIV, HBV and HCV infection for the six-month period immediately following exposure;
- j. The healthcare professional's written opinion shall be made available to the employee within 15 days of completion. The evaluation shall contain the following information:
 - (i) Hepatitis B vaccination status of the employee and vaccination or booster advisability;
 - (ii) Statement that the employee has been informed of the results of the evaluation and has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation. All other findings or diagnoses shall remain confidential and shall not be included in the written report;
- k. Human Resources will ensure that all pertinent information is received from the healthcare provider, and copies retained in the exposed employee's

permanent file.

C. Records for employees included in this plan shall be kept on file in Human Resources for at least the duration of employment plus 30 years, in accordance with 29 CFR 1910.20.

Records will include the following:

- Employee name and ID number
- Infectious Materials Exposure Determination Form
- Training documentation
- Hepatitis B Vaccination Consent/Refusal Form
- Medical records indicating receipt of all three shots for those who have consented to the series, including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive the vaccination as required by this rule
- Medical records indicating receipt of the titer if the person consented to have the vaccination series during or after 1999.
- If applicable, a copy of all results of post exposure examinations, medical testing, and follow-up procedures required by the regulation.

Employee medical records will be kept confidential and will not be disclosed or reported without the employee's express written consent to any person within or outside the University, except as required by this section or by law.

D. Procedure for Evaluating an Exposure Incident

Human Resources will forward a copy of the URI Incident/Injury Report Form (USP-14A) to Environmental Health & Safety.

EHS will use the following information to evaluate exposure incidents:

- Location of the incident
- Procedure being performed when the incident occurred
- A description of the device being used (if applicable)
- Work practices followed
- Engineering controls in use at the time
- Employee's training history

EHS will review the circumstances of exposure incidents to determine if and how the incident could have been prevented or avoided. Following an interview with the employee and evaluation of the exposure incident, recommendations may be made to change the procedure in order to reduce the risk of a similar event in the future.

Section IX

Hazard Communication

- A. Labels and signs:
 - 1. Proper signage shall be used to identify laboratories where blood or OPIM are used.
 - 2. Biohazard warning labels shall be affixed to equipment or containers used to store, transport or ship blood or other potentially infectious materials. This includes containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material (OPIM), water baths, incubators and any other equipment used with human blood or OPIM. Labels shall be purchased by user.
 - 3. Labels required by this section shall include the universal biohazard symbol and the word BIOHAZARD.
 - 4. Labels shall be fluorescent orange or orange-red with lettering and symbols of a contrasting color, usually white, black or yellow.
 - 4. Required labels shall be affixed as close as feasible to containers by adhesive, string or wire, or other method that prevents their loss or unintentional removal.
 - 5. Red bags or red containers marked with the biohazard symbol may be substituted for labels.
 - 6. Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.
 - 7. Labels required for contaminated equipment shall be in accordance with this section and shall also state which portions of the equipment remain contaminated (Appendix I, J).
 - 8. Regulated medical waste shall be accumulated, stored and disposed of in accordance with established University policy. Refer to the EHS web site.
Section X

Training and Recordkeeping

- A. Training required by the Bloodborne Pathogens Standard shall be provided within 10 days of initial assignment to tasks where occupational exposure may take place, and at least annually thereafter.
- B. Training records will be maintained by EHS, and shall include the dates of the training session, contents or summary of the training session, name(s) and qualifications of the trainer(s) and names and job titles of all persons attending the sessions. The records shall be maintained for a minimum of 3 years from the date on which training occurred.
- C. Availability of medical records:
 - 1. Medical records for at-risk employees will be maintained in Human Resources.
 - 2. Employee medical records shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative and to the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Section XI

Sharps Injury Log

A sharps injury log shall be maintained for recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The injury log is used to track devices that are causing injuries and may need to be replaced by better-engineered products.

The log shall contain the type and brand of device involved in the incident, the department and work area where the exposure occurred, and an explanation of how the incident occurred. Employee identification shall be kept confidential and not be used as part of the log. The sharps injury log shall be retained for 5 years.

If you have any questions about this Exposure Control Plan, the OSHA Bloodborne Pathogens Standard or their applicability to you or your workplace, please contact Environmental Health & Safety at (401) 874-7019.

IBC APPENDIX B Standard and Special Microbiological Practices SOP Rev. February 2019

References

The information in this SOP was sourced from the following publications:

- 1. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), National Institutes of Health
- 2. *Biosafety in Microbiological and Biomedical Laboratories*, 5th Ed., Centers for Disease Control and National Institutes of Health
- 3. *Bloodborne Pathogens Standard, 29 CFR 1910.1030*, Occupational Safety and Health Administration

In accordance with the above-referenced publications, the following standard and special microbiological practices shall be observed in laboratories working with Biosafety Level 1 or 2 materials. This SOP summarizes those practices and can be used as a training and information tool. This SOP should be incorporated into the laboratory–specific biosafety manual as well as the lab's training materials. Principal Investigators (PI's) are advised to supplement these standard and special practices with laboratory or procedure-specific guidance as appropriate.

Scope

This SOP applies to all work at URI conducted at Biosafety Level 1 or 2, and is subject to the guidelines established in *Biosafety in Microbiological and Biomedical Laboratories*, 5th Ed.

Standard and Special Practices

- 1. Laboratory access is restricted.
 - a. Laboratory doors are posted with current and accurate biohazard warning placards provided by EHS.
 - b. Laboratory doors are closed at all times, and locked when the lab is not occupied.
 - c. At containment level BSL-2, only persons who have been adequately trained, advised of the potential hazards, meet specific entry requirements, and who comply with all entry and exit procedures are allowed to enter the laboratory.
 - d. If the containment level is BSL-2, access for minors is restricted.
- 2. Good personal hygiene practices are observed.
 - a. Eating, drinking and smoking; handling contact lenses and applying cosmetics; and storing food for human consumption are not permitted in the laboratory.
 - b. Persons wash their hands: after handling potentially infectious materials, rDNA molecules, animals and before exiting the laboratory.
 - c. Mechanical pipetting devices are used; mouth pipetting is prohibited.
- 3. Appropriate Personal Protective Equipment (PPE) is available and used.

IBC APPENDIX B STANDARD AND SPECIAL MICROBIOLOGICAL PRACTICES SOP

Rev. February 2019

- a. At containment level BL-2, barrier coats are worn while in the laboratory, and removed before exiting the laboratory. Personnel are not allowed to launder lab coats at home.
- b. Appropriate protective gloves are used when contact with rDNA, infectious materials and animals are likely. Gloves are changed when contaminated, their integrity has been compromised, or when otherwise necessary. Hands are washed after removing gloves, before touching clean surfaces, before exiting the laboratory and before donning new gloves. Disposable gloves are not reused and are managed as RI Regulated Medical waste (biohazardous waste) when removed.
- c. Eye protection is worn. Goggles may be required if there is risk for substantial splashes and/or aerosols. Additional PPE may be required for special tasks (e.g. full face shield, goggles). Eye and face protection must be decontaminated before re-use. Contaminated, disposable face protection (e.g. surgical mask, face mask with shield) is managed as regulated medical waste.
- 4. Disinfection and Decontamination
 - a. Work surfaces are decontaminated at the end of each day, and after any spill of potentially infectious materials, with appropriate disinfectant (as specified in the IBCapproved protocol).
 - b. Laboratory equipment is routinely decontaminated as well as after spills, splashes, or other potential contamination. Equipment is decontaminated before repair, maintenance, or removal from the laboratory.
 - c. Spills involving infectious materials must be promptly contained, decontaminated, and cleaned up. Laboratory staff is trained in spill clean-up and have appropriate spill clean-up materials readily available for immediate use (See Appendix J: Spill Management Plan SOP). Liquid wastes containing biohazardous materials are decontaminated prior to disposal. Dispose contaminated solid waste as RI Regulated Medical Waste in a biohazard waste box. Full boxes must be packed for shipment following the Instructions for Packaging and Disposal of Biohazardous Waste.
- 5. All procedures are performed carefully to minimize the creation of splashes and aerosols. For BL-2, all activities that are anticipated to present a splash or aerosol hazard are conducted in biological safety cabinets or other physical containment devices.
- 6. Use of sharps (e.g., needles, scalpels, pipettes, glassware) is avoided. Plastic ware is substituted for glassware whenever possible.
 - a. When absolutely necessary, the following general precautions are taken:
 - i. Needles are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
 - ii. Used sharps are carefully placed in puncture-resistant containers.



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- iii. Broken glassware is not handled directly. Instead, it is handled using mechanical assistance (e.g., brush and dustpan, tongs, forceps).
- b. If the containment level is BL-2, hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used. Extreme caution is used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles are not bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use.



IBC APPENDIX C SAFE USE OF BIOSAFETY CABINETS SOP

Rev. February 2019

Purpose

- To provide details for the safe operation of biological safety cabinets (BSCs) and ensure adequate containment of biohazards.
- Biological safety cabinets shall be used:
 - a. For handling biohazardous materials at BSL-2 to protect lab workers from accidental exposures.
 - b. To provide the clean environment necessary for propagation of cell cultures.
- All users of BSCs shall follow the procedures described below.

Basic Safety Guidelines

- 1. All operators shall receive training in the safe operation of the BSC prior to use. Training may be delegated to a qualified individual, however it remains the responsibility of the Principal Investigator (PI) to ensure that lab personnel are appropriately trained.
- 2. Wear the required PPE, including barrier lab coat, gloves, eye/face protection to protect you and your samples from contamination.
- 3. Ensure the work area inside the BSC is unobstructed. Place items to be used in the experiment adjacent to the side wall to ensure unobstructed airflow.
- 4. Keep sashes as low as possible when working in the BSC.
- 5. Keep sashes fully closed when the BSC is not in use.

See Appendix A, Biosafety Cabinets, in the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories, 5th Ed. https://www.cdc.gov/labs/BMBL.html for airflow patterns of the four BSC types (Type A1, Type A2, Type B1 or Type B 2). If the type is not identified on the front of your BSC, you can find it on the metal plate that includes the model and serial number.

Become familiar with the airflow pattern for your particular type of BSC. It will help you understand what makes the BSC a safe work environment. It will also help you see how easy it is to disturb the air curtain and create an unsafe work environment.

For additional information on the safe use of biosafety cabinets see: https://learn.nuaire.com/lab-equipmentvideos

STANDARD OPERATING PROCEDURES

Preparing for Work within a Class II BSC

- 1. Have a written checklist of materials needed for a particular activity.
- 2. Disinfect the work area before use. Wipe down the work surface, interior walls (except the supply filter diffuser), and inside of the window with 70% Ethanol or a suitable disinfectant such as Wescodyne, an iodophor, or a quaternary ammonium compound. Several applications of 70% Ethanol may be necessary. Do not spray 70% Ethanol in a BSC when the blower is running as the LEL of Ethanol is quickly reached; vapor may be drawn through the motor (an ignition source) and cause a fire. Ten percent bleach is highly corrosive to stainless steel and should only be used with great care and rinsed multiple times with sterile water. Wiping with non-sterile water may re-contaminate the cabinet.
- 3. Wipe down all materials with 70% Ethanol before placing in the BSC. This simple step will help reduce introduction of mold spores and other contaminants and minimize contamination of cultures. Further reduction of the microbial load on materials in BSCs may be achieved by periodic decontamination of incubators and refrigerators.
- 4. Place decontaminated materials in the BSC before beginning work to minimize disruptions to the fragile air curtain inside the BSC. Movement of hands or arms in a sweeping motion into and out of the cabinet will disturb the air curtain and create a non-sterile working environment. Move arms in and out slowly, perpendicular to the face opening of the cabinet, to reduce this risk. Other personnel activities in the room (e.g. walking traffic behind a BSC operator, room fans, opening/closing room doors) may also disrupt the air curtain and should be avoided.
- 5. Segregate clean items from those that will become contaminated. Work from "clean" to "dirty" in the BSC. Place materials toward the back of the BSC, but do not to block the rear grille.
- 6. If there is a drain valve under the BSC, make sure it is closed prior to beginning work.
- 7. If the BSC is equipped with an alarm, test the alarm and switch it to the "ON" position. Never operate a BSC while a warning light or alarm is on.
- 8. Operate the BSC blower fan for five minutes to allow the cabinet to purge and clear particulates suspended in the cabinet.
- 9. Lift the sash to recommended height.
- 10. Tape or hold a Kimwipe to confirm inward air flow at the middle of the BSC.
- 11. Adjust the stool height so the operator's face is above the front opening.
- 12. Lab coats are worn buttoned over street clothing; latex, vinyl, nitrile or other suitable gloves are worn for hand protection; eye protection is worn to protect the operator against eye splashes.
- 13. Delay manipulation of materials for at least one minute after placing hands/arms inside the cabinet. This will allow the cabinet to stabilize, to "air sweep" the hands and arms, and allow time for reduction of turbulence inside the BSC. Perform all work using a limited number of slow movements, since quick movements will disrupt the air barrier.
- 14. Take care not to block the front grille with absorbent matting, research notes, discarded wrappers, pipetting devices, etc.

- 15. When the user's arms rest flat across the front grille, they block the grille opening and contaminated room air may flow directly into the work area. Raising the arms slightly off the grille will correct this problem.
- 16. Perform all tasks in the BSC at least four inches from the inside edge of the front grille for proper protection of your work. Protection is optimal toward the middle of the BSC.

Material Placement in the BSC

- 1. Materials and equipment placed inside the BSC cause disruption in the airflow. The higher the profile of each piece, the greater the disruption. The objective is to keep this disruption to a minimum. Use the fewest possible supplies in the BSC and maintain the lowest profile possible for each. This will help reduce turbulence and possible cross-contamination, or an outright breach of containment.
- 2. Store extra supplies (e.g., additional gloves, culture plates or flasks, culture media) on a lab cart outside the cabinet. Only the materials and equipment required for the immediate work should be placed in the BSC.
- 3. Plastic-backed absorbent matting can be placed on the flat work surface but not over the front or rear grille openings. Anchor the matting well to prevent movement and possible blocking of the grilles. The use of matting will facilitate routine cleanup. When contaminated or at the end of the day, it can be folded and disposed in a biohazard bag or biohazard waste disposal box.
- 4. The workflow should be from "clean to dirty". To prevent contamination, place materials and supplies in the cabinet in a way that limits the movement of "dirty" items over "clean" ones.
- 5. Materials should be placed at the side or as far back in the cabinet as practical, toward the rear of the work surface but not blocking the rear grille.
- 6. Aerosol-generating equipment (e.g., vortex mixers, tabletop centrifuges) should also be placed toward the rear of the cabinet. Keep bulky items such as biohazard bags and discard pipette trays to the "dirty" side in the cabinet.
- 7. The correct sash position (usually 8" or 10" above the base of the opening) should be indicated on the front of the cabinet. If the sash has to be lifted to accommodate equipment, return it to the proper height before beginning work. On most BSCs, an audible alarm will sound if the sash is in the wrong position while the fan is operating.
- 8. Certain common practices interfere with proper operation of the BSC. For example, movement in and out of the BSC creates turbulence which disrupts the integrity of the air barrier, compromising protection of both personnel and product. To minimize turbulence, it is important to observe the following: do not tape the biohazard waste bag to the outside of the cabinet or use upright pipette collection containers either in or outside the BSC. Use only horizontal pipette discard trays containing an appropriate chemical disinfectant inside the BSC. Place the trays on the "dirty" side of the cabinet.
- 9. Contaminated materials should not be brought out of the cabinet until they have been surface decontaminated.

Hazards

- 1. Many procedures conducted in BSCs can create aerosols or splatter. Use good microbiological techniques when working to minimize generation of splatter and aerosols and reduce the risk of exposure to infectious materials.
- 2. Keep clean materials at least one foot away from aerosol-generating activities in the BSC to minimize the potential for cross-contamination.
- 3. To reduce contamination, do not hold opened tubes or bottles in a vertical position. Hold lids of Petri dishes and tissue culture plates above them to shield the contents. Do not place bottle or tube caps on the matting. Recap or cover items as soon as possible.
- 4. Open flames are prohibited in biological safety cabinets at URI. On an open bench, flaming the neck of a culture vessel will create an upward air current that prevents microorganisms from falling into the tube or flask. However, an open flame in a BSC creates turbulence inside the BSC that disrupts the pattern of HEPA-filtered air supplied to the work surface, compromising the air curtain, creating an unsafe condition. Open flames can also damage HEPA filters in the BSC. When absolutely necessary, touch-plate micro burners equipped with a pilot light to provide a flame on demand may be used. Cabinet air disturbance and heat buildup will be minimized. Turn the burner off as soon as work has been completed. Small electric "furnaces" or micro incinerators are available for decontaminating bacteriological loops and needles, and are preferred inside the BSC. Use disposable or recyclable sterile loops when possible.
- 5. To protect vacuum pumps and personnel who service them, use a suction flask connected to an overflow flask. Insert an in-line HEPA or equivalent filter just before the line connects to the vacuum pump. Flasks should be in secondary containment to prevent breakage.
- 6. Aspirated materials are inactivated by adding a chemical decontaminant to the flask. Once inactivation is complete, liquid materials can be disposed as noninfectious waste by flushing down the sink with copious amounts of water. If using 10% bleach, change the flask at least once a week, but preferably twice a week as the bleach breaks down quickly and loses its effectiveness in a short period of time.
- 7. The PI must determine the appropriate method of decontaminating materials removed from the BSC when work has been completed. This information must be described in the lab's "Safe Use of the Biosafety Cabinet SOP". Contaminated items can be placed in a biohazard bag prior to removal from the BSC.
- 8. Decontaminate the exterior surfaces of items, including biohazard waste bags, just prior to removing from the cabinet and dispose waste in the biohazard waste disposal box. Wipe down (don't spray) with 70% Ethanol.
- 9. Used pipettes are decontaminated in the tray inside the BSC. Do not dispose them in the biohazard waste box. Instead, dispose them in a cardboard box lined with a plastic bag to contain any residual disinfectant from the tray. When the box is full, tape it up and carry it out to the Dumpster for disposal in the solid waste stream. Change the disinfectant in the tray frequently.



Operation

- 1. BSCs are designed to be used by a one person at a time. Multiple users will disturb the air curtain within the cabinet, greatly reducing its containment capabilities and creating an unsafe work environment.
- 2. If the BSC is located next to a door, the door should be kept closed when the BSC is in use. Also, the BSC should not be positioned directly under an air duct as this will also disturb the air curtain.
- 3. All operations should be performed on the work surface, at least four inches in from the front grille but preferably toward the middle of the BSC for optimal protection.

Decontamination

- 1. Clean up small spills in the BSC when they occur. Remove contaminated absorbent matting and dispose it in a biohazard waste box. Clean up splatter on the sides of the cabinet with a towel dampened with an appropriate decontaminating solution. Change gloves before placing clean absorbent matting in the cabinet. Wash hands whenever gloves are changed or removed.
- 2. Spills large enough to cause liquids to flow through the front or rear grilles require more extensive decontamination. See the University's Spill Management Plan for specifics.
- 3. If the spilled liquid contains radioactive material, a similar procedure can be followed. Contact the Radiation Safety office for specific instructions and have a spill response plan in place before an incident occurs.
- 4. When you have finished working and with the BSC blower still running, decontaminate all containers and equipment. Wipe down the work surface, the sides and back of the BSC, and the inside of the glass with 70% Ethanol. Do not spray Ethanol inside a BSC.
- 5. Turn the BSC blower off.
- 6. Remove gloves and lab coat in a way that prevents contamination of unprotected skin. Wash hands as the final step in safe microbiological practices.

Ultraviolet Light Use

Statement from National Institutes of Health (NIH)

Use of Ultraviolet (UV) Radiation in Laboratories

"The NIH does not recommend or support the use of ultraviolet (UV) radiation in laboratories. Although UV is effective against most microbes, it requires an understanding of its abilities and limitations. The 253.7-nm wavelength emitted by the germicidal lamp has limited penetrating power and is primarily effective against unprotected microbes on exposed surfaces or in the air. It does not penetrate soil or dust. The intensity or destructive power decreases by the square of the distance from the lamp. Thus, exposure time is always related to the distance. The intensity of the lamp diminishes over time. This requires periodic monitoring with a UV



IBC Appendix C Safe Use of Biosafety Cabinets SOP Rev. February 2019

meter. The intensity of the lamp is drastically affected by the accumulation of dust and dirt on it. The bulbs require frequent maintenance. In addition, there are safety hazards associated with the use of UV that require personal protective equipment or other safety devices to protect users. UV lights in biosafety cabinets require the cabinet be decontaminated prior to performing maintenance on the system. Past experience has proven that good techniques in conducting experiments are highly effective in preventing contamination. The use of UV radiation does not eliminate the necessity for using good practices and procedures."

http://www.ors.od.nih.gov/sr/dohs/BioSafety/decon/Pages/decontamination.aspx

Other Safety Considerations:

1. If a BSC is malfunctioning, do not attempt to use it. Post a sign to indicate the cabinet is out of service and notify the PI. An outside vendor will need to be brought in to repair and re-certify the unit.

Call EHS at (401) 874-7019 to schedule a service call from an NSF-certified biosafety cabinet testing firm.

The PI is responsible for all costs unless the equipment is still under warranty.

- 2. Close BSC sash when not in use.
- 3. Keep BSCs clean and clean up minor spills as they occur. Decontaminate the BSC properly after each use.
- 4. If the BSC alarm begins to sound while you are using it, or if there is a power failure, secure all biohazardous materials, close the sash and leave the room. If the room lights are still on, the PI needs to initiate a service call. If there has been a general power failure, raise the sash as soon as power has been restored, and allow the cabinet to purge for 5 minutes before using again.

Inspection and Certification:

- 1. Biological Safety Cabinets are certified annually and certification tags posted on the equipment.
- 2. Pl's are responsible for annual certification.
- 3. Do not use a BSC unless the certification is up to date.



A centrifuge is an important tool in a research lab. It can also be a dangerous instrument if not used or maintained properly. Most hazards associated with centrifugation stem from one of two sources: mechanical conditions and/or from processing hazardous materials. This SOP discusses both, and presents methods for controlling the risks associated with them.

There are three types of centrifuges in use at URI. Low speed centrifuges do not exceed 5,000 rpm are commonly found on bench tops. High speed centrifuges do not exceed 25,000 rpm and are generally floor models. Ultracentrifuges which operate at speeds in excess of 100,000 rpm are the most expensive and also the most dangerous.

TRAINING

Before using any centrifuge for the first time:

- Review the operator's manual. If a manual is not available in the lab, obtain a copy from the manufacturer or find one online.
- Additionally, the lab supervisor should also provide complete hands-on instruction on how to use the instrument correctly. This instruction should parallel what you have read in the manual.
- View the Howard Hughes Medical Institute (HHMI) centrifuge safety video from Lab Safety Institute on YouTube.

http://www.youtube.com/watch?v=L3MK8Euz3HQ

- Read Centrifuge Rotor Selection and Maintenance, T. Goodman, American Laboratory, June/July 2007. <u>http://www.enviroequip.com.au/Uploads/file/Scientific/Applications/Equipment-</u> Furniture/Centrifuge-Rotor-Selection-and-Maintenance.pdf
- Be able to recognize unsafe centrifuge operations and situations.

METALLURGICAL AND MECHANICAL CONSIDERATIONS

Stress

Centrifugal force puts a load on the rotor that causes stretching or other change in the dimensions of the metal. Rotors are designed to withstand a certain amount of stress and return to their original dimensions. However, if the upper level of stress is exceeded, the rotor will not return to its original size and shape. Minute cracks develop that will cause the rotor to deteriorate over time, leading to possibly dangerous consequences.

To prevent undue stress on the rotor, always:

- Ensure that loads are evenly balanced before a run.
- Observe the manufacturer's maximum speed and sample density ratings.



 Observe speed reductions when running high density solutions, plastic adapters, or stainless steel tubes.

Metal Fatigue

Even when manufacturer's recommendations are closely followed, rotors can suffer metal fatigue. Repeated cyclical stretching and relaxation changes the metal's microstructure which can result in cracks and eventual failure. Centrifuge manufacturers typically give both an expiration date (the date beyond which the rotor should not be used under <u>any</u> circumstances) and a maximum number of runs. To prevent mechanical rotor failure due to metal fatigue, observe the following:

- Do not use a rotor past the manufacturer's expiration or safe-service date.
- Keep a rotor-use log to prevent over-use. (Note: newer equipment may have data logging capability. Consult the manufacturer's instructions for specific record-keeping requirements.)

Corrosion

Many rotors are made from titanium or aluminum alloy, metals that are chosen for their advantageous mechanical properties. Although titanium alloys are quite corrosion-resistant, aluminum alloys are not. While a rotor may be made of titanium alloy, other centrifuge components may be made of aluminum or other materials due to design or cost considerations. When corrosion occurs, the metal is weakened and is less able to bear stress from the centrifugal force exerted on it during operation. This combination of stress and corrosion causes the rotor to fail more quickly and at lower stress levels than a non-corroded rotor.

To prevent corrosion, observe the following:

- Select titanium alloy or comparable rotors for areas where corrosive solutions will be used regularly.
- Alternatively, consider using a rotor made of carbon fiber for superior performance *without corrosion or fatigue*.
- Never clean rotors or associated parts with abrasive wire brushes.
- Avoid using alkaline detergents or cleaning solutions on aluminum parts. (Note: most cleaning solutions designed for radioactive decontamination are highly alkaline).
- Minimize exposure of aluminum rotor components to strong acids or bases, alkaline lab detergents, salts (chlorides) or heavy metals (e.g. cesium, lead, or silver). Corrosion will compromise the structural integrity of the rotor.
- If corrosive or alkaline materials have been run or spilled, thoroughly wash affected parts of the centrifuge, rinse well with deionized water, wipe with a towel and allow to air dry.

To Prevent Mechanical Failure

• Maintain a service contract with the manufacturer or other service provider and



service the centrifuge according to the manufacturer's recommendations to ensure the operational integrity of the instrument at all times.

- Use only rotors that are compatible with your centrifuge. Consult the operator's manual for a list of compatible rotors.
- Inspect the rotor before use and after it has been dropped. Do not use the rotor if any cracks, rough spots, pitting, discolorations, or other abnormalities are visible. The PI should contact the manufacturer for service or possible replacement if any of these conditions are observed.
- Never attempt to open the door while the rotor is spinning or attempt to stop the rotor by hand while the rotor is still in motion. *Serious injury may result.*
- Do not move a centrifuge while it is in operation.

Rotor Care and Use

- Each rotor should have a maintenance/usage log to detail the number of runs, hours of use, age of the rotor, rotation speed per run, and dates of servicing.
- Use only the rotor designed for your specific instrument. Using the wrong rotor can cause an explosion in an ultracentrifuge.
- Do not use a damaged rotor. Inspect rotors for wear and/or damage before using. If the rotor appears to be visibly damaged or you know it has been dropped, send it back to the manufacturer for proper evaluation. It may need to be replaced.
- Keep rotors and other exposed parts of centrifuges clean, free of chemicals, chemical residues and infectious materials.
- Metal rotors that are in contact with moisture for extended periods of time may be subject to corrosion and damage. Leave the rotor clean and dry after each use. Wash the rotor with mild detergent and rinse well with deionized water; use a soft nylon bottle brush if necessary. Do not use a wire brush as it may damage the rotor. Dry thoroughly. Check the operator's manual for specific recommendations.
- Both Beckmann and Sorvall recommend taking ultracentrifuge rotors out of service after either 10 years or after the rotor has reached a specified number of runs. If you have an older unit, check with your technical service representative regarding rotor retirement.
- Do not autoclave rotors at temperatures above 100°C.
- Check to ensure that the centrifuge chamber, drive spindle, and tapered mounting surface of the rotor are clean and free of scratches.
- Wipe drive surfaces prior to installing the rotor.
- Make sure rotor, tubes and spindle are dry and that the rotor is properly seated and secured to the drive hub. Do not operate the centrifuge without having the appropriate rotor cover securely fitted, with seals properly in place.
- If the temperature of the chamber is below room temperature, pre-cool the rotor to the lower temperature before securing the rotor. Make sure it is completely dry or it could freeze to the tapered spindle.



- Balance the rotor to within the limits specified (ensure materials of *similar densities, not just similar volumes,* are in opposite positions).
- Do not exceed the design mass for the maximum speed of the rotor. Failure to observe this
 precaution can result in dangerous and expensive rotor disintegration.
- Do not exceed maximum rotor speed under any circumstance. Speed reduction may be necessary because of weight considerations of tubes, adapters, condition of the rotor, or the density of the solution being centrifuged.
- Excessive vibration of a high-speed centrifuge indicates a grossly unbalanced rotor. Stop the run immediately, remove all bottles from the rotor and check counterbalancing of the bottles in accordance with the centrifuge manufacturer's recommendations. Most high/super centrifuges require counterbalancing within ±1.0 gram. Ultra speed, fixed angle rotors require counterbalancing better than ±0.5 gram. Ask the manufacturer of your centrifuge for the proper counterbalancing procedure.
- Make sure the centrifuge has a safety locking device in place and that it works properly before using the centrifuge. Do not use the instrument if the locking device does not work properly or has been inactivated. Have the centrifuge serviced before someone is injured.

Inspection

- Inspect rotors for damage and/or wear before each use.
- The cone area is highly stressed during rotation and should be checked for cracks.
- If there are gouges in the rotor body, the rotor should be serviced. If there are light scratches, check for corrosion.
- Look for corrosion or cracks in the tube cavity.
- Dual row rotors are highly stressed and any damage to these rotors cannot usually be repaired.
- Vertical rotors: check the sealing cap for thread wear. Replace if necessary.
- Swinging bucket rotors: damage to the bucket seat pins cannot be repaired.

When to Derate the Rotor Speed?

- It may be necessary to derate a rotor after it has seen extensive service. Derating is defined as "reducing the maximum safe speed at which the manufacturer recommends using a rotor".
- Not reducing rotor speed on an older rotor can lead to rotor failure and possible injury to personnel and/or damage to the laboratory.
- Derate the rotor speed whenever:
 - The rotor speed, temperature or a combination of the speed and temperature during operation exceed the solubility of the gradient material and cause it to precipitate; or
 - The compartment load exceeds the maximum specified by the manufacturer; or



 When a manufacturer recommends, based on the amount of use the rotor has received, limiting the maximum speed at which the rotor is used at some lower level than was listed for the rotor when it was new.

Tube Care

- Before each use, check tubes for cracks and deformities.
- Inspect the inside of cups for rough walls caused by corrosion. Do not use if present.
- Metal or plastic tubes (other than nitrocellulose) should be used whenever possible.
- Make sure each tube compartment is clean and corrosion-free.
- Tubes must be properly balanced in the rotor (0.5 gram at 1G is roughly equivalent to 250 Kg at 500,000G's).
- Use only correctly fitting tubes
- Never fill centrifuge tubes above the maximum recommended by the manufacturer, not to exceed ¾ full.

CENTRIFUGING INFECTIOUS MATERIALS

- Centrifugation of infectious materials, including human blood and cell cultures, should be done using sealed rotors, sealed buckets, or a guard bowl cover complete with gasket, as well as safety centrifuge tubes (tube or bottle carrier with sealable cap or "O" ring cap).
- If a spill or leakage is apparent in the centrifuge, disinfect the inside of the unit; disinfect the rotor in a biosafety cabinet, rinse thoroughly with deionized water, and allowed to air dry completely.
- Do not use abrasive or corrosive materials to clean the rotor as this could damage the rotor permanently.

Follow these recommendations when centrifuging infectious materials:

- Examine tubes and bottles for cracks or stress marks before using them.
- Fill and decant all centrifuge tubes and bottles inside a biosafety cabinet.
- Wipe the outside of tubes with disinfectant before placing in safety cups or rotors.
- Never overfill centrifuge tubes as leakage may occur if tubes are filled to capacity. The maximum for centrifuge tubes is ¾ full.
- Use screw cap tubes and cap all tubes securely before spinning.
- Place tubes in safety buckets or sealed rotors. Inspect the "O" ring seal of the safety bucket and the inside of safety buckets or rotors. Open only inside a biosafety cabinet.
- Ensure that the load is properly balanced.



- Never exceed recommended safe rotor speed.
- Stop the centrifuge immediately if an unusual noise or vibration develops.
- If there is evidence of leakage or tube damage after centrifuging infectious materials, close the lid immediately, allow aerosols to settle, and plan the disinfection procedure following URI's Spill Management Plan.

If a centrifuge malfunctions while centrifuging BL-2 materials:

- Contact your supervisor or PI to initiate a service call.
- The unit must be decontaminated completely before it can be serviced. Work with the rotor in a biosafety cabinet. Line the work surface with absorbent matting first.
- When decontamination of the centrifuge has been completed, attach a URI "Notice of Decontamination" label (Appendix O – Equipment Decontamination Label).
- To prevent corrosion, do not use bleach or other high pH or low pH disinfectants if the centrifuge's components are made of aluminum. Consult the operator's manual and follow the manufacturer's recommendation.
- If you think a tube has broken while centrifuging, immediately turn off the unit; do not attempt to open the lid until aerosols have settled. Allow a minimum of 30 minutes before beginning clean-up and decontamination.

Information in this document was sourced from: University of California – Berkeley University of California – San Diego University of Nebraska – Lincoln University of Hawaii University of Massachusetts – Amherst Thermo Scientific Fiberlite Rotor User Manual THE UNIVERSITY OF RHODE ISLAND DIVISION OF RESEARCH AND ECONOMIC DEVELOPMENT

IBC Appendix E Avoiding the Production of Biological Aerosols SOP

Rev. February 2019

There are many documented cases of laboratory-acquired infections which resulted from the production and inhalation of infectious aerosols. If adequate precautions are not taken, aerosol production can occur when using laboratory equipment, even when the equipment is used properly and under normal conditions. This SOP covers procedures to be used to avoid the production of bioaerosols.

Centrifuge Operations

When microorganisms are not adequately contained within a centrifuge, aerosols can escape during the high-speed spin process. This may occur when spinning uncapped samples, or when a leak, spill, or tube breakage occurs. Minimize the risk of aerosol production during centrifuging by observing the following precautions:

- Use unbreakable tubes (i.e. not glass).
- Avoid overfilling the tubes. Allow sufficient headroom for sample to rise as it spins.
- Use only centrifuge tubes with O-ring screw caps to ensure a secure seal.
- Ensure that the centrifuge is properly balanced, with materials of similar densities opposite each other.
- Use outer, sealable safety cups and load/unload them only in a biosafety cabinet.
- Do not open the centrifuge lid during or immediately after operation. Allow the centrifuge to come to a complete stop and wait at least 30 minutes before opening. This allows time for any aerosol to settle if leakage or breakage occurred during the run.
- Never exceed the specified speed limitations of the rotor as listed in the owner's manual.
- Decontaminate the inside and outside of the cups or buckets before and after use, and inspect seals regularly for deterioration. Replace as needed.
- When possible, install the centrifuge in an enclosed, specially ventilated area that discharges air from the space through a HEPA filter.

Mixing Operations

Sonicators, shakers, and homogenizers can generate aerosols during operation. Minimize the risk of aerosol production when mixing by observing the following precautions:

- Operate mixing equipment in a biological safety cabinet.
- Use heavy-duty screw caps that include an O-ring.
- Use sealed vessels during mixing. Wait 30 minutes to allow any aerosol that might have developed (due to the build-up of pressure within the container) to settle.
- Open all mixing vessels inside a biosafety cabinet.
- Check the condition of the mixing equipment routinely for wear or deterioration.
- Decontaminate all surfaces of mixing devices before and after use.
- If manual tissue grinders are used, surround the tube with absorbent material.
- **Do not** use household blenders/homogenizers in the lab.

IBC Appendix E Avoiding the Production of Biological Aerosols SOP

Rev. February 2019

Vacuum and Aspirating Equipment

Minimize the risk of generating aerosols during vacuum and aspiration operations by observing the following precautions:

- Use non-breakable (i.e. not glass) flasks.
- Ensure that vacuum equipment is equipped with a HEPA or similar filter.
- Place a disinfectant in the overflow flask of the aspirating equipment.
- Use containment for the flasks (a grey bin).

Needles and Syringes

Minimize the risk of aerosol production while using needles and syringes by observing the following precautions:

- Perform all operations with needles and syringes in a biological safety cabinet.
- Discharge air from the syringe before inserting it into a stopper.
- Fill syringes carefully. Avoid frothing or introducing air bubbles.
- Wrap the needle and stopper in a cotton ball or pad moistened with an appropriate disinfectant when removing the needle from the rubber-stoppered bottle.
- Expel excess liquid and air bubbles from the syringe vertically into a cotton ball moistened with an appropriate disinfectant or into a small bottle containing cotton.
- **Do not** use syringes to mix infectious liquids.

Pipettes

Minimize the risk of aerosol production while using pipettes by observing the following precautions:

- Use cotton-plugged pipettes.
- Gently expel the contents of the pipette against the wall of the container and allow it to flow down the side (tip-to-wall technique).
- Do not mix the contents of a container by alternating suction and blowing with a pipette.
- Use TD pipettes instead of TC pipettes. The last drops from a TD pipette do not need to be expelled or blown out to get an accurate measurement.
- Submerge used non-disposable pipettes into a horizontal tray of disinfectant solution inside the BSC immediately after use.
- Dispose decontaminated pipettes to a cardboard box lined with a plastic bag. When the box is full, seal it with packaging tape, label it "Decontaminated Pipettes" and carry out to the dumpster.



IBC APPENDIX E Avoiding the Production of Biological Aerosols SOP Rev. February 2019

Transfer Loops

Minimize the risk of aerosol production while using transfer loops by observing the following precautions:

- Substitute an enclosed micro-incinerator for an open flame burner.
- Use disposable inoculating tools. Decontaminate with a suitable disinfectant prior to disposing in a sharps container.

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IBC Appendix F Transporting Biohazardous Materials SOP

Rev. February 2019

Transporting Cell Cultures Research/Clinical Specimens or Biohazardous Materials

When moving biohazardous materials from one lab to another:

- Transport in a sealed, leak-proof primary container within a sealed, leak-proof secondary container (e.g. Tupperware or other snap-lid container) lined with absorbent matting. The secondary container shall be identified with the universal biohazard symbol.
- Disinfect the outside of the secondary container so gloves are not necessary when handling the container. *Refer to the Lab Disinfectants SOP to select the appropriate disinfectant.*
- Remove <u>all PPE</u> before leaving the lab.
- Avoid public areas and elevators if possible when moving biohazardous materials. If public areas or elevators must be used, gloves and lab coats must not be worn.
- Under no circumstances are gloves to be used on common surfaces such as computer keyboards, door knobs or elevator buttons.
- Even though a spill is unlikely when secondary containment is used, URI Public Safety Dispatch (401-874-2121) must be notified immediately if there is a release of biohazardous materials during transport. A first responder from EHS will be dispatched to help with cleanup and decontamination if the spill is in a public area.

THE UNIVERSITY OF RHODE ISLAND DIVISION OF RESEARCH AND ECONOMIC DEVELOPMENT

IBC APPENDIX G Sharps – Handling and Disposal SOP Rev. February 2019

Sharps are items that can easily puncture the skin. Examples include needles, razor blades, scalpel blades, Pasteur pipettes, microscope slides, and cover slips. All sharps must be handled and disposed in a manner that protects you and others from exposure and possible injury.

General Precautions:

- Substitute plastic-ware for glass whenever possible. Routinely inspect glassware and remove from service items that are damaged, starred, cracked or chipped. Dispose in the box marked "Broken Lab Glassware." Seal the box and carry out to the Dumpster when full.
- Make sure lighting is adequate and the work space is not crowded. If it is, take a few minutes to clear the area before working with sharps.
- Be alert at all times when handling sharps. Don't look away or otherwise become distracted when handling a sharp object.
- Use rounded or blunt end devices when practicable.
- Keep sharp tools sharp and use the right tool for the task.
- Use cut-resistant gloves if practicable. In some cases, heavy rubber gloves (i.e. when washing glassware) or double-gloving with surgical gloves (when dexterity is important) may be appropriate.
- Do not handle sharp objects (i.e. broken glass) with bare or even gloved hands. Use engineering controls such as tongs or a dust pan and broom instead.
- Do not leave unprotected sharps on bench tops or loose in drawers. Use protective shields, cases, Styrofoam blocks, tube holders, etc.
- Protect the sharp when passing from one person to another. If not feasible, use verbal communication when passing.
- Use needle syringes only when absolutely necessary. If a needle syringe is absolutely necessary to the procedure, use a syringe that automatically re-sheathes the needle.
- Do not try to recap the needle of a syringe. An accidental puncture might occur. If recapping is absolutely necessary, use the one-handed technique
- Used needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
- Keep a sharps disposal container accessible in the immediate work area and put used sharps directly into the sharps container. Do not lay used sharps on the bench top.
- Do not overfill the sharps container. Leave room to seal the lid properly.
- Do not try to retrieve items from sharps disposal containers.
- Sharps containers are managed as Rhode Island Regulated Medical Waste. When the container is full, dispose in a biohazard waste box or contact EHS for pick-up. Do not store sharps containers in the chemical hazardous waste accumulation area (SAA).

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APPENDIX H MANAGING REGULATED MEDICAL WASTE (RMW/BIOHAZARDOUS WASTE)

SOP

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Regulated Medical Waste (RMW/Biohazardous waste/biowaste) is managed under the State of Rhode Island's Regulated Medical Waste Regulations (250-RICR-140-15-1).

https://rules.sos.ri.gov/regulations/part/250-140-15-1

RMW is defined as any waste generated in the diagnosis (including testing and laboratory analysis), treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining to humans or animals, or in the production or testing of biologicals, or in the development of pharmaceuticals. Plasticware used in research is also included in these regulations if it has been used with cell cultures. Regulated medical wastes that are mixed with non-hazardous solid wastes shall be considered regulated medical wastes. Regulated medical waste shall also include certain waste, as listed in this section that is generated in any process where it is likely to have been in contact with human blood or body fluids. Regulated medical wastes mixed with nonhazardous solid wastes shall be considered regulated medical wastes. For the purposes of these regulations, the following categories of medical wastes are Regulated Medical Waste:

This policy governs all University activities involving any of the types of RMW (biological waste) listed

below:

- A. <u>Cultures and Stocks</u>: Cultures and stocks of infectious agents and associated biologicals including: cultures from medical and pathology laboratories; cultures and stocks of infectious agents from research laboratories; wastes from the production of biologicals; discarded live and attenuated viruses; culture dishes, plasticware and devices used to transfer, grow, inoculate and mix cultures.
- B. Pathological Wastes: Human pathological wastes, including tissues, organs, and body parts that are removed during surgery or other medical procedures.
- C. Human Blood, Body Fluids and Blood Products:
 - 1. Liquid waste human blood or body fluids;
 - 2. Products of blood;
 - 3. Items saturated and/or dripping with human blood or body fluids;
 - 4. Items that were saturated and/or dripping with human blood or body fluids; including, but not limited to, serum, plasma, and other blood components, and their containers (e.g. blood bags and blood vials) and body fluids as described in Section I, C of the regulation; or
 - 5. Specimens of body fluids and their containers.
 - Human cell cultures



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D. Sharps:

- 1. Sharps that have been used in animal or human care or treatment, including sharps generated in medical or research laboratories, including, but not limited to, hypodermic needles, syringes with or without the attached needle, Pasteur pipettes, scalpel blades, blood vials, needles with attached tubing and glass carpules. Also included are other types of broken or unbroken glassware that have been used in animal or human care or treatment, including used microscope slides and cover slips. Disposable syringes and needles are considered Sharps RMW after one use.
- 2. Sharps must be segregated and disposed of in leak-proof, rigid, puncture-resistant, shatterproof containers (Sharps containers are available from lab supply vendors). If contaminated with infectious agents, sharps must be rendered non-infectious by autoclaving or chemical disinfection. Dispose all Sharps containers in Biohazard waste boxes. Call EHS to arrange pickup when a sharps container is full if a Biohazard Waste Box is not available in your lab or on your floor.
- E. Animal Waste: Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research, including research in veterinary hospitals, production of biologicals, or testing of pharmaceuticals.
- F. Unused sharps: Unused, discarded sharps, as described above.
- G. Spill/Cleanup Material: Any material collected during or resulting from the cleanup of a spill of regulated medical waste.
- H. Mixtures and Waste in Medical Waste Containers: Any waste which is a mixture of regulated medical waste and some other type of waste which is neither radioactive nor a hazardous waste of a type other than regulated medical waste. Also, any waste, when placed in a sharps container, bag with a biohazard symbol, or other container labeled and/or designed for the packaging of regulated medical waste, must be handled and treated as a regulated medical waste, even if the contents may not have previously met the definitions in this section. If the waste is a radioactive and/or a hazardous waste it must also be handled in accordance with Regulations appropriate for radioactive and/or hazardous wastes.
- I. Crime Scene/Accident Cleanup Waste: any waste generated by commercial entities hired to clean crime scenes or accidents that are saturated with human blood or are sharps or sharp objects contaminated with human blood.

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Federal Department of Transportation (DOT) Shipping Regulations as they apply to RMW (Biohazardous Waste)

RMW is regulated by the RI Dept. of Environmental Management (RIDEM). RIDEM also licenses medical waste transporters to legally transport medical waste from the waste generator's facility to the final disposal site. Because transportation is involved, US Department of Transportation (DOT) shipping regulations also apply when managing RMW.

Anyone who offers medical waste for transport (the offeror, i.e. PI), must ensure that the box is prepared in compliance with DOT regulations, which include having proper markings and labels on each box.

Our RMW vendor provides pre-printed shipping containers so proper labels and markings are printed in the appropriate locations on the boxes. Lab staff must ensure compliance with DOT regulations by setting the box up properly; when complete, the box presented for transport must be right side up and the writing must be legible to anyone looking at the box. If the box is upside-down box, the offeror (PI) is non-compliant with the hazard communication component of the regulation.

The driver will reject all boxes that are improperly prepared, including those that are presented upside down. Drivers are subject to periodic inspections on the highway. An out of compliance box means a large fine for a driver who has accepted an improperly prepared box.

Preparing RMW for Shipment

Biohazard waste boxes and red liner bags are available from EHS (401-874-7019); in room 275-A College of Pharmacy and from Nasir Hamidzada in CBLS.

It is important to take a few minutes to set the box up properly:

- 1. <u>Begin with the box upside down</u> so the writing is the right way up when finished.
- 2. Fold the box into shape.
- 3. Tape the bottom first. Run a central strip of tape the length of the seam where the two flaps meet. Anchor the ends to the sides as shown on the photo below, then run a strip of tape on each side of the first strip so you use 3 strips per seam.
- 4. Follow the same procedure for the outer edges of the box. The bottom of the box should look like the picture below:

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5. Flip the box over so it is right side up, and the writing is legible from any direction.

6. Tape the flaps to the sides of the box. Line the box with a red bag, carefully fitting it over the edge of the box as shown below. The box is now ready for use.





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NOTE: Do not four-way the bottom or top flaps as shown in the photo below. This is not a secure closure and it will not hold in transit. YOUR BOX WILL BE REJECTED AND YOU WILL HAVE TO RE-PACK IT.



FILLING THE BOX

Although the boxes are pre-printed to hold 55 pounds, URI LIMITS THE FILL TO 35 POUNDS. BOXES THAT ARE OVERWEIGHT WILL BE REJECTED AND YOU WILL HAVE TO RE-PACK THEM.

- 1. Red bags are containment for your waste. Line the box with 2 red bags. Disposable pipet tips as well as contaminated lab plastic ware, lab coats and gloves can be collected in the box.
- 2. Red bags must be kept closed except when adding waste. A twist tie can be used for this.
- 3. Prohibited items include liquids as well as free sharps (not in a proper Sharps container) or other materials that can puncture the red bag, including serological pipettes.

SEALING THE BOX

When the box is full and ready to be sealed, follow these simple steps:

- 1. Squeeze the air out of the bag, twist the top several times and tie into a knot. The box is now ready to be sealed with tape.
- 2. Seal the top and edges of the box following the method used earlier on the bottom.
- 3. Write the Pl's name on the top of the box with a Sharpie.

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PICK-UPS

- Pickups are scheduled every other Tuesday. The schedule can be found at: <u>https://web.uri.edu/ehs/files/BIOWASTE-PICK-UP-SCHEDULE-2019.pdf</u>
- 2. Pharmacy is the only scheduled stop. If you are in Pharmacy you do not need to schedule a pickup. EHS will remove your boxes from 275-A. For all other buildings you can schedule a pickup by calling (401) 874-7019 at least 48 hours in advance, earlier if bad weather is in the forecast as your box may need to be picked up sooner. Boxes should be properly packed and ready to go by 9:30 am the morning of pick-up at the designated pick-up site.

NOTE: This is a regulated waste. Do not leave boxes unattended on the loading dock or in the hallway the day/night before the pick-up.

3. If it is raining, leave the box just inside the door so it doesn't get wet. Do not block the exit.

BOXES WILL BE REJECTED

RMW boxes will be rejected if:

- 1. The boxes are packed upside down.
- 2. The seams on the box are not properly taped or are taped with anything other than clear packing tape (i.e. duct tape, masking tape, blue painter's tape).
- 3. The flaps are "4-wayed" see photo above.
- 4. The box is wet. The cardboard box is for dry waste only. Infectious liquids can be autoclaved or decontaminated with 10% bleach and disposed to the sink with running water, or they can be autoclaved and disposed to the sink. Do not add bleach if autoclaving liquids.
- 5. The boxes are damp because they have previously been stored in a freezer.
- 6. The box is overweight. While the boxes are printed for 55 pounds, do not exceed 35 pounds per box.

SPECIAL NOTES

College of Pharmacy

1. Because Medical Waste is a regulated waste, it must be stored in a locked/secure area until it is

picked up by the RMW driver. Room 275-A Pharmacy is the temporary storage location. A permanent room will be built off the loading dock in the future.

- 2. Waste disposal supplies, including boxes, totes, red bags and tape are all stocked in 275-A.
- 3. When you have filled a box or tote, use a hand cart to move it down to 275-A. Do not allow full boxes to accumulate in the lab.
- 4. Place the box on the spill pallet in 275-A. Do not leave boxes on the floor.
- 5. Use a Sharpie to write the PI's name on your box. Don't forget to do this!!



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MANAGING REGULATED MEDICAL WASTE

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6. Before leaving 275-A, verify that the box has been packaged correctly and there is no reason for the driver to reject it. **IF REJECTED, YOU WILL HAVE TO REPACK IT.**

Cell and Molecular Biology and Microbiology Teaching Labs (CBLS)

- 1. Autoclave BL-1 materials in clear bags (no international biohazard symbol) till the contents are no longer recognizable, dispose to the Dumpster.
- 2. Supplies for disposal of BL-2 materials are available from the building manager, Nasir Hamidzada.
- 3. Autoclave plates and dispose in biohazard waste boxes as RI Regulated Medical Waste.
- 4. Take the boxes down to the loading dock by 9:30 am the morning of the pick-up. Do not take them down the night before. Regulated medical waste must always be under control of the generator.

NEW!! SEROLOGICAL PIPETTE DISPOSAL

DO NOT DISPOSE SEROLOGICAL PIPETTES IN RMW (BIOHAZARD) WASTE BOXES. They can pierce the side of the box and cause a breach in containment.



PHARMACY

Cell Culture: decontaminate pipettes in 10% bleach in a flat Nalgene tray inside the BSC. If you don't generate a lot of pipettes, collect them horizontally in a cardboard box (like a shipping carton) that has been lined with a plastic bag. When the box is full, tie off the bag, seal the box with tape, label it "Used Pipettes" and dispose to the Dumpster.

If your lab generates large numbers of plastic serological pipettes, decontaminate them in the BSC as you use them. When you have finished working, collect them in a 31-gallon tote provided by our waste vendor. Empty totes are available in 275-A. Line the tote with a plastic bag before using to contain any residual liquid. Totes must be kept closed except when adding pipettes.



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NOTE

This is not a traditional RMW waste stream, but we are managing pipettes this way to keep them out of landfill. Our current RMW vendor participates in a waste-to-energy program and this is an opportunity for the University to be environmentally responsible and reduce its carbon footprint.

ALL OTHER BUILDINGS

31 gal totes are available from EHS on request. Call (401) 874-7019. If an individual lab doesn't generate enough pipettes for a 31-gallon tote to make sense, several labs might collaborate and share a single tote.

NEW!! Plastic Pipet Tip and Box Disposal

Since our RMW vendor participates in a waste-to-energy program, decontaminated pipet tips and boxes can also be disposed in the RMW (biohazard) waste box if the box is lined with 2 red bags, but *do not use RMW boxes for disposal of general lab trash.*



IBC APPENDIX I DISINFECTANTS FOR BIOHAZARDOUS MATERIALS SOP

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The following table provides information regarding surface disinfectants for use in laboratories working with biological agents. Efficacy of every disinfectant varies by a number of factors: 1) organic load, 2) microbial load, 3) type of organism, 4) condition of surfaces to be disinfected (i.e. porous or non-porous), and 5) disinfectant concentration, pH, temperature, contact time and environmental humidity. Prior to selecting a specific disinfectant, consider the relative resistance of microorganisms.

			TYPE OF MICROBE	EXAMPLES
MORE RESISTANT			Prions	Bovine spongiform
				encephalopathy (Mad Cow)
				Creutzfeld-Jakob disease
			Bacterial spores	Bacillus subtilis
				Clostridium sporogenes
			Mycobacteria	Mycobacterium tuberculosis
				Mycobacterium bovis
			Hydrophillic viruses	Rhinovirus
			(non-lipid, non-enveloped)	Adenovirus
			Fungi	Cryptococcus sp.
				Candida sp.
		_	Vegetative bacteria	Streptococcus pneumonia
				Staphylococcus aureus
LESS RESISTANT		IT	Lipophilic viruses	Herpes simplex
			(lipid-containing, enveloped)	Cytomegalovirus
				HIV

For added assurance, perform kill determinations in your own laboratory with your own biological materials.

Decontamination reduces microbial contamination of materials or surfaces to prevent inadvertent infection. Disinfection is the elimination of virtually all pathogenic organisms on inanimate objects and surfaces; it reduces the level of microbial contamination to an acceptably safe level. Sterilization refers to the destruction of all microbial life, including bacterial endospores.

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The appropriateness of a decontamination procedure depends on your objective: disinfection or sterilization. Other factors must also be considered. Will the disinfectant be used on hard surfaces, in a biosafety cabinet, on instruments, or on waste? Surgical instruments must be sterile but this level of microbial killing is generally unnecessary for laboratory surfaces such as floors and walls. When choosing a disinfectant, consider the organism, the item to be disinfected, the disinfectant's cost and ease of use.

Hospital-approved disinfectants are acceptable for use in laboratories. Consult the manufacturer's directions to determine efficacy against the biohazards used in your lab. These could include household bleach, quaternary ammonium compounds, and Phenolic compounds. A popular disinfectant for use in biological safety cabinets is Wescodyne, available through Fisher Scientific; its primary benefit is that it is not corrosive like oxidizing disinfectants.

The following disinfectants are effective against a wide range of infectious agents. Approximate contact times are given for each disinfectant. Links to the MSDS files are included. Disinfectant solutions should be made up and stored according to manufacturer directions. A clean surface is more effectively decontaminated than a soiled surface. While disinfectants are not necessarily detergents, some disinfectants also include a detergent or surfactant. Various disinfectants are discussed in detail below.

Chlorine (Sodium Hypochlorite)

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Chlorine is a fast-acting oxidant that is widely available for use as a broad-spectrum chemical disinfectant. Sold as household bleach, it is an aqueous solution of sodium hypochlorite (5.25% NaOCI) which can be diluted with water to provide various concentrations of available chlorine.

While it can be highly effective as a disinfectant, chlorine is highly alkaline and can be corrosive to metal. Care must be taken when using even 5% bleach on metal; multiple clear water rinses are required to completely remove all residue. The disinfectant activity of chlorine is considerably reduced by organic matter (protein). Stock or working solutions that are stored in open containers, particularly at high temperatures, release chlorine gas thereby reducing their disinfectant potential. Undiluted household bleach, stored at room temperature in the original container, has a shelf-life of approximately six months. However, since the date of manufacture is not stamped on containers, it is impossible to know the age of bleach when it reaches the lab. Using bleach is therefore a risky proposition as it may not be as effective as it should be due to degradation. However, if used, working solutions of bleach should be prepared fresh daily. Household bleach is diluted 1:10 to obtain final concentration of 0.5% NaOCI. Industrial strength bleach has a higher sodium hypochlorite concentration (up to 6.25%) and must be diluted accordingly to obtain the correct final concentration. To increase the efficacy of sodium hypochlorite solutions against spores, vinegar may be added to the solution. If your lab works with spore formers, combining 5 ounces of household bleach with one gallon of water and adding 8 ounces of 5% distilled white vinegar yields a disinfectant that is effective against spores.



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Chlorine gas is highly toxic. Store and use bleach only in well-ventilated areas. To prevent the rapid release of chlorine gas, do not mix undiluted bleach with acids or other incompatible chemicals, such as ammonia-containing compounds.

Phenolic Compounds

Phenolic compounds were among the earliest germicides. However, more recent safety concerns restrict their use. They are active against vegetative bacteria and lipid-containing viruses, and also show activity against mycobacteria when properly formulated. They are not active against spores and their activity against non-lipid-containing viruses is variable. Many phenolic products are used for the decontamination of environmental surfaces and some (e.g. triclosan and chloroxylenol) are among the more commonly used antiseptics. Some phenolic compounds are sensitive to and may be inactivated by water hardness and therefore must be diluted with distilled or deionized water. They may be absorbed by latex gloves and can also penetrate the skin. Phenolic compounds can be irritating to the skin and eyes and may have an associated odor that is irritating to respiratory tissue.

Hil-Phene is a broad spectrum phenolic disinfectant typically used at a dilution of 1-5%. Contact time of 10 minutes is recommended. Hil-Phene provides effective disinfection for HIV and many other infectious agents; it is also tuberculocidal.

Hillyard Hil-Phene <u>http://www.hillyard.com/Images/MSDS/MSDSHIL00191.pdf</u> <u>http://www.hillyard.com/images/ProductData/HIL00191.pdf</u>

Quaternary Ammonium Compounds

Many types of quaternary ammonium compounds are used as mixtures and in combination with other germicides. Depending on the quaternary compound type, germicidal activity can be reduced by organic matter, water hardness, and anionic detergents. Therefore, care should be taken in selecting proper agents for pre-cleaning. When properly diluted, quaternary ammonium compounds have low odor and are not irritating, however potentially harmful bacteria can grow in quaternary ammonium compound solutions.

Vindicator+ is a disinfectant that is cost-effective and has good broad spectrum disinfecting strength. A dilution of 0.1-2% and contact time of 10 minutes are recommended. Vindicator+ provides effective disinfection for HIV, HBV, Adenovirus, many animal viruses, and others.

http://www.hillyard.com/images/ProductData/HIL00168.pdf http://images.hillyard.com/IMAGES/MSDS/MSDSGWN00168.pdf

Lysol I.C. is another quaternary ammonium disinfectant. It is available from Fisher Scientific and various other sources as well. A dilution of 1:256 and contact time of 10 minutes are recommended. Lysol I.C. is a highly-concentrated hospital approved disinfectant that provides virucidal, fungicidal, and bactericidal protection in the presence of up to 5% organic matter.



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Lysol I.C. Quaternary Cleaner Disinfectant

http://www.rbnainfo.com/MSDS/US/LYSOL-%20IC-Quaternary-Disinfectant-Cleaner-Concentrate-US-English.pdf

Alcohols

Mixtures of alcohols with other agents are more effective than alcohol alone; a contact time of at least 10 minutes must be observed. When used alone, alcohols do not leave a residue on treated items. Alcohols are volatile and flammable and must not be used near open flames because the lower explosive limit (LEL) is easily attained. If 70% ethanol is used to decontaminate a BSC, it must be wiped on and not sprayed. If sprayed, the vapor will pass over the sparking motor, a potential source of ignition. Alcohol containing solutions must be clearly labeled to prevent their being autoclaved. Store all working solutions of alcohol in tightly capped containers to prevent evaporation. Include Alcohol in the lab's chemical inventory and monitor its use to minimize the chance of it being used for non-lab use.

Ethanol and isopropyl alcohol have similar disinfectant properties. They are active against vegetative bacteria, fungi, and lipid-containing viruses, but not against spores. Their action on non-lipid-containing viruses is variable. For highest effectiveness they should be used at concentrations of approximately 70% (v/v) in water; higher or lower concentrations may not be as germicidal. In addition to being relatively inexpensive, another advantage of aqueous alcohol solutions is that they do not leave any residue on treated items. Alcohol-based hand-rubs and alcohol mixed with emollients are recommended for decontaminating lightly soiled hands in situations where proper hand-washing is inconvenient or not possible. However, ethanol is ineffective against spores such as HBV and Mycobacterium tuberculosis (TB) and may not kill all types of non-lipid-containing viruses.

Iodine and Iodophors

The action of these disinfectants is similar to that of chlorine, although they may be slightly less inhibited by organic matter. Iodine can stain fabrics and environmental surfaces and is generally unsuitable for use as a disinfectant. However, iodophors and tinctures of iodine are good antiseptics and polyvidone-iodine is a reliable and safe surgical scrub and preoperative skin antiseptic. Antiseptics based on iodine should not be used on aluminum or copper. Iodine-based products must be stored at 4–10°C to prevent the growth of potentially harmful bacteria. Iodine can be toxic.

References:

World Health Organization Laboratory Biosafety Manual, 3rd ed.

EPA Approved Disinfectants Website http://www.epa.gov/oppad001/chemregindex.htm

IBC APPENDIX J BIOHAZARD SPILL MANAGEMENT PLAN Rev. February 2019

OVERVIEW

Prevention is the most important part of any spill management plan.

- Be sure to read and understand standard operating procedures (SOPs) and protocols for safe manipulation of biohazards before you begin work.
- Identify the location of the nearest eye wash, and make sure access is clear and not obstructed.
- Verify that spill kits, spill containment and clean-up supplies, including the appropriate disinfectant, are readily available. Re-supply spill kits after each use so they will be ready for the next incident.

Spill kit and clean-up supplies located:

PI:	
Lab Supervisor:	
URI EHS: Connie Heird	(401) 874-7019
URI Public Safety Dispatch	
(Emergency, Medical, Fire)	(401) 874-2121

- Report any loss of containment to the PI immediately. B + V Testing or Air Systems Technologies must be brought in to repair the BSC. Post an "Out of Service" sign.
- Report any potential exposure to the PI.
- Minimize the consequences of spills of biological material by performing all work on absorbent liner in the biosafety cabinet (BSC).
- Work only in a certified BSC and alert fellow lab occupants when active manipulation is in progress. Restrict foot traffic behind operator when a BSC is in use.
- Routinely practice spill clean-up procedures as a component of the lab's training program and Emergency Action Plan. The best time to do this is the beginning of each semester when new personnel join the lab so everyone knows their roles and responsibilities, especially during an emergency.
- Restrict access to the area by non-essential personnel during active manipulation of biohazards.

SPILL RESPONSE

Proper mitigation of a release or spill of biohazardous material requires knowledge of several factors including the agent or material spilled and its associated risks; the amount of material; as well as the type and location of the spill. The following guidelines provide a quick reference for employees who might have to respond to an incident.

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Each lab working with biohazards should have its own spill response procedures which will be specific to the way that laboratory is set-up and operated. Consult with your supervisor to be sure you have received specialized training for your area.

SMALL BL2 SPILL CLEAN-UP (< 100 mL)

- Avoid inhaling aerosols and quickly leave the room. Notify others to leave. Close the lab doors, and post "Biohazard Spill – Do Not Enter" signage.
- Inform your supervisor, and, if assistance is needed, call URI Police Dispatch at (401) 874-2121.
- Allow aerosols to settle for at least 20 minutes before re-entering the laboratory.
- Assemble clean-up materials (disinfectant, paper towels, sharps container, biohazard bags, forceps, and a clear plastic bag).
- Put on protective clothing (lab coat, surgical mask, safety glasses, utility gloves, and waterproof shoe covers if necessary).
- Cover the area with paper towels and carefully pour disinfectant over the spill, starting from the outside and working inward toward the center to keep from enlarging the contaminated area. Allow at least 10 minutes of contact time for proper decontamination.
- If the spill is large (but < 100 mL), a second or third round of disinfectant should be applied. Allow at least 10 minutes contact time between applications for proper decontamination.
- Pick up sharp objects with forceps and discard in a sharps container. Carefully pick up soaked paper towels and dispose. Smaller pieces of glass may be collected with wet paper towels held with forceps. Discard in the sharps container. If used, dispose red or orange bags as biohazard waste.
- Wipe surrounding areas where the spill may have splashed with disinfectant.
- Remove contaminated lab coat, turning exposed areas inward. Spot decontaminate with a hospital grade disinfectant and swap out on the regular lab coat cycle.
- Wash exposed skin with soap and warm water.
- Wash hands and exposed skin areas with disinfectant or antiseptic soap and water and dry with clean paper towels.

LARGE BL2 SPILL CLEAN UP (> 100 mL)

Evacuate the lab and post "Biohazard Spill" signage at all entrances. It may be necessary to physically block lab entrances with chairs since the doors between labs cannot be locked (College of Pharmacy and CBLS).

Request clean-up assistance from EHS by calling Public Safety Dispatch (401) 874-2121

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Tell Dispatch you have had a large biohazard spill and need help with clean-up. Technical support will be dispatched to the spill site.

BLOOD SPILLS

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

- Wear gloves, eye protection, and a lab coat. If there has been a lot of splatter, shoe covers may also be necessary.
- Pre-clean by absorbing blood with paper towels; place soiled towels in a biohazard bag.
 Collect any sharp objects with forceps and place in a sharps container.
- Use a detergent solution to pre-clean the spill site of visible blood. Dispose paper towels in biohazard bag.
- Carefully pour freshly made 10% household bleach over the contaminated area.
- After 10 minutes of contact time, wipe up then rinse with water.
- Discard clean-up materials and contaminated personal protective equipment (except safety glasses) in a biohazard bag and place the bag in a biohazard waste disposal box.
- Wash your hands with soap and warm water.
- Document the spill and your spill response procedures in the lab's biosafety manual.
- Re-supply the spill kit so it is ready the next time there is an event.

OCCUPATIONAL EXPOSURE

- If exposure to personnel has occurred, wash the area thoroughly with soap and warm water and call URI Public Safety Dispatch (401) 874-2121 immediately.
- If the exposure occurred through mucous membrane contact of the eye, nose, or mouth, use the eye wash to rinse the area for 15 minutes.
- If the exposure occurred due to accidental injection or piercing, wash the area thoroughly with soap and warm water and apply pressure behind the wound to "bleed it out", then apply a triple antibiotic ointment and Band-Aid.
- Occupational exposures require medical evaluation.

Faculty, staff and graduate students must file a USP-14a with Human Resources within 24 hours of the incident. This will generate a Worker's Compensation case number and ensure that medical bills are sent to the University.

Faculty and staff are to be evaluated at South County Hospital. Call URI Police Dispatch for an ambulance (401) 874-2121.

Undergraduate and graduate students who have paid the URI Health Services fee report to Potter Health Services for initial evaluation. They may be subsequently transported
to South County Hospital for post-exposure evaluation and follow-up if medically appropriate.

NOTE: If BL-2 material simply <u>comes in contact with intact skin</u>, this is called an incidental exposure. Wash the area thoroughly with soap and warm water. Medical follow-up is not required.

SPILL DOCUMENTATION

Large biohazard spills (> 100 mL), injuries and exposures MUST be reported to your supervisor and URI Police Dispatch immediately.

Document all near misses, major and minor spills in the lab's biosafety manual. It is important to discuss with your PI, Lab Supervisor and fellow lab members the details of what happened, how and why it happened, and what was learned from the incident. Since major incidents are almost always preceded by numerous near misses, procedures should be revised and clarified to prevent similar incidents in the future

BL-2 SPILL INSIDE THE BIOSAFETY CABINET

A spill or release inside a biosafety cabinet (BSC) does not pose a risk to others in the lab or to the environment as the BSC functions to contain the spill and protect personnel in the lab from exposure. Decontaminate all material inside the BSC, including the operator's hands and arms, any equipment located in the BSC, and the interior surfaces of the BSC itself.

If the work surface of the BSC has been lined with absorbent material, clean-up will be straightforward. Simply roll the liner up so the contaminated surface is on the inside and dispose to a biohazard waste box. Close the bag.

Otherwise:

- Leave the BSC turned on.
- To keep from contaminating the area outside of the BSC, have someone else in the lab bring over a biohazard waste box and fresh PPE. Remove contaminated gloves and sleeve covers if wearing, and dispose in the biohazard waste box. Spot decontaminate the barrier coat if possible; if not, take a fresh barrier coat from the supply room.
- Put on fresh PPE before placing arms and hands back inside the cabinet.
- Wipe down reusable materials with a chemical disinfectant before removing from the BSC.
- Place disposable materials in the biohazard waste box.
- Dispose all sharps in a sharps container.
- Wipe cabinet walls, work surfaces and equipment in the BSC with an approved

IBC Appendix J Biohazard Spill Management Plan

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commercial disinfectant such as Wescodyne. Bleach is not recommended for use inside the BSC because it is highly corrosive and requires multiple rinses to remove completely.

- If you have had a large spill into the drain pan, make sure the BSC's drain valve is closed before pouring disinfectant through the grilles into the pan. Be careful while pouring not to create splashes. Allow the disinfectant to stand for 20-30 minutes (or longer if indicated based on the material and disinfectant).
- To further ensure complete decontamination, use a funnel to empty the drain pan into a large container with additional disinfectant by attaching a hose barb and flexible tube to the drain valve; the tube should be long enough to submerge the open end in the container to minimize generation of infectious aerosols. Flush the drain pan with water and remove the drain tube. Dry the pan well with paper towels before returning to the BSC.
- Dispose liquid based on chemical constituents and pH. Sink disposal with copious amounts of water is permitted only if the pH of the solution is between pH 5-9. If it is higher or lower, apply a URI hazardous waste label to the container, include the name of the disinfectant and pH, and place the container in the lab's Satellite Accumulation Area for disposal as hazardous chemical waste.
- Remove PPE and dispose in the biohazard waste box.
- If clothing was contaminated, remove and change into fresh clothing prior to returning to work. Spot disinfect where possible.
- Wash hands thoroughly with soap and warm water.
- If the spill flowed into the interior of the BSC, extensive decontamination requiring the services of an outside vendor may be necessary. The BSC should not be used until decontamination has been completed by Air Systems Technologies or B + V Testing. Contact EHS directly for guidance.

SPILL, RELEASE OR AEROSOLIZATION INSIDE A CENTRIFUGE

First:

- Do not inhale
- Close centrifuge lid
- Notify others to leave the lab

Then:

- Immediately leave the lab
- Post biohazard spill signs at lab entrances

Notify URI Public Police Dispatch (401) 874-2121.

Tell them there has been a biohazard spill in the centrifuge. Tech support will be dispatched to the site to assist with clean-up.

Notify PI or Supervisor.

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- DO NOT RE-ENTER THE LAB until PI and EHS have given clearance (at least 30 minutes to allow the aerosol to settle)
- With assistance from EHS, proceed with the clean-up.

Decontaminate

- Remove PPE, spot decontaminate where possible.
- Place disposable PPE in biohazard waste disposal box
- Wash any exposed areas with antiseptic soap and warm water
- Wash hands thoroughly

CENTRIFUGE EXPLOSION

- Evacuate the room immediately
- Notify PI and URI Police Dispatch (401) 874-2121
- Tell them there has been a centrifuge explosion. Tech support will be dispatched to the site.

SPILL OF A SOLID BIOHAZARD (contaminated plates, pipets, tubes, PPE, waste, etc.)

- Notify lab occupants.
- Put on appropriate PPE: lab coat, gloves, eye/face protection, etc.
- Contain spilled materials.
- Collect the spilled materials with a scoop, dustpan and broom, tongs/forceps.
- Disinfect all contaminated surfaces with freshly prepared 10% bleach or hospital grade disinfectant; allow appropriate contact time.
- Dispose clean-up materials in a biohazard waste disposal box. Non-disposable clean-up materials must be decontaminated and cleaned prior to reuse.

CONTAMINATED EQUIPMENT

- Place absorbent material such as paper towels, gauze, etc. on and around area of contamination and saturate with appropriate disinfectant for minimum 30 minutes.
- After decontamination, rinse equipment with water and dry.
- All equipment must be decontaminated and cleaned prior to maintenance/service or use by another.
- Complete <u>Notice of Laboratory Equipment Decontamination</u> form and attach to equipment.

NOTICE OF DECONTAMINATION

Decontamination must be completed before equipment can be moved

This equipment released for:					
Service/Repair	□ Relocation		🗆 Disposal		
Exterior and interior surfaces have been de	econtaminated	□ Yes	□ No		
Decontamination performed by:					
Chemical or disinfectant used:					
Date of decontamination:					
Location of equipment:					
Responsible party (PI):					
Lab telephone number:					

□ Biohazard labels required under the Bloodborne Pathogens Standard have been removed.

Signature _________________________________PRINCIPAL INVESTIGATOR

February 2019

IBC APPENDIX K CENTRIFUGE SAFETY POSTER

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CENTRIFUGE SAFETY

- Each operator must be trained and follow the proper operating procedures
- Keep a log book detailing operation records for centrifuges and rotors
- Do not exceed safe rotor speed established by the manufacturer for each rotor
- Place a biohazard label on the centrifuge if used for infectious materials
- Always use sealed safety buckets or sealed rotors with O-rings
- Check tubes and bottles for cracks and deformities before using
- Examine O-rings and replace if worn, cracked, or missing
- Do not overfill primary containers used for centrifuging; do not exceed ¾ full
- Wipe exterior of tubes or bottles with disinfectant prior to loading into safety buckets or rotor
- Wipe the exterior of safety buckets or rotors with disinfectant before removing from biosafety cabinet
- Stop the centrifuge immediately if an unusual condition such as noise or vibration begins
- Wait 10 minutes after the run has finished before opening the centrifuge to allow aerosols to settle in the event of a breakdown in containment
- Decontaminate safety buckets or rotors and centrifuge interior after each use
- Wash hands after removing gloves

CENTRIFUGE SPILL

If you see there has been a leak outside the safety bucket or rotor when opening the centrifuge:

First:

- Hold breath
- Close centrifuge lid
- Notify others to evacuate the lab

Then:

- Immediately leave the lab
- Post biohazard spill sign

Notify PI or Supervisor:

- DO NOT re-enter lab until EHS and PI have given clearance (at least 30 minutes)
- Follow centrifuge spill clean-up instructions in the Biosafety Manual

Decontaminate:

- Remove PPE
- Place disposable PPE in biohazard waste disposal box (decontaminate reusable PPE or contaminated clothing)
- Wash any exposed areas with antiseptic soap and water
- Wash hands thoroughly

For Centrifuge Explosion:

Evacuate room immediately; Notify PI and URI Police Dispatch (401) 874-2121

DO NOT ENTER

BIOHAZARD SPILL

CONTACT INFO

Name: ____

Phone: () _____

February 2019

(PRINT CLEARLY)



- A. <u>Blood</u> means human blood, human blood components and products made from human blood.
- B. <u>Bloodborne Pathogens</u> means pathogenic microorganisms that are or may be present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), Hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
- C. <u>Engineering Controls</u> means controls (e.g.: sharps disposal containers and self-sheathing needles) to isolate or remove the bloodborne pathogens hazard from the workplace.
- D. <u>Occupational Exposure</u> means reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.
- E. <u>Other Potentially Infectious Materials (OPIM) means</u>:
 - 1. the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids,
 - 2. any unfixed tissue or organ (other than intact skin) from a human (living or dead), and HIVcontaining cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.
- F. <u>Parenteral</u> means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.
- G. <u>Personal Protective Equipment</u> is specialized clothing or equipment worn by an employee for protection against a hazard (e.g.: gloves, face protection, masks, gowns, etc.). General work clothes (uniforms) not intended to function as protection against a hazard are not considered to be personal protective equipment.
- H. <u>Universal Precautions</u> is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

Additional definitions may be found in the text of the regulation at: <u>https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDA_RDS</u> The following is a list of job classifications in which some employees have occupational exposure. Included is a list of tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure may occur for these individuals:

Kingston Campus

JOB TITLE	DEPARTMENT	TASK/PROCEDURE
Professor, Associate Professor,	College of Pharmacy	Analysis of blood and OPIM;
Assistant Professor, Lecturer,		research using materials of
Graduate Student, Post-doctoral		human origin including cell
fellow; Lab Manager, Research		cultures
Assistant		
Professor, Associate Professor,	Cell and Molecular Biology	Analysis of blood and OPIM;
Assistant Professor, Lecturer,		research using materials of
Graduate Student; Post-doctoral		human origin including cell
fellow; Lab Manager, Research		cultures
Assistant		
Professor, Associate Professor,	Nutrition and Food Sciences	Analysis of blood and OPIM
Assistant Professor, Lecturer,		
Graduate Student, Lab Manager,		
Research Assistant		
Professor, Associate Professor,	Kinesiology	Analysis of blood and OPIM
Assistant Professor, Lecturer,		
Graduate Student, Lab Manager,		
Research Assistant		
Coordinator of Hazardous Waste	Environmental Health and	Handling regulated medical
and Chemical Waste; Chemical	Safety/Dept. of Public Safety	waste; inspection of areas where
Hygiene Officer; Industrial		blood and OPIM are stored or
Hygienist; other personnel		used
designated by the Director		
Professor, Associate Professor,	College of Engineering	Exposure to blood or body fluids
Assistant Professor, Lecturer,		developing analytical devices
Graduate Student; Post-doctoral		
fellow; Lab Manager, Research		
Assistant		

IBC APPENDIX M EXPOSURE DETERMINATION Rev. February 2019

JOB TITLE	DEPARTMENT	TASK/PROCEDURE
Professor, Associate	Center for Vector-Borne	Analysis of blood and OPIM;
Professor, Assistant Professor,	Disease	work with bloodborne
Lecturer, Graduate Student;		pathogens
Post-doctoral fellow, Lab		
Manager, Research Assistant		
Professor, Graduate Student,	Plant Sciences and	Work with bloodborne
Research Assistant	Entomology	pathogens
Director, Criminalist I, II, III,	RI State Crime Lab	Analysis of blood and OPIM

Providence Campus – CCE

JOB TITLE	DEPARTMENT	TASK/PROCEDURE
Professor, Associate	Cell and Molecular Biology	Analysis of blood and OPIM;
Professor, Assistant Professor,		research using materials of
Lecturer, Graduate Student;		human origin including cell
Post-doctoral fellow; Lab		cultures
Manager, Research Assistant		
Professor, Associate	Cell and Molecular	Human cell cultures
Professor, Assistant Professor,	Biology/Clinical laboratory	
Lecturer, Graduate Student;	Science (Biotechnology	
Post-doctoral fellow; Lab	Program)	
Manager, Research Assistant		
Professor, Associate	Cell and Molecular	Human blood and OPIM
Professor, Assistant Professor,	Biology/Clinical laboratory	
Lecturer, Graduate Student;	Science (Cytopathology	
Post-doctoral fellow; Lab	Program)	
Manager, Research Assistant		

IBC APPENDIX N UNIVERSAL BIOHAZARD SYMBOL Rev. February 2019

OFFICE OF Research integrity



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IBC APPENDIX O EQUIPMENT DECONTAMINATION LABEL Rev. February 2019

NOTICE OF DECONTAMINATION

Decontamination must be completed before equipment can be moved

This equipment released for: □ Service/Repair Relocation Disposal 🗆 No Decontamination performed by: _____ Chemical or disinfectant used: Date of decontamination: ______ Location of equipment: Responsible party (PI): _____ Lab telephone number: □ Biohazard labels required under the Bloodborne Pathogens Standard have been removed. □ Areas of the instrument *that have not been decontaminated* are clearly labeled. PI: _____ PLEASE PRINT

Signature: _____

PRINCIPAL INVESTIGATOR

IBC APPENDIX Q GUIDANCE ON THE USE OF HUMAN. Primate. and Mammalian Cell Lines

Rev. February 2019

Objective

To ensure the safety of those working with human, primate, or mammalian cell lines. Even in the absence of overt contamination, these materials may contain adventitious viruses and/or other opportunistic pathogens or zoonotic agents that pose a risk to lab personnel.

Rationale

Human or primate cell lines may harbor viruses, bacteria, or parasites characterized as human bloodborne pathogens. For example, these pathogens can include human immunodeficiency virus (HIV), hepatitis B or C viruses, Neisseria, Treponema, or Plasmodium.

Please note that some bio-resource organizations, such as American Type Culture Collection, do not typically screen their material for bloodborne pathogens. Consequently, the handling of human and primate cell lines must conform to the OSHA Bloodborne Pathogens (BBP) Standard. Generally, this includes annual training with information on hazard communication, engineering controls, work practices, PPE, housekeeping, regulated medical waste, a written exposure control plan, and access to the hepatitis B vaccine. See the OSHA letter of interpretation for applicability of the BBP Standard with human cell lines.

Since it is extremely difficult to screen for every pathogen, all human, primate, and mammalian cell lines must be handled with Standard (Universal) Precautions - treat them as though they are contaminated with infectious agents and utilize Biosafety Level 2 (BSL-2) practices and procedures (defined below). These cell lines include, but are not restricted to those:

- Obtained from an outside source (e.g., repositories such as the American Type Culture Collection, other institutions, and investigators)
- Established within a laboratory without a complete history (passages, attempts to infect, sources of nutrient media, are all unknown)
- Contaminated with an infectious agent
- Derived from genetically manipulated cells capable of supporting the replication of infectious agents .
- Previously exposed to viruses containing recombinant DNA or RNA

BSL-2 Practices and Procedures

Containment practices and procedures at BSL-2:

- Restricted access to the laboratory
- Activities within the laboratory are supervised by a competent and knowledgeable scientist
- Hand washing after contact with materials, after removing gloves, before eating, etc. ٠
- Routine decontamination of surfaces and equipment with a disinfectant known to decontaminate • agents likely to be present in the cell line - ensure adequate contact time. Refer to the IBC Manual Appendix I - Disinfectants for Biohazardous Materials.
- Handle all waste as regulated medical waste (see Disposal section below) •
- Minimize the creation of aerosols, droplets, and splashes if this is unavoidable, use an engineering ٠ control such as a certified biosafety cabinet to conduct manipulations. Also utilize a biosafety cabinet when handling concentrated or large volumes (e.g., >500 mL)

IBC APPENDIX Q GUIDANCE ON THE USE OF HUMAN, PRIMATE, AND MAMMALIAN CELL LINES

Rev. February 2019

- ٠ Use needles only when absolutely necessary. Consider the use of Safety Engineered Sharps systems or blunt tip needles (e.g., Harvard Apparatus)
- Suitable personal protective equipment
 - Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. It is recommended that laboratory clothing not be taken home.
 - Eye and face protection (goggles, mask, face shield or other splatter guard) must be used for 0 anticipated splashes or sprays of infectious or other hazardous materials (e.g., chemicals) when the biological materials are handled outside the BSC or containment device.
- Safe Operating Procedures for higher risk procedures

Additional detail about BSL-2 practices and containment can be found in Section IV of Biosafety in Microbiological and Biomedical Laboratories, or in Appendix G-II-B of the NIH Guidelines for Research Involving Recombinant DNA Molecules available on the URI Biosafety Guidelines and Regulations Website.

Authorization for Use

You must utilize BSL-2 practices and procedures when working with cell lines regardless of how cell lines are regulated under the NIH Guidelines for Research Involving Recombinant DNA Molecules (i.e., Exempt, Nonexempt). The use of human and primate cell lines requires that the principal investigator submit a protocol to the Institutional Biosafety Committee (IBC) for review and approval. The IBC may require additional practices, controls, and containment depending on the nature of the cell lines or laboratory activities.

The IBC will evaluate each IBC protocol for the risks an individual well-established cell line may pose, the procedures and activities that will be used with the cell lines, and the skill level and experience of the research staff. The IBC may recommend that personnel fully observe the BBP Standard (e.g., annual OSHA BBP training, exposure control plan, access to hepatitis B vaccine). Alternatively, the IBC will require that researchers utilize BSL-2 practices and procedures at all times, satisfy the training points outlined above, and treat any human cell line as potentially contaminated with an infectious agent (even if ATCC, for example, recommends handling at BSL1). Attend Bloodborne Pathogen and Biosafety training (see Training section below).

For information on procedures regarding implanting human, primate, or other mammalian cells into rodents, refer to the IBC Manual Appendix R- Animal Biosafety Level Determination Matrix

Training

All individuals working with any human, primate, or mammalian cell lines must receive adequate training. Individuals must complete the Bloodborne Pathogens and Biosafety training provided by URI EH&S. Training is required annually. Following initial training by URI EH&S, refresher training can be taken online via CITIprogram.org. Additionally, the principal investigator must provide or ensure that personnel receive appropriate orientation and specific training for the safe performance of the work. This training must include:

- Communication about the potential hazards of working with cell lines ٠
- Work practices, and instruction on engineering controls used to minimize exposure •
- Suitable personal protective equipment
- Familiarity with laboratory Safe Operating Procedures and the approved IBC protocol •
- ٠ What to do in case of exposure or accidental release of contaminated materials (see Personnel Exposures and Accidental Spills sections below

IBC APPENDIX Q GUIDANCE ON THE USE OF HUMAN, PRIMATE, AND MAMMALIAN CELL LINES

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Disposal

Human, primate, and mammalian cell lines and items in contact with these materials must be disposed as Regulated Medical Waste to increase the safety of individuals who must handle the waste, as well as comply with the Rhode Island Medical Waste Regulations (Regulation DEM-OWM-MW-1-2009, amended July, 2010). Briefly:

- Segregate disposable solid waste (e.g., intact plastic ware, gloves, paper) in red biohazard bags inside biohazard waste boxes
- Dispose of sharps waste (e.g., syringes, needles, Pasteur pipettes, broken glass, microscope slides and coverslips) in sharps disposal containers
- Bags and containers must be disposed via URI EH&S Guidelines. Regulated medical waste must not enter the normal solid waste stream
- Decontaminate liquid wastes with disinfectant (e.g., household bleach to a final dilution of 1:10 for ٠ 30-60 min), or in an autoclave, and dispose in the sanitary drain followed with water.

For more detailed information, refer to the IBC Manual Appendix H - Managing Biohazardous Waste SOP.

Accidental Spills

- Don suitable personal protective equipment (PPE) such as gloves and lab coat. Wear PPE to prevent mucous membrane exposure (face mask and safety glasses) if the spill is large (beyond what could be handled with a few paper towels) or if you anticipate splashing
- Remove any sharps such as broken glass with a secondary device (e.g., tongs, forceps) and discard in a sharps disposal container
- Cover spill with absorbent material (e.g., paper towels, gelling substances) and add disinfectant (e.g., freshly prepared 10% bleach). Alternatively, wipe up gross contamination and add disinfectant to the "cleaned" surface. With either approach, allow adequate contact time for the disinfectant (at least 5-
- 10 min, depending on disinfectant used), and perform a second application of disinfectant
- Segregate spill cleanup materials into red biohazard bags or sharps disposal containers. Refer to section above on Disposal
- Remove PPE, discard in red biohazard bag, and wash hands with soap and water •

For more detailed information, refer to the IBC Manual Appendix J - Biohazard Spill Management Plan SOP.

Personnel Exposures

The consequences of exposure and appropriate post-exposure treatments are not well defined. Thus, the emphasis should be placed on prevention. Follow safe work practices as described in the IBC Manual Appendix B - Standard and Special Microbiological Practices; use engineering controls and practice Standard (Universal) Precautions to prevent lab acquired infections.

Personnel who sustain an exposure to non-intact skin or mucous membranes from any cell culture • fluids should wash the affected areas with soap and water. Use an eye wash to rinse exposures in the mucous membranes



IBC Appendix Q Guidance on the Use of Human, Primate, and Mammalian Cell Lines

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- If the exposure results in a puncture wound, encourage bleeding under running water and perform necessary first aid
- Notify a supervisor and seek medical evaluation.
- Complete the <u>URI Incident/Injury Report Form</u>.

References

- American Type Culture Collection, I have just received a human tumor cell line. What are the biohazards associated with this line? How should I work with it? <u>http://www.atcc.org/FrequentlyAskedQuestions/tabid/469/Default.aspx#4</u>, accessed 7 June 2008.
- 2. American Type Culture Collection, Are ATCC human cell lines tested for viruses such as Epstein-Barr (EBV) virus, human immunodeficiency virus (HIV, AIDS virus), human T cell leukemia (HTLV), and hepatitis B virus? Are ATCC cell lines tested for bovine viral diarrhea virus (BVDV)? http://www.atcc.org/FrequentlyAskedQuestions/tabid/469/Default.aspx#5, accessed 7 June 2008.
- 3. CDC/NIH. 2007. Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition. <u>Working</u> with Human, NHP and Other Mammalian Cells and Tissues.
- 4. College of Veterinary Medicine, <u>Medical Waste Disposal</u>, accessed 7 June 2008.
- 5. New York State Department of Environmental Conservation, <u>Guidance for Regulated Medical Waste</u> <u>Treatment, Storage, Containment, Transport and Disposal.</u>
- 6. New York State Department of Health, <u>Managing Regulated Medical Waste.</u>
- 7. Pauweis, K., et al., 2007. Animal cell culture: Risk assessment and biosafety recommendations. Applied Biosafety, 12, 26-38
- 8. <u>http://www.dem.ri.gov/pubs/regs/regs/waste/medwaste10.pdf</u>

IBC

APPENDIX R

OFFICE OF Research integrity

ANIMAL BIOSAFETY LEVEL (ABSL) DETERMINATION MATRIX

Rev. February 2019

A guideline based on the current edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL)* which is to be used for determining BSL and ABSLs for research (* http://www.cdc.gov/biosafety/publications/bmbl5/index.htm)

NOTE: The following PPE must be worn in all facilities when entering animal rooms or labs where animals are manipulated: facility dedicated scrubs/shoes, gloves, surgical mask, eye protection (or face shield). Additionally, all cage dump stations must be ventilated. ANIMAL BIOSAFETY BIOSAFETY LEVEL HOUSING **PRE/POST INFECTION** LEVEL MATERIAL **CAGE CHANGES** IMAGING (applicable REQUIREMENTS MANIPULATIONS (applicable for to injections/ animal housing / necropsy) cage changes) MATERIALS NOT KNOWN TO BE TRANSMITTED VIA AEROSOL ROUTES (* "Retroviral" is inclusive of lentiviral vectors) No special requirements - cages Murine cell lines All injections and can be changed on benchtop. transduced with an necropsies in BSC for Bedding does not need No special 1 ecotropic retroviral* BSL2 ABSL1 **DURATION** of project No special requirements requirements autoclaved prior to disposal / vector with benign (following BSL2 cages do not need insert (ex. GFP) practices) autoclaved prior to washing For first week: 1. ALL cage All manipulations inside Murine cell lines Microisolator All injections and changes in BSC; 2. bag and BSC where feasible. transduced with an ABSL2 for 1 technique for 1 week necropsies in BSC for autoclave bedding; 3. bag and Maintain BSL2/ABSL2 **DURATION** of project 2 amphotropic BSL2 week / then post dosing; after 1 autoclave caging before wash; practices where feasible, retroviral* vector with ABSL1 week, no special (following BSL2 After one week, resume especially during the first benign insert (ex. GFP) requirements practices) normal cage change. week. No special requirements - cages Murine cell lines All injections and can be changed on benchtop. transduced with an necropsies in BSC for No special Bedding does not need 3 ecotropic retroviral* BSL2 ABSL1 **DURATION** of project No special requirements requirements autoclaved prior to disposal / vector with 'hot' insert (following BSL2 cages do not need practices) (ex. oncogene) autoclaved prior to washing All manipulations inside Murine cell lines For first week: 1. ALL cage Microisolator All injections and transduced with an changes in BSC; 2. bag and BSC where feasible. ABSL2 for 1 technique for 1 week necropsies in BSC for autoclave bedding; 3. bag and Maintain BSL2/ABSL2 amphotropic BSL2 **DURATION** of project 4 week / then post dosing; after 1 retroviral* vector with autoclave caging before wash; practices where feasible, ABSL1 week, no special (following BSL2 'hot' insert After one week, resume especially during the first requirements practices) (ex. oncogene) normal cage change. week.

IBC

APPENDIX R

ANIMAL BIOSAFETY LEVEL (ABSL) DETERMINATION MATRIX

Rev. February 2019

A guideline based on the current edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL)* which is to be used for determining BSL and ABSLs for research (* http://www.cdc.gov/biosafety/publications/bmbl5/index.htm)

NOTE: The following PPE must be worn in all facilities when entering animal rooms or labs where animals are manipulated: facility dedicated scrubs/shoes, gloves, surgical mask, eye protection (or face shield). Additionally, all cage dump stations must be ventilated. ANIMAL BIOSAFETY BIOSAFETY LEVEL HOUSING **PRE/POST INFECTION** LEVEL MATERIAL **CAGE CHANGES** IMAGING (applicable REQUIREMENTS MANIPULATIONS (applicable for to injections/ animal housing / necropsy) cage changes) For first week: 1. ALL cage All manipulations inside Murine cell lines Microisolator All injections and changes in BSC; 2. bag and BSC where feasible. transduced with an ABSL2 for 1 technique for 1 week necropsies in BSC for autoclave bedding; 3. bag and Maintain BSL2/ABSL2 5 pantropic retroviral* BSL2 week / then post dosing; after 1 **DURATION** of project autoclave caging before wash; practices where feasible, vector with 'hot' insert ABSL1 week, no special (following BSL2 After one week, no special especially during the first (ex. oncogene) requirements practices) requirements week. No special requirements - cages can be changed on benchtop. **Unmodified murine** Bedding does not need No special BSL1 ABSL1 6 No special requirements No special requirements cells into mice requirements autoclaved prior to disposal / cages do not need autoclaved prior to washing MATERIALS KNOWN TO BE TRANSMITTED VIA AEROSOL ROUTES For first week: 1. ALL cage All manipulations inside Adenovirus/Adeno-Microisolator All injections and changes in BSC; 2. bag and BSC where feasible. ABSL2 for 1 technique for 1 week Cre: Adenoviral necropsies in BSC for Maintain BSL2/ABSL2 autoclave bedding; 3. bag and **DURATION** of project 7 vectors; cells BSL2 week / then post dosing; after 1 autoclave caging before wash; practices where feasible, transduced with ABSL1 week, no special (following BSL2 After one week, resume especially during the first adenoviral vectors requirements practices) normal cage change. week. **Known Human** Pathogens (ex. For first week: 1. ALL cage Toxoplasma gondii; All injections and All manipulations inside changes in BSC; 2. bag and Microisolator Listeria monocytogenes; necropsies in BSC for BSC where feasible. technique for autoclave bedding; 3. bag and Helicobacter pylori; 8 BSL2 ABSL2 **DURATION** of project Maintain BSL2/ABSL2 LCMV; Citrobacter **DURATION** of autoclave caging before wash; (following BSL2 practices where feasible. rodentium: experiment After one week, resume practices) Certain toxins (i.e. normal cage change. Diphtheria); others as reviewed by IBC

IBC

APPENDIX R

OFFICE OF RESEARCH INTEGRITY

ANIMAL BIOSAFETY LEVEL (ABSL) DETERMINATION MATRIX

Rev. February 2019

A guideline based on the current edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL)* which is to be used for determining BSL and ABSLs for research (* http://www.cdc.gov/biosafety/publications/bmbl5/index.htm)

NOTE: The following PPE must be worn in all facilities when entering animal rooms or labs where animals are manipulated: facility dedicated scrubs/shoes, gloves, surgical mask, eye protection (or face shield). Additionally, all cage dump stations must be ventilated.							
	MATERIAL	BIOSAFETY LEVEL (applicable to injections/ necropsy)	ANIMAL BIOSAFETY LEVEL (applicable for animal housing / cage changes)	HOUSING REQUIREMENTS	CAGE CHANGES	PRE/POST INFECTION MANIPULATIONS	IMAGING
HUN	AN CELL LINES (* "Retro	oviral" is inclus	ive of lentiviral vect	tors)			1
9	Unmodified (established) Human cell lines inserted into an Immuno- compromised mouse	BSL2	ABSL1	No special requirements	No special requirements - cages can be changed on benchtop. Bedding does not need autoclaved prior to disposal / cages do not need autoclaved prior to washing	All injections and necropsies in BSC for DURATION of project (following BSL2 practices)	No special requirements
10	Human cell lines transduced with retroviral* vector then inserted into an immuno- compromised mouse	BSL2	ABSL2 for 1 week / then ABSL1	Microisolator technique for 1 week post-dosing; after 1 week, no special requirements	For first week: 1. ALL cage changes in BSC; 2. bag and autoclave bedding; 3. bag and autoclave caging before wash; After one week, resume normal cage change.	All injections and necropsies in BSC for DURATION of project (following BSL2 practices)	All manipulations inside BSC where feasible. Maintain BSL2/ABSL2 practices where feasible, especially during the first week.
11	PRIMARY human tissue transplant into mice	BSL2	ABSL2	Microisolator technique for DURATION of experiment	 ALL cage changes in BSC; 2. bag and autoclave bedding; 3. bag and autoclave caging before wash 	All injections and necropsies in BSC for DURATION of project (following BSL2 practices)	All manipulations inside BSC where feasible. Maintain BSL2/ABSL2 practices where feasible.

IBC Appendix S Zoonotic Agents of Concern in Birds, Amphibians, Reptiles, and Fish

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Zoonotic Disease and Agent	Host	Transmission & Incubation Period	Signs/Symptoms	Personal Protective Equipment
Campylobacteriosis Campylobacter jejuni Campylobacter fetus	Birds	Fecal – oral route. C. jejuni 1 – 10 days C. fetus 2–5 days	 C. <i>jejuni</i> – Watery diarrhea, may be with mucus and blood; abdominal pain, fever and nausea and vomiting, usually brief and self-limiting. C. <i>fetus</i> – Chills, sweats, fever, cough, headache, weight loss and abortion in the latter half of pregnancy. 	Lab coat/overall, nonporous gloves, face protection when splashing is anticipated.
Cryptosporidiosis Cryptosporidium spp.	Many animal species	Fecal – oral route. May involve contaminated air. 3 – 7 days	Characterized by cramping, abdominal pain, profuse watery diarrhea, anorexia, and weight loss. Immunosuppressed people may develop severe disease.	Lab coat/overall, nonporous gloves, face protection when splashing is anticipated.
Erysipiloidiosis Erysipelothrix rhusiopathiae	Birds, Fish	Direct contact with pharyngeal or intestinal lymphoid tissue, feces of carrier animals, lesions (especially skin), or contaminated fomites including soil. 1 – 7 days	If localized, usually on the hands, a slightly raised, nonpitting dark reddened cutaneous zone slowly progressing peripherally, severe burning pain, sometimes intense itching. If generalized, fever, generalized weakness, muscle aches and headache.	Lab coat/overall, nonporous gloves, face protection when splashing is anticipated from handling feces.
Histoplasmosis Histoplasma capsulatum	Birds, Bats	 H. capsulatum grows in soil and material contaminated with bat or bird droppings. Spores become airborne when contaminated soil is disturbed. Breathing the spores causes infection. The disease is not transmitted from an infected person to someone else. 3-17 days, average 10 days 	Most infected persons have no apparent ill effects. The acute respiratory disease is characterized by respiratory symptoms, a general ill feeling, fever, chest pains, and a dry or nonproductive cough. Distinct patterns may be seen on a chest x-ray. Chronic lung disease resembles tuberculosis and can worsen over months or years. The disseminated form is fatal unless treated.	Lab coat/overall, nonporous gloves, face protection and respirator when risk of aerosolized spores is anticipated.
Leptospirosis Leptospira interrogans	Amphibian, reptiles	Through non-intact skin and mucous membranes and is often related to direct contact with urine or tissues of infected animals. Inhalation and ingestion may be possible routes. 2 - 30 days, usually $7 - 12$ days	Fever with sudden onset, headache, chills, generalized weakness, and conjunctival suffusion (reddened, watery eyes).	Lab coat/overall, nonporous gloves, face protection when splashing is anticipated.
Listeriosis Listeria monocytogenes	Birds, isolated from fish	Vertical transmission, either transplacental or milkborne (ingestion). Also by direct contact. Uncertain, probably a few days to 3 weeks.	Infection is usually subclinical except in neonates. Febrile systemic, neurologic or respiratory tract disease. May include abortion, reddened eyes and pustular skin lesions.	Lab coat/overall, nonporous gloves, face protection when splashing is anticipated.
Mycobacterioses Mycobacterium marinum, M. ulcerans, M. avium	Birds, fish, amphibians	Direct contact or inhalation of infectious materials from soil, milk, water, and fish, especially with exposure with non-intact skin With the exception of organisms causing skin lesions, transmission is not due to person-to-person contact 2-4 weeks up to 2-4 months	Skin ulcers and soft tissue wound infections- Slowly developing nodule at entry wound followed by Ulceration. Pulmonary disease resembling tuberculosis – SeeTuberculosis.	Lab coat/overall, nonporous gloves, face protection when splashing is anticipated.

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Zoonotic Disease and Agent	Host	Transmission & Incubation Period	Signs/Symptoms	Personal Protective Equipment
Pastuerellosis Pasteurella spp.	Birds, cats	Animal bite or scratch, non-intact skin contamination from infected materials, ingestion, and inhalation through contaminated bird feces. For a wound infection – more than 24 hours. Unknown for other routes.	Wound infection – local redness, swelling, severe pain, occasionally mild fever and regional lymph node swelling. Upper and lower respiratory tract infections and abdominal/pelvic infection are possible with signs related to the area that is affected. Septicemia – infrequent form of infection with fever and generalized signs.	Lab coat/overall, nonporous gloves, face protection, and respirator when inhalation is anticipated.
Psittacosis Chlamydia psittaci	Birds, amphibians	Direct contact or inhalation of infectious materials from exudates, secretions or desiccated feces. 4 – 15 days, usually 10 days	Fever, headache, generalized weakness, chills and upper or lower respiratory tract disease. May see extensive pneumonia and inflammation of the liver in serious infections.	Lab coat/overall, nonporous gloves, face protection, and respirator when inhalation is anticipated.
Q Fever Coxiella burnetii	Many animal species	Inhalation, ingestion. 2-4 weeks.	Sudden onset with fever, chills, retrobulbar headache, weakness muscle aches and profuse sweating. Some cases- nonproductive cough and chest pains.	Lab coat/overall, nonporous gloves, face protection, and respirator when inhalation is anticipated.
Salmonellosis Salmonella spp.	Many animal species	Fecal – oral route. 6 – 72 hours, usually 12 – 36 hours.	Infection causes a sudden onset of headache, abdominal pain, diarrhea and sometimes vomiting. Focal infections can be localized in any tissue of the body with signs related to the area of infection. Immunosuppressed people are at extra risk.	Lab coat/overall, non- porous gloves, face protection when splashing is anticipated.
Tuberculosis Mycobacterium tuberculosis, M. africanum, M. bovis, M. leprae	Many animal species	Aerosols from infected animals or tissues, ingestion or wound contamination. 4 – 12 weeks.	Most common form reflects involvement of the pulmonary system and is characterized by cough, sputum production and eventually coughing up blood. Extrapulmonary forms of the disease can involve any tissue or organ system. General symptoms as the disease progresses include weight loss, fatigue, fever, chills and wasting.	Lab coat/overall, non- porous gloves, face protection, and respirator when aerosolization is anticipated.
Tularemia Francisella tularensis	Many animal species, arthopods	Direct contact of skin with blood or tissues of infected animals, bite from an infected ectoparasite or animal, ingestion of contaminated meat or water, inhalation. 1 – 10 days, usually 3 – 5 days	Symptoms are associated with portal of entry. Skin exposure most common – sudden onset of fever, chills, headache and generalized weakness with decaying ulcer at the site. Ingestion – vomiting and diarrhea. Inhalation – pneumonia.	Lab coat/overall, non- porous gloves, face protection, and respirator when inhalation is anticipated.
Vibriosis Aeromonas hydrophila, Vibrio spp.	Shellfish, freshwater or marine fish	Often associated with trauma such as a penetrating fish spine, exposure to untreated water, ingestion of raw or undercooked fish. 4 – 96 hours, usually 12 – 24 hours.	Diarrhea, occasionally bloody, abdominal pain, vomiting, fever. Wound infection – variety of skin lesions, including cellulitis and necrosis usually progressing to systemic involvement. Septicemia – systemic illness, fever or hypotension.	Lab coat/overall, non- porous gloves, face protection when splashing untreated water is anticipated.

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Zoonotic Disease and Agent	Host	Transmission & Incubation Period	Signs/Symptoms	Personal Protective Equipment
West Nile Virus Flavivirus spp.	Birds are reservoir, mosquito vector	Most commonly spread through mosquito bite from infected bird, not spread through casual contact. <i>3-14 days.</i>	Symptoms vary but range from asymptomatic to fever, headache, and body aches, nausea, vomiting, and sometimes swollen lymph glands or a skin rash on the chest, stomach and back	Lab coat/overall, non- porous gloves when handling infected birds.

References:

- Occupational Health and Safety in the Care and Use of Research Animals, National Research Council, National Academy Press, Washington D.C. 1997.
- Hugh-Jones M.E. et al. 1995. An Outline of the Zoonoses. Iowa State University Press, Ames, Iowa.
- Benenson, A.S. 1995. Control of Communicable Disease in Man. Am. Public Health Assoc., Washington D.C.
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IBC APPENDIX T HAND CARE SOP FOR RESEARCHERS

Rev. February 2019

Researchers wear gloves to protect themselves and always wash their hands after removing gloves. However, frequent glove changes lead to frequent hand washing which can lead to dry, chapped hands (hand dermatitis). This is not only uncomfortable, but provides an entry point for pathogens as well. Careful hand care is therefore an essential part of keeping yourself safe in the lab.

Hand Washing

What is the right way to wash your hands? Follow the procedure outlined by the Centers for Disease Control and Prevention:

- Wet your hands with clean, warm running water, turn off the tap, and apply soap.
- Lather your hands by rubbing them together. Be sure to lather the backs of your hands, between your fingers, and under your nails.
- Scrub for at least 20 seconds. Need a timer? Hum "Happy Birthday" from beginning to end twice.
- Rinse your hands well under clean, running water.
- Use a clean paper towel to turn off the tap.
- Dry your hands using a clean towel or air dry them with cool air if a blower is available.

Cause of Hand Dermatitis

Constant wetting and drying of hands removes protective oils from the skin, making it less pliable and more prone to cracks and fissures. The frequency of washing, the time of exposure to water/cleansing agents, and temperature of the water are also important factors in causing hand dermatitis. Low humidity and cold weather make the dermatitis even worse.

Prevention of Hand Dermatitis

To reduce the risk of developing dermatitis:

- Follow hand washing guidelines and use warm (not hot) water with mild soap; dry hands thoroughly after washing.
- Use a moisturizer to help replace the barrier function of skin. Water-based formulations are readily absorbed into the skin without leaving an unpleasant, greasy feeling.
- Petroleum-based moisturizers are not appropriate in the lab because they can compromise the integrity of gloves.

For long-term skin protection, a heavier, oil-based moisturizer can be used under cotton gloves at home to help heal severely dry skin.



Treatment of Hand Dermatitis

If the skin on the hands is red, inflamed and/or fissured, seek medical attention to clear the skin. This may require the use of topical steroids, soaks or antibiotics if there is evidence of infection.

- The longer hand dermatitis is present, the more difficult it is to treat and the more chronic it may become. Follow the preventive steps described in this SOP.
- Personnel with active hand dermatitis can develop secondary irritation and aggravation of the dermatitis when wearing gloves over inflamed skin. Seek treatment early to prevent this.

Persistent Hand Dermatitis

- If hand dermatitis is persistent despite treatment with topical steroids and minimizing exposure to water/soap/cleansing agents, consultation with a dermatologist or allergist may be appropriate.
- Allergies may be due to contact with antibacterial agents in hand washing products, *and/or* preservatives or fragrances in moisturizers, etc. Use fragrance-free moisturizers as a precaution.
- A history of eczema in childhood has been shown to increase one's susceptibility to hand dermatitis from chronic exposure to water and cleansing agents.

Prevention

There are numerous products available today to help keep researchers hands in good condition and free of the cracks that are potential entry points for infectious agents.

Lab vendors such as Fisher and VWR Scientific sell products designed specifically for laboratory personnel who wash frequently.

VWR International

VWR[®] Hand Cream 473 mL pump bottle 89005-468

3.8 L refill jug 89005-482

Non-greasy skin moisturizer absorbs quickly upon application

Prevents irritation from latex gloves, harsh soaps, and other irritants

Fragrance-free, petroleum free non-greasy skin moisturizer absorbs quickly and provides a barrier that prevents irritation from latex gloves, harsh soaps and other irritants. Fragrance-free and contains no petroleum products that would compromise latex integrity.

ThermoFisher Scientific

04-355-21Decon[™] Proguard[™] Professional Hand Cream 16 oz.

Does not contain grease, oil, perfume, aloe, or other ingredients that can compromise the integrity of gloves. Absorbs instantly, leaving skin soft and pliable.



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Resources:

1. Handwashing: Clean Hands Save Lives Centers for Disease Control and Prevention <u>http://www.cdc.gov/handwashing/</u>

2. Prevention of Hand Dermatitis in the Health Care Setting Safety and Health Assessment and Research for Prevention (SHARP) Program Washington Department of Labor and Industries