University Of Delaware

# BIOSAFETY MANUAL

## EMERGENCY PHONE NUMBERS

| | |
|---|---|
| Fire | 911 |
| Police | 911 |
| Ambulance | 911 |
| Student Health Service | 831-2226 |
| Nurse Managed Primary Care Center | 831-3195 |


Department of Environmental Health and Safety
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http://www.udel.edu/ehs



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# Chapter 1 University Policy

## 1.1 EHS Protocol L-02

EHS Protocol L-02, as presented in Appendix A of this manual, addresses the control of biological materials in research and education. No person shall purchase, possess, use, transfer, propagate, or dispose of any biological material listed in Appendix B of this manual except with the approval of and in accordance with procedures established by the Department of Environmental Health and Safety (EHS) and the University Biosafety Committee (UBC).

The definition of a biohazardous agent is one that is biological in nature, capable of self-replication, and capable of producing deleterious effects upon other biological organisms, particularly humans. Biohazards are biological agents or substances present in or arising from the work environment that present or may present a hazard to the health or well being of the worker or community.

Biological agents or substances that could be biohazardous include, but are not limited to, infectious or parasitic agents; non-infectious microorganisms such as some fungi, yeast, and algae; plants and plant products; and animals and animal products that cause occupational disease. The level of biohazard established for a specific agent is made on the basis of the potential hazard of the agent and of the specific laboratory functions or activities.

## 1.2 Categories of Biohazardous Agents

a. Bacteria
    1. Bacterial pathogens
    2. Bacteria with drug resistance plasmids
b. Fungi
c. Viruses
    1. Oncogenic viruses
    2. Other animal viruses
d. Rickettsiae
e. Chlamydiae
f. Parasites
g. Recombinant nucleic acids (DNA and RNA) and products
h. Allergens
i. Cultured animal cells and the potentially infectious agents these cells may contain
j. All clinical specimens (tissues, fluids, etc.)
k. Tissues from experimental animals (including animal dander)
l. Plant viruses, bacteria and fungi
m. Toxins (bacterial, plant, etc.)
n. Prions

## 1.3 Biosafety Program Enforcement

The following procedure will be used for the enforcement of violations. If there is an imminent hazard, the Provost will be notified of the safety violation and the lab will be closed until such a time as the violation has been corrected.

1.3.1 The Biosafety Officer will send a written communication to the Principal Investigator (PI) describing the violation. The letter will include the date by which correction of the infraction must occur, typically 7-10 days.

1.3.2 If the infraction has not been corrected by the appointed date, the Director of EHS will send a letter to the PI. The department Chair, UBC chair, and the dean of the college will be copied on this letter. A written response will be required from the PI within 30 days outlining how the problem will be addressed and prevented in the future.

1.3.3 If the response is not received or the problem is not corrected the PI will be advised that EHS and the UBC will advise the Vice President for Research, Scholarship, and Innovation to deny future grant applications pending a satisfactory reinspection or correction of the violation.

# Chapter 2 Principles of Biosafety

## 2.1 Biosafety

The goal of the biosafety program is to ensure the safety of the university's researchers, students, and the environment. The most current edition of the Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) manual is the basis for the university's biosafety program.

"Containment" is used to describe safe methods for managing infectious agents in the laboratory. Primary containment is the protection of the personnel and the immediate lab environment from exposure to the agents. This is achieved through good microbiological techniques and the use of safety equipment. Secondary containment is the protection of the environment external to the laboratory. It is achieved through the combination of facility design and operational practices. The three elements of containment include laboratory practice and technique, safety equipment, and facility designs. All of these topics are addressed further throughout this manual.

## 2.2 Biosafety Levels

The BMBL describes four biosafety levels. The levels consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Work is assigned a biosafety level based on the operations to be performed, the documented or suspected routes of transmission for the agent, and the laboratory functions and activities. The NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*Guidelines*) and the ABSA International's (ABSA) *Risk Group Classification for Infectious Agents* list recommended biosafety levels for most infectious agents. Specific requirements for each biosafety level can be found in the BMBL.

### 2.2.1 Biosafety Level 1 (BSL1) practices, safety equipment, and facilities are for work with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. Some of these agents may be opportunistic pathogens and cause infection in the young, the aged, or immunocompromised individuals. BSL1 consists of standard microbiological practices with no special primary or secondary barriers except for a sink for handwashing.

### 2.2.2 Biosafety Level 2 (BSL2) is used in the majority of the university's labs. It is appropriate for indigenous moderate-risk agents present in the community and associated with human disease of varying severity. Using good microbiological techniques, these agents can be used safely on the open bench as long as aerosol generation is minimized. BSL2 at a minimum must be used with human blood, body fluids, and tissues. The greatest hazard to the individual is percutaneous injury, mucous membrane exposure, or ingestion of the materials. If aerosol generation may occur the work must be performed within a biosafety cabinet.

2.2.3 Biosafety Level 3 (BSL3) is used for work on indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection. The primary hazards to the personnel are from autoinoculation, ingestion, and exposure to aerosols. BSL3 facilities require more primary and secondary barriers to protect personnel and the environment. All work should take place in a biosafety cabinet, access to the labs must be controlled, and ventilation systems must include filtration to prevent the release of organisms.

2.2.4 Biosafety Level 4 (BSL4) is used for dangerous and exotic agents which pose a high individual risk of life-threatening disease, which may be transmitted by an aerosol route, and for which there is no available vaccine or treatment. Any agents which have a close or identical antigenic relationship with a BSL4 agent should also be handled at the BSL4 level. The hazards to the personnel include infectious aerosols, mucous membrane exposure and autoinoculation. The lab workers use either a Class III biosafety cabinet or a full-body, air-supplied positive-pressure personnel suit. The facility is a completely isolated zone with specialized ventilation and waste management systems to prevent release to the environment. There is no BSL4 facility at the University of Delaware.

2.2.5 There are specific animal biosafety levels designated for working with infectious agents in vertebrate animal models. These are designated Animal Biosafety Level (ABSL) 1-4. The levels combine work practices, safety equipment, and facilities for experiments on animals infected with agents which are capable of producing human infection. Further information on the specific requirements of each level is available in the BMBL.

## 2.3 Modes of Transmission

There are several routes of transmission for infectious agents. Each agent has different ways of obtaining access to a new host and causing infection.

### 2.3.1 Inhalation

A variety of agents infect by the respiratory route. This can be caused by aerosolization of the agent. An aerosol may be generated during a lab procedure or an infected patient or animal may create an aerosol by coughing or sneezing.

### 2.3.2 Ingestion

Some organisms are enteric pathogens and can infect by being eaten or drunk. Contamination of a food or beverage may allow an agent to gain access to the individual. Hand-to-mouth contamination may occur. Fomites, which are inanimate objects such as the telephone, pens, and pencils, may also become contaminated. When an individual touches

these items they may pick up the agent and it may gain entry through the mouth or the mucous membranes if touched.

2.3.3 Penetration

Some agents may gain entry into the body through accidental penetration. This could be by needlesticks, cuts with contaminated sharp objects, broken glass, scalpels, razor blades, or animal bites or scratches. Agents may also enter the body through previous penetrations or openings in the skin, such as open wounds, chapped skin, or skin conditions such as dermatitis and eczema. Some parasitic agents are capable of directly penetrating intact skin. Certain agents may also enter the body through the mucous membranes of the eyes, nose, or mouth. Examples of these are the bloodborne pathogens.

2.4 Biological Reproductive Hazards

Certain biological materials may pose an increased risk for personnel who are, or wish to become, pregnant. These reproductive hazards may affect fertility, conception, growth and health of a fetus or infant. Keep in mind that during pregnancy, any infectious disease or pathogen may cause a more severe illness than when the woman is not pregnant, so precautions must be taken with any infectious organism or material. Some of these agents may cause physical malformations or result in miscarriage. The risk for each of these varies depending on the stage of pregnancy. Some can cause damage very early, possibly before the woman is even aware she's pregnant.

Some examples of biological reproductive hazards include:

| **Agent** | **Complications** |
|---|---|
| Arboviruses | Congenital infections, miscarriage |
| Brucella | Miscarriage |
| Chlamydia | Neonatal conjunctivitis |
| *Coxiella burnetii* (Q fever) | Premature birth, fetal or newborn death |
| Coxsackie virus | Meningitis or sepsis (blood infection) |
| Cytomegalovirus | Growth and developmental retardation, microcephaly |
| Group B strep | Meningitis, septicemia |
| Hepatitis B virus | Acute or chronic infection |
| Herpes simplex virus (Types I and II) | Disseminated disease, encephalitis |
| Human immunodeficiency virus (HIV) | Transmission to fetus |
| Human parvovirus B19 (Erythema infectiosum) | Miscarriage |
| *Listeria monocytogenes* | Miscarriage or stillbirth, premature delivery, infection of newborn |
| Mumps virus | Sterility (males), pregnancy loss |

| | |
|---|---|
| Rubella (German measles) | Birth defects, disruption of fetal growth |
| Syphilis | Abnormal teeth and bones, mental retardation |
| Toxoplasmosis | Hydrocephalus, blindness, mental retardation |
| Varicella zoster virus (chickenpox/shingles) | Skin scarring, limb reduction defects, muscle atrophy, mental retardation |
| Zika virus | Microcephaly, miscarriage, still birth |

Employees and students must be made aware of the hazards before beginning work in the laboratory. If someone is considering becoming pregnant, or thinks they might be, and is concerned about their lab work, they should contact EHS to discuss the research and any precautions that should be taken. It is especially important to discuss the materials to be handled, whether they are biological, chemical, or radioactive, with a physician. The final decision to continue to work in the laboratory rests with the employee or student. They may wish to consider changing the work or project to eliminate the exposure to the agent during the pregnancy, or request a medical leave. If appropriate work practices, equipment controls, and personal protective equipment are used, pregnant women should be able to remain safe from biological exposures in the lab.

Conduct a risk assessment for the research and agents to be used to determine practices and procedures to reduce or eliminate the risk. Consult the infectious agent Pathogen Safety Data Sheets for safety information. Follow the appropriate biosafety level precautions for the agent. Use appropriate PPE and follow good microbiological techniques and lab procedures, such as washing your hands when leaving the lab and before eating or drinking. Follow proper disinfection and decontamination procedures. For agents of particular concern, such as *Listeria monocytogenes*, the lab may be placarded to warn anyone who is/may be pregnant that the agent is in use in that location.

## 2.5 Risks to Immunocompromised Persons

Certain biological materials may pose an increased risk for personnel who are immunocompromised. Personnel may be immunocompromised due to various conditions, including examples such as undergoing organ transplants, undergoing medical treatment for cancer, taking medications such as steroids which may affect their immune system, or suffering from a medical condition that decreases their immune responses. These individuals may be more at risk from agents which wouldn't typically cause illness in otherwise healthy adults.

Employees and students must be made aware of the hazards before beginning work in the laboratory. If someone may be immunocompromised, and is concerned about their lab work, they should contact EHS to discuss the research and any precautions that should be taken. It is especially important to discuss the

materials to be handled, whether they are biological, chemical, or radioactive, with a physician. The final decision to continue to work in the laboratory rests with the employee or student. They may wish to consider changing their work or project to eliminate the exposure to the agent if there is an increased risk.

Conduct a risk assessment for the research and agents to be used to determine practices and procedures to reduce or eliminate the risk. Consult the infectious agent Pathogen Safety Data Sheets for safety information. Follow the appropriate biosafety level precautions for the agent. Use appropriate PPE and follow good microbiological techniques and lab procedures, such as washing your hands when leaving the lab and before eating or drinking. Follow proper disinfection and decontamination procedures.

# Chapter 3 The Biosafety Committee

The University Biosafety Committee (UBC) consists of representatives from the colleges that perform biological work. The committee also includes a representative from the Provost's office, the Biosafety Officer and Biosafety Specialist, and two public members. The UBC is responsible for the review and approval of grants involving recombinant DNA research for the NIH and other agencies. See Chapter 9 of this manual for further information on recombinant DNA work. A roster of the UBC members appears in Appendix E.

Below is the SOPs and charter for the UBC.

University Biosafety Committee
Standard Operating Procedures

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2. UBC Policy Statement
3. UBC Charter
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5. Committee Votes
6. Conflict of Interest
7. UBC Minutes
8. Reporting to NIH- annual registration, changes to committee, incident reporting
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11. Training for UBC members
12. Training for Researchers using rDNA
13. UBC Authority
14. Record Retention
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University of Delaware Biosafety Committee
Standard Operating Procedures

1. Mission Statement

The University of Delaware recognizes the importance of conducting a broad spectrum of original research that may employ the use of biological agents. Cognizant that these activities may be accompanied by some risks and regulatory requirements, the University requires that research activities using biological agents be reviewed and approved by the University Biosafety Committee (UBC) to ensure that it is conducted in accordance with the National Institutes of Health *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, the methods outlined in the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) manual, and the University of Delaware Biosafety Manual.

As a research intensive institution, the University of Delaware supports basic research in these fields, but recognizes limitations on the types of agents that may be currently employed in research at the University. We do not currently have the capacity at the University of Delaware to work with Biosafety Level 4 agents or perform research involving the use of non-human primates. Moreover, research involving Biosafety Level 3 agents is highly restricted and reviewed on a case-by-case basis.

2. Policy Statement

It is the policy of the University of Delaware to ensure all activities related to the use of biological materials are conducted in a safe manner and in compliance with all federal, state, local, and University regulations (EHS Protocol L-02).

This policy governs the receipt, storage, transport, use, and disposal of hazardous biological agents and materials. It applies to all research, teaching or other activities using hazardous biological materials conducted at the University campus or by University faculty, staff or students when acting as representatives of the University at off-campus locations. All projects must conform to the guidelines and requirements set forth in the National Institutes of Health *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) manual, and/or the University Biosafety Manual.

3. UBC Charter

Date approved by committee: 1/16/2020

Meetings:

The Committee shall meet no less than twice per year.

A quorum of the smaller of four or the majority of members shall be required to conduct the business of the Committee, to include at least a representative from Environmental Health and Safety, a faculty member, and a plant and/or animal expert if research involving this work will be reviewed at the meeting. Teleconference or videoconference meetings may be used.

Membership:

The committee will consist of at least one representative from each college performing biological research at the University, with a minimum of five members. There will be at least one animal containment expert and one plant containment expert on the committee. In addition, two community members who are not affiliated with the University will be appointed to the committee. A representative from the Provost's office is an ex-officio non-voting member of the Committee. The Biosafety Officer and Biosafety Specialist are ex-officio voting members of the Committee. The Biosafety Officer will serve as the Executive Secretary for the committee.

Prospective members of the committee are identified by the Biosafety Officer and the departments/colleges to be represented. Community members are identified by the Biosafety Officer or other members of the UBC. Once a member is identified who is interested in serving, the recommendation is sent to the Vice President for Research, Scholarship, and Innovation for his/her consideration and appointment. Members of the committee will be appointed for three year terms, with the option of being re-appointed. Committee members are expected to attend the UBC meetings.

The candidate for chair of the committee will be selected by a vote of the committee membership. The recommendation is submitted to the Vice President for Research, Scholarship, and Innovation for his/her consideration and appointment. The chair should be a tenured faculty member. The chair will serve for three years, with the option of being re-appointed.

Responsibilities:

Review and approve grants involving recombinant DNA research in accordance with the NIH *Guidelines*. This will include the following responsibilities:

Establish review procedures. Conduct initial review and approve or disapprove all proposals involving recombinant DNA research. Investigators will be notified of committee decisions.

Conduct periodic review of recombinant DNA research at the University of Delaware to ensure compliance with NIH *Guidelines*. Reviews will be done on an annual basis.

Set containment levels as specified in NIH *Guidelines*.

Adopt emergency plans for accidental spills and personal contamination.

Report any problems, violations, accidents, or illnesses and their investigation/resolution related to recombinant DNA research to the Provost or his designee and to NIH/Office of Science Policy (OSP).

Withhold authorization of any experiments involving recombinant DNA not explicitly covered by NIH *Guidelines* until NIH establishes the containment requirements.

Maintain records of meeting minutes, protocol reviews, and other documents related to the committee's work and the use of recombinant DNA at the University.

Arrange for dissemination of review requirements, containment levels, emergency plans, and other information related to recombinant DNA research to researchers and technical staff.

Assume the responsibility for the biological safety aspects of all University programs involving the use of biohazardous agents (reference EHS Protocol L-02).

The Biosafety Officer will act on behalf of the UBC to review and grant (or deny) permission for the use of biohazardous agents within the University. Approval is necessary before a project involving these agents can be initiated.

Review and prescribe special conditions, requirements, and restrictions that may be necessary for safe handling of biohazardous agents. For example, the Committee may require: students, staff and researchers to pass an oral or written examination, worker physical examinations (e.g. blood titers, PPD, respiratory protection, required vaccinations, etc.), upgrading of facilities (biosafety cabinets, hoods, autoclaves, etc.), special designation of areas of use within the laboratory, posting of additional caution signs, use of special disposal methods, use of special handling procedures, and special procedures to be followed after contamination events or incidents.

The Biosafety Officer and/or the Research Office will serve as a liaison with the NIH for research involving materials covered under the NIH *Guidelines*.

Receive and review periodic and/or urgent reports from the Biosafety Officer regarding:

A. Exposures of individuals to biohazards and subsequent investigations.
B. Loss or theft of biohazardous agents and subsequent investigations.
C. Records of Select Agent purchase/transfer.

Recommend and/or initiate remedial actions when safe procedures are not followed under an authorized project, jeopardizing personnel or environmental safety, or when procedures are not in compliance with government regulations or University policy. If necessary, this may involve the termination of permits or authorizations of personnel, or confiscation of biohazardous agents. Authorize the resumption of operations, stopped by the Director of Environmental Health and Safety, when the

operations are again in compliance with the regulations. This will be done according to the procedures in the University Biosafety Manual.

Keep a written record of actions taken in approving or disapproving the use of biohazardous agents and reports involved in the work of the Committee.

Delegate to the Biosafety Officer or their designee the authority to review, grant, or deny temporary authorizations for the use of biohazardous agents during the interim between meetings. Such authorizations shall be subject to final approval or denial after a review at the next scheduled Committee meeting.

Arrange for and/or conduct a periodic management audit of the Biosafety Program. The audit shall include a review of the overall effectiveness of the University Biosafety program. An audit report shall be presented to the Vice President for Research, Scholarship, and Innovation.

4. Scheduling of Meetings

Meetings will be scheduled in advance and the dates will be posted on the UBC web page. If additional meetings are necessary they will be scheduled. Meetings are open to the public.

5. Committee Votes

At meetings where 2/3 or more of the committee members are present, majority approval is needed for any committee business including rDNA project approvals. If a meeting consists of less than 2/3 membership, but above quorum, a unanimous approval is needed for committee business including rDNA project approvals.

6. Conflict of Interest

UBC members will not be involved in the review or approval of a project in which they are taking part. Members will be expected to recuse themselves during review of projects in which they are involved. If needed, an alternate expert will be identified by the Biosafety Officer to advise on the project if the only area expert on the committee is involved in the project.

7. UBC Minutes

Minutes will be maintained for all UBC meetings that take place. The meeting minutes will include at least the date, time, and place of the meeting, a list of persons in attendance of the meeting, approval of meeting minutes, major points of order and major motions, lists of rDNA approvals reviewed and/or approved, and time of adjournment. Minutes will be available upon request to the public.

8. Reporting to NIH- annual registration, changes to committee, incident reporting

The committee membership registration will be updated with NIH OBA at least annually or when membership changes as per current NIH *Guidelines*. The UBC will notify NIH OSP of any significant problems or violations and any significant research related accidents and illnesses within 30 days as per the NIH *Guidelines*. This will be done by

the Biosafety Officer and will be copied to the Compliance Officer. Information on incident reporting to NIH is available at https://osp.od.nih.gov/biotechnology/faqs-on-incident-reporting/ .

9. Procedures for rDNA protocol reviews

Any research involving work with recombinant DNA must be registered with the UBC according to the NIH and University Policy. The *Recombinant DNA Registration Form* is completed by the researcher to initiate the process. A copy of the current NIH *Guidelines* is available on the website (http://www.udel.edu/ehs) as reference.

Upon completion of the registration form, a UBC member must review the project. Any UBC member may request additional members assist with this initial review of the proposal. When the committee member completes the review, the form is sent to the Biosafety Officer. If the UBC member and Biosafety Officer approve of the project, a copy of the signed registration form will be sent to the researcher as provisional approval of the project for grant application purposes. Exempt level projects may be initiated once the approval of the UBC member and Biosafety Officer are obtained. For non-exempt projects, the protocol must be reviewed at a UBC meeting in order to obtain final approval, thus permitting work to begin. The project must be reviewed and updated on an annual basis. The Biosafety Officer initiates this process.

A researcher may apply for a single approval of all related work that meets the **exempt** definition under the NIH *Guidelines*, rather than be approved on a project-by-project basis. To receive approval, the Principal Investigator (PI) must complete the *Recombinant DNA Registration Form*. Section I must be completed, using the "General Work Description" option to describe the type of procedures to be done by the lab group. "Project Title" is left blank. In Section II, Category A is marked. A description of the types of recombinant DNA procedures to be performed by the lab group is attached. The *Registration Form* is then submitted to a UBC member for approval, followed by the Biosafety Officer. This approved form is valid for one year from the date of the Biosafety Officer's signature. After one year, the *Recombinant DNA Registration Form* must be resubmitted and approved. It is the PI's responsibility to assure that the work being submitted with the grant complies with the submitted and approved procedures. If it is found that the grant was not under the exempt status, or the work procedures differed from what had been approved, the approval and funding for the project may be jeopardized. If a PI wishes to perform work that varies from what has been approved, he or she must complete a new registration form. These procedures apply to exempt work ONLY. All non-exempt work must be approved on a project-by-project basis.

Related rDNA projects may be registered using one “blanket” form, to cover more than one related rDNA project. This decreases the number of forms completed, as well as expediting the start of new, yet related, projects immediately, without having to wait for a new approval. This can be done if the rDNA work **does not** result in different gene functions of the recombinant DNA, relative to what is native in the genome.

An example of related projects includes analysis of gene function through targeted deletions of genes in one organism; if a handful of genes will be studied, they could be described in the registration form as "Targeted deletion of genes in the genome of organism X, in order to study gene function". This will eliminate the need to fill out a new form and get a new approval for each gene being deleted. A second example is if the rDNA work involves fusion proteins with reporter genes, a blanket rDNA form might be described as "Analysis of multiple gene functions in organism X, using reporter constructs".

Blanket registration forms may not be written for anything where the gene function is going to be altered or increased. Examples include, but are not limited to, over-expression of genes, and placing a gene from one organism into another.

If a "blanket" registration form is submitted, it will be up to the discretion of the UBC to determine whether this is acceptable and fits into the preceding guidelines.

10. Lab Inspections

Lab inspections for biological use labs will be performed by an EHS member at least once every two years and in accordance with the risk assessment for the lab. Lab inspection records will be maintained for three years.

11. Training for UBC members

The UBC committee will take part in training regarding their responsibilities. This will be provided at the committee meetings and may be provided as separate training sessions as well. The training will include, at a minimum, the committee's responsibilities, implementation of the NIH *Guidelines*, and lab safety especially in regards to recombinant DNA. Records of this training will be maintained for three years.

12. Training for Researchers using rDNA

All users of biological materials must complete biosafety training prior to work with biologicals. In addition, anyone working on a non-exempt rDNA project must complete rDNA Research Training. This training can be completed through a live session provided by EHS, or by a web-based training. Biosafety Training is required every two years, and rDNA Research Training is required every three years. Records are maintained for three years.

13. UBC Authority

If an imminent hazard is identified, EHS will act to mitigate the imminent hazard and then advise the Research Office and the UBC Chair. EHS and the UBC will work with the Research Office to ensure the hazard or compliance issue is addressed before operations are reinstated. In the event of an issue that is not of immediate concern from a safety or regulatory compliance perspective, the issue will be reported to the Research Office by EHS or the UBC Chair and the Vice President for Research, Scholarship, and Innovation or his/her designee will act to address the issue.

14. Record Retention

UBC meeting minutes and documents will be maintained for three years. Recombinant DNA registration forms will be maintained for three years or until a project is completed, whichever is longer. Lab inspection reports and training records will be maintained for three years.

15. Charter Revisions

The UBC charter will be reviewed and updated by the committee. The committee will vote to approve any changes to the charter.

# Chapter 4 Approval Procedures for Work with Biological Agents

The UBC is responsible for the biological safety aspects of all university programs involving the use of biological agents. It is responsible for reviewing and granting approval for any project involving biological agents, as well as determining any special conditions, requirements, and restrictions necessary for safe handling of the agents.

## 4.1 Biological Research Registration

### 4.1.1 Biological Registration Forms

Researchers are required to register their work with the UBC and update it on an annual basis. This is done by completing the Biological Registration Form. This form is available on the EHS web page or through EHS. It is also provided in Appendix E of this manual or can be completed through Webforms. Once the Biological Registration Form is completed, all lab staff must be trained according to the biosafety level of the lab's work. See Chapter 17 for further information regarding training. Any necessary hazard postings and labels will be applied to the work areas. The Biosafety Officer may inspect the laboratories.

### 4.1.2 Biological Inventories

Researchers are required to maintain a Biological Material Inventory Form as well. This must also be updated on an annual basis. The inventory must include all biologically hazardous materials listed individually. If materials are at BSL1 or considered nonhazardous, such as some plasmids, phages, or categories of organisms, they can be listed as a group rather than individually. A copy of an available form, as well as an example, are provided in Appendix E of this manual as well as on the EHS web page or through EHS. Alternatively, the biological inventory may be maintained online by the lab.

### 4.1.3 Other Biological Requirements

If research is to involve bloodborne pathogens, recombinant DNA, or select agents, consult the respective sections in this manual for further information and requirements.

### 4.1.4 Permits

If research will require a permit, such as through the CDC or United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), or Veterinary Services (VS), the Biosafety Officer must be notified. A copy of the permit must be provided with the Biological Registration Form.

## 4.2 Safety Responsibilities during PI Leaves/Absences

Laboratory PIs hold increased responsibility for safety in laboratory and other research operations (e.g. field work) in that they must monitor and enforce safety requirements and practices to assure that faculty, students, staff, and visitors adhere to these protections. In the situation where a PI may be absent from the lab, such as for sabbatical leaves, medical leaves, maternity/paternity leaves, vacations, unpaid summer internships, and FMLA qualifying leaves, it is critical that a qualified individual be identified to address the routine as well as unique safety concerns that may arise during such absences.

4.3 Volunteer Workers involved in Laboratory Research and Teaching Activities

University volunteers are individuals who are uncompensated by the University of Delaware and who perform services directly related to the business of the University to support the research, teaching or public service activities of the University or to gain experience in specific endeavors.

Volunteer workers under the age of 18 will be handled by the Minors Involved in Laboratory Research and Teaching Activities Policy, found in Chapter 6 of the University Chemical Hygiene Plan and at http://www.udel.edu/ehs/forms/downloads/minorsresearchpolicy.pdf.

Tours and visitors to laboratories are handled under Chapter 6 of the University Chemical Hygiene Plan and are not subject to this policy provided the obligations under the Chemical Hygiene Plan are met.

*Under **no** circumstances shall individuals unable to understand safety training be permitted in University of Delaware laboratories except as research study participants in an approved research protocol.*

Volunteer workers are permitted to perform research and teaching activities at the University of Delaware provided the following requirements are met:

1) Faculty Members or Principal Investigators must notify the Departmental Safety Committee and receive documented approval from the Chair of the Department or Director of the Program.

2) The volunteer worker must attend all applicable safety training sessions, including but not limited to:

- a. Right-To-Know
- b. Chemical Safety/Hygiene Plan
- c. Any or all of the following, based on work performed:
  - i. Corrosive Chemical Safety
  - ii. Laboratory Ventilation Safety
  - iii. Chemical Waste Disposal
  - iv. Laser Safety
  - v. Radioactive Materials Safety
  - vi. Biosafety

vii. Bloodborne Pathogens
viii. X-Ray Device Safety

3) The volunteer worker is under the supervision of a faculty member in the laboratory or area where the work will occur.

4) The responsible researcher must meet with the volunteer worker and review all Job Hazard Analysis (JHA) and Standard Operating Procedures (SOP). Written copies shall be provided. EHS shall review the JHA's or SOP's to assure all safety issues are addressed.

5) The volunteer worker must use all required personal protective equipment. Each college, school, department, division or unit should make available to each volunteer required to wear personal protective equipment the devices appropriate for the activity and hazards involved. The volunteer may be required to purchase certain individualized items of personal protective equipment.

6) The volunteer worker must be monitored and supervised by a knowledgeable and experienced adult employee until the principal investigator is comfortable that the volunteer can work independently. They must not work alone while performing hazardous operations or while working with hazardous materials.

7) The volunteer must follow all departmental and university safety procedures and policies.

8) The Departmental Safety Committee or Departmental Chemical Hygiene Officer should perform spot inspections of the work and assure that all training is complete.

9) The Release of Liability and Waiver Claim Form must be completed by the volunteer worker. This form is available in Appendix E of this manual.

10) The responsible faculty member must complete the Principal Investigator/Supervisor Commitment Form. This form is available in Appendix E of this manual.

4.4 Minors Involved in Laboratory Research and Teaching Activities

Persons under 18 years of age are not allowed in University laboratories where hazardous materials are present or hazardous activities take place except under the following circumstances:

1) The minor is employed by the University or has been formally accepted as a volunteer worker; and

a. has been trained in safe laboratory procedures; and

b. has supervision by a knowledgeable and experienced adult employee at all times; and
c. has received and completed the appropriate State of Delaware, Department of Labor forms and approvals. Contact Human Resources for more information; or

2) The minor is enrolled in a University class with a laboratory component; or

3) The minor is participating in a University-sponsored program; and
a. has been trained in safe laboratory procedures; and
b. has supervision by a knowledgeable and experienced adult employee at all times; and
c. has a parental hazard-acknowledgement form on file with the host department.

Tours involving minors are handled under Chapter 6 of the University Chemical Hygiene Plan and are not subject to this policy provided the obligations under the Chemical Hygiene Plan are met.

*Under **no** circumstances shall children too young to understand safety training be permitted in University of Delaware laboratories except as research study participants with the signed consent of a parent or legal guardian.*

The following must be adhered to:
1) Faculty Members or Principal Investigators must notify the Departmental Safety Committee and receive documented approval from the Chair of the Department or Director of the Program.

2) The minor must attend all applicable safety training sessions, including but not limited to:
a. Right-To-Know
b. Chemical Safety/Hygiene Plan
c. Any or all of the following, based on work performed:
i. Corrosive Chemical Safety
ii. Laboratory Ventilation Safety
iii. Chemical Waste Disposal
iv. Laser Safety
v. Radioactive Materials Safety
vi. Biosafety
vii. Bloodborne Pathogens
viii. X-Ray Device Safety

3) The minor is under the responsibility of a faculty member in the laboratory or area where the work will occur.

4) In situations where the minor is not participating in a laboratory science course, the responsible researcher must meet with the minor and review all Job Hazard Analysis (JHA) and Standard Operating Procedures (SOP). Written copies shall be provided. EHS shall review the JHA's or SOP's to assure all safety issues are addressed.

5) The minor must use all required personal protective equipment. Each college, school, department, division or unit shall provide or otherwise make available to each minor required to wear personal protective equipment the devices appropriate for the activity and hazard involved. Minors enrolled in a University of Delaware laboratory science course may be required to purchase their own personal protective equipment.

6) The minor must be monitored and supervised at all times by a knowledgeable and experienced adult employee. They must not work alone. Each task shall be evaluated. Work with reproductive toxins, chemical carcinogens and highly toxic materials shall not occur. Any procedures involving a hazardous operation shall be limited and controlled by the responsible researcher.

7) The minor must follow all Departmental and University safety procedures and policies.

8) The Departmental Safety Committee or Departmental Chemical Hygiene Officer should perform spot inspections of the work and assure that all training is complete.

9) The minor must follow all applicable state and federal requirements and guidelines.

10) The Release of Liability and Waiver Claim Form must be completed by the parent or guardian of the minor. This form is available in Appendix E of this manual.

11) The responsible Faculty member must complete the Principal Investigator/Supervisor Commitment Form. This form is available in Appendix E of this manual.

# Chapter 5 Safe Work Practices

## 5.1 Personal Protective Equipment

The use of personal protective equipment (PPE) is required by EHS Protocol G-06. Equipment must be selected based on the hazards inherent to the work. Equipment is made available to the employees by their departments. PPE may include, but is not limited to, gloves, eye protection, respirators or masks, face shields, lab coats or gowns, and Tyvek suits.

Contaminated PPE should remain in the work area and not be worn into any "clean" areas such as offices, lounges, or break rooms. PPE that is contaminated must be discarded as infectious waste or disinfected prior to routine laundering.

### 5.1.1 Gloves

There are many styles of gloves available. It is essential that the hazards of the materials to be used be evaluated prior to selecting gloves.

Latex or nitrile exam gloves are appropriate for most routine work with biohazards. These gloves are single-use only; they can not be washed and reused. Gloves must be checked for holes or tears.

Leather gloves may be necessary if the work involves sharps hazards or the risk of cuts or scratches.

### 5.1.2 Latex Allergy Minimization

Allergies to latex have become a major concern in the healthcare field. Latex allergy can result from repeated exposure to proteins in natural rubber latex. Exposure can be due to skin contact with a latex-containing item or inhalation of the proteins. Reactions can range from skin rash to anaphylaxis and shock. The National Institute for Occupational Safety and Health (NIOSH) recommends reducing exposure to these proteins by selecting latex-free or low protein products. Use nonlatex gloves for activities that are not likely to involve contact with infectious materials. Use powder-free gloves with reduced protein content. Additional information on latex allergies is available on the EHS web page.

### 5.1.3 Respiratory Protection

Respiratory protection may be necessary if aerosol generation can not be prevented or contained by other means. It is essential that the proper level of protection be selected. EHS has a respiratory protection program and can answer questions regarding respiratory protection.

### 5.1.4 Eye and Face Protection

Eye protection is covered by EHS Protocol G-06. Anyone working in a laboratory where eye hazards exist must wear safety glasses at a minimum. The glasses must meet ANSI Standard Z87.1. Safety glasses must have side shields. Chemical splash goggles may be necessary if the work involves chemicals. A face shield may be necessary in addition to the safety glasses or goggles if the potential for splashing, spraying, or aerosol generation exists.

5.1.5 Laboratory Clothing

Shorts, sandals, and open-toed shoes should not be worn in the laboratory. Skirts and shorts should be long enough to cover the knee. Long hair should be tied back while working in the lab. Laboratory coats or gowns should be worn, buttoned up, to protect street clothing from potential contamination. Lab coat sleeves should be long enough to enable the wearer to overlap the glove cuffs with the sleeves.

5.2 Pipetting

Mouth pipetting is prohibited. Mechanical pipetting devices must be used.

5.3 Housekeeping and Personal Safety

5.3.1 Housekeeping

Laboratory work areas should be maintained in a clean and orderly fashion. Any spills must be cleaned up immediately.

5.3.2 Handwashing

Hands must be washed after handling viable materials, after removing gloves, and before leaving the laboratory.

5.3.3 Contamination Prevention

Eating, drinking, smoking, food preparation, applying of cosmetics or lip balm, handling of contact lenses, and food or cosmetic storage shall not be permitted in laboratory areas.

5.3.4 Lab Access

Access to laboratories should be limited or restricted by the PI when work with organisms is in progress.

5.3.5 Decontamination

All equipment, environmental and working surfaces shall be cleaned and decontaminated after contact with potentially infectious materials and at the end of the work shift using an appropriate disinfectant. Any equipment which is to be serviced by maintenance personnel or contractors must be disinfected as well as possible prior to servicing. Maintenance staff or contractors must be informed as to what areas may be contaminated and the potential for exposure.

5.3.6 Sharps Hazards

Broken glassware and sharps that may be contaminated with infectious materials shall be cleaned up using mechanical means, such as brush and dust pan, tongs, or forceps. Broken glass should not be picked up by hand.

5.3.7 Plastic Use

Whenever possible, replace glass and other breakable materials with plastic or nonbreakable items.

5.4 Sharps

Special care and caution must be exercised by all research, health and animal care personnel in the use and disposal of sharps. Needlesticks or cuts from contaminated sharps present a significant occupational health risk because such injuries may directly introduce pathogens, chemicals or radioactive materials into the body. Sharps include needles, syringes, razor blades, lancets, slides, scalpels, pipettes, micropipettes, pipette tips, broken plastic or glassware, and other devices capable of cutting or piercing the skin. They should only be used when no other alternative exists.

5.4.1 Contaminated needles shall not be bent, recapped, or removed unless there is no feasible alternative. If recapping or needle removal is required, it shall be approved by EHS and accomplished through the use of a mechanical device or a one-handed technique.

5.4.2 Safety devices or alternatives to needles should be used when available.

5.4.3 Sharps containers for disposal of these items should be conveniently located and easily accessible in all work places in which sharps are used.

5.4.4 Disposal Procedures

5.4.4.1 Syringes with or without a needle attached must go into a sharps container.

5.4.4.2 Contaminated micropipettes, pipette tips, and Pasteur pipettes must be treated as sharps. They shall be discarded in a puncture-resistant container or a sharps container for disposal through the infectious waste program. Large contaminated pipettes may go into an infectious waste box if care is used to prevent them from puncturing the box and bags, or they may be discarded into the original cardboard or fiberboard box after the original container has been lined with plastic to contain any liquid. This container is then discarded through the infectious waste program.

5.4.4.3 Razor blades, lancets, scalpels, broken contaminated glassware and any other contaminated items that could cut or pierce the skin will go into a sharps container.

5.5 Biohazard Symbol and Labeling

Below is the universal sign for biohazards. Universal colors for a biohazard are red or fluorescent orange.

BIOHAZARD

According to the BMBL, the entrance to any laboratory where BSL2 or higher agents are present must be placarded with the biohazard symbol and the word "Biohazard." The emergency contact card at the door sign must include the name and phone number of the PI at a minimum. Refrigerators and cabinets used for the storage of human blood and other potentially infected materials must be placarded with the biohazard symbol. Infectious waste containers must be placarded as biohazardous.

# Chapter 6 Laminar Flow Equipment

## 6.1 Principles

Laminar flow equipment consists of biosafety cabinets and laminar flow clean benches. Biological safety cabinets (BSCs) are primary containment devices for use with infectious agents. They are divided into three classifications regarding level of containment. The cabinet class required is dependent on the type of work to be performed. Laminar flow clean benches are used for work with nonhazardous materials only. It is vital that the appropriate equipment is selected for each application.

### 6.1.1 HEPA Filters

The basis to laminar flow equipment is the High Efficiency Particulate Air (HEPA) filter. A HEPA filter consists of a thin sheet of boron silicate microfibers that is pleated. Corrugated aluminum separators are placed between the pleats to direct the air through the filter.

A HEPA filter removes airborne particles and microorganisms. Gases pass through it freely. HEPA filters remove over 99.95% of particles 0.3 micrometers in diameter or larger. A HEPA filter typically lasts three to five years, depending on hours of operation, cleanliness of the laboratory, and type of work being performed. The annual certification of BSCs and laminar flow clean benches tests for the functional status of the HEPA filters among other things.

## 6.2 Types of Laminar Flow Equipment

### 6.2.1 Class I Biological Safety Cabinet

Class I BSCs provide personnel and environmental protection. They do not, however, protect the product or research from contamination because air entering the cabinet is not filtered. All exhaust air passes through a HEPA filter prior to being released. Personnel protection is provided by the constant airflow into the cabinet and away from the operator.

### 6.2.2 Class II Biological Safety Cabinet

Class II BSCs provide personnel, environmental and product protection. Air drawn into the cabinet passes through a HEPA filter before it passes over the work surface. Contaminated air is HEPA filtered prior to being exhausted or recirculated. Class II BSCs purchased before 2002 are further broken down into types A, B1, B2, and B3.

The Class IIA cabinet recirculates approximately 70% of its airflow within the cabinet. This cabinet exhausts into the room.

The Class IIB1 cabinet recirculates approximately 30% of its airflow within the cabinet. This cabinet exhausts to the outside through a dedicated hard duct system.

The Class IIB2 cabinet does not recirculate any air within the cabinet. All exhaust leaves the cabinet through a duct to the outdoors.

The Class IIB3 cabinet recirculates approximately 70% of its airflow within the cabinet. This cabinet exhausts through a duct to the outdoors.

The Class II cabinets were reclassified in the 2002 NSF Standard. This included some changes to the certification procedures as well. The new classifications are Class IIA1, IIA2, IIB1, and IIB2. Any cabinets purchased after 2002 would be defined and tested under this new standard.

The Class IIA1 cabinet has its contaminated plenums under positive pressure. The face velocity is about 75fpm. It recirculates approximately 70% of its airflow, and ducting is optional.

The Class IIA2 cabinet has all contaminated plenums under negative pressure. The face velocity is about 100fpm. Like the IIA1, 70% of its airflow is recirculated and ducting is optional.

Class IIB1 cabinets are ducted to the outdoors. The contaminated plenums are under negative pressure. The face velocity is about 100fpm, and it only recirculates about 30% of its airflow.

Class IIB2 cabinets are also ducted. These are considered “total exhaust” hoods since there is no recirculation of the airflow. The face velocity is about 100fpm, and contaminated plenums are under negative pressure.

### 6.2.3 Class III Biological Safety Cabinet

Class III BSCs provide maximum personnel, environmental, and product protection. They are totally enclosed, ventilated cabinets. The cabinet is maintained under negative pressure. Work is done inside the cabinet through portals with attached rubber gloves. Air passes through a HEPA filter when it enters the cabinet. The exhaust air passes through two HEPA filters prior to its release to the outdoors through a hard ducted system.

### 6.2.4 Laminar Flow Clean Benches

*Laminar flow clean benches (LFBs) are not BSCs. They protect the product or research from contamination, but they do not protect personnel or the environment. The clean bench discharges HEPA filtered*

*air across the work surface and toward the user*. The airflow can be directed either horizontally or vertically.

For this reason, biohazardous, radioactive, chemical, toxic, mutagenic, and carcinogenic agents must not be used in a laminar flow clean bench. All LFBs on campus should have a warning label attached stating that the above agents should not be used in these units.

6.3 Use of Laminar Flow Equipment

Measures must be taken to minimize airflow pattern disturbances when using BSCs and LFBs. The effectiveness of a BSC can be reduced when airflow disturbances are caused by moving your arms or equipment in and out of the cabinet, people walking rapidly by the cabinet, open lab doors, and blocking the grilles with equipment or supplies.

6.3.1 Before starting work, wipe down the BSC or LFB work surfaces with 70% alcohol. Turn unit on and let it run for approximately 10 minutes prior to starting work.

6.3.2 Plan your work; place any materials needed into the cabinet.

6.3.3 Do not block the front air intake grill or the rear exhaust grill.

6.3.4 Segregate the contaminated and clean items. Work from clean to dirty.

6.3.5 Minimize or eliminate the use of flames inside the cabinets. They can cause airflow disturbances and damage to the cabinet filters.

6.3.6 Chemicals in general should not be used within a BSC. If they must be used, only small quantities can be used in a Class I or Class II BSC that exhausts to the outside through a duct system. Flammables should not be used in any BSC. Contact EHS with questions regarding chemical use and BSCs.

6.3.7 Do not store excess equipment in the cabinets; this can cause airflow disturbances.

6.3.8 Clean the interior of the cabinet using 70% alcohol immediately following a spill or splash and at the end of the work session.

6.3.9 Allow the cabinet to run for several minutes at the end of the work session to ensure all contaminants have been removed.

6.4 Purchase of Laminar Flow Equipment

BSCs and LFBs must be approved by EHS prior to their purchase. EHS must confirm that the equipment is appropriate for the application. By approving the purchase of new equipment, cabinets can be added to the list of units to be certified annually. New cabinets must be certified upon installation and prior to their use. EHS funds the required annual certifications of these units.

Laminar flow clean benches provide product protection only and must not be used in conjunction with any hazardous materials due to their inability to protect the personnel using them or the environment. A properly used biosafety cabinet will, however, protect personnel, the environment, and the work itself. Because of the flexibility these cabinets provide, the University Biosafety Committee and the Biosafety Officer recommend the purchase of Biosafety Cabinets for both purposes. The committee discourages the acquisition of additional laminar flow benches on campus. If anyone wishes to purchase/acquire a laminar flow clean bench, it must be approved by the Biosafety Officer.

6.5 Certification of Laminar Flow Equipment

BSCs and LFBs are certified on an annual basis by an outside vendor contracted by EHS. Cabinets must also be certified upon installation at the university. The certification is necessary to verify proper function of the cabinets. Recertification is necessary if a cabinet is moved to a new location. Please notify the Biosafety Officer as soon as possible of any plans to move BSCs or LFBs, thereby allowing EHS to address any special hazards or concerns and to schedule any necessary decontamination procedures. EHS must have an accurate listing of all BSCs and LFBs for the annual certification.

# Chapter 7 Equipment Controls

## 7.1 Centrifuges

Centrifuges pose a hazard for aerosol generation. The hazard is particularly high if a tube breaks during centrifugation, but may also occur when opening tubes, decanting supernatant, and resuspending materials.

7.1.1 Follow the manufacturer's directions for safe use of the centrifuge, paying particular attention to proper balancing of the load.

7.1.2 Use sealed tubes, safety buckets, or rotors whenever possible to minimize the generation of aerosols in the event a tube breaks.

7.1.3 When possible, fill and open centrifuge tubes and safety buckets inside a BSC.

7.1.4 Disinfect centrifuges prior to any maintenance being performed on them.

7.1.5 If it sounds as if a tube has broken inside a centrifuge containing potentially infectious materials, stop the centrifuge. Have everyone leave the lab. DO NOT OPEN THE CENTRIFUGE. Contact EHS for guidance on how to proceed. Waiting time is necessary to allow any aerosols to settle.

7.1.6 If it is determined upon opening the centrifuge that a tube of potentially infectious materials has broken, close the lid to the centrifuge and have everyone leave the lab. Contact EHS for instruction on how to proceed. Waiting time is necessary to allow any aerosols to settle.

## 7.2 Autoclaves

Autoclaving is one of the most dependable methods for decontaminating laboratory waste. Autoclaves use saturated steam under pressure to achieve high temperatures to kill microorganisms. Attaining the proper temperature and length of time is essential for an effective kill. Material must be properly packaged to allow the steam to come in contact with the materials. Container lids must be loosened and bags of waste left unsealed or loosely sealed to allow steam to penetrate. Water may need to be added to a load of dry materials so enough steam is generated. Directions for the particular autoclave must be followed to attain an adequate kill. Wear heat-resistant gloves when adding or removing material from the autoclave.

Anyone operating an autoclave must be trained in the use of the unit. Records should be maintained on each load that is run. Indicators should be used to evaluate the effectiveness of the sterilization. Chemical indicators such as autoclave tape may be used on each load. Biological indicators should be used

regularly. The indicators are typically *Geobacillus stearothermophilus* spore strips or ampoules that are placed at locations throughout the autoclave. These spores are more resistant to heat than most. They can be killed at 250°F in 13 minutes. By killing the spores, verification of time and temperature of the unit is established, with reasonable certainty that most common agents have been killed.

7.3 Other equipment

A large concern with the use of many types of laboratory equipment is the generation of aerosols. Blenders, ultrasonic disrupters, grinders, loop sterilizers and Bunsen burners all have the potential for generating biohazardous aerosols. When possible, alternative equipment should be selected, such as using safety blenders that prevent leakage from the jar and have lids that seal. Equipment that may generate aerosols should be used inside of a biosafety cabinet, or the containers should only be opened inside a biosafety cabinet. Disposable plastic inoculating loops and needles are preferred over reusable styles. If a reusable style must be used, electric incinerators or glass bead sterilizers are preferred for loop sterilization. Continuous flame gas burners should not be used inside a biosafety cabinet because they create air turbulence, the continuous heat may damage the HEPA filters, and they present a fire hazard.

# Chapter 8 Bloodborne Pathogens

The University of Delaware's bloodborne pathogen (BBP) program was established in 1993 to protect workers who are exposed to blood or other potentially infectious materials in the workplace. It is designed to provide compliance with the Occupational Safety and Health Administration (OSHA) BBP Standard, 29 CFR1910.1030. EHS Protocol L-02 addresses the BBP program; a copy of the protocol is in Appendix A of this manual. Groups working with BBPs must be registered with EHS. A copy of the Exposure Control Plan (ECP) is provided in Appendix C of this manual. Employees covered under this program must receive annual training. Their departments provide them with PPE. The hepatitis B vaccine is provided to employees, or they are required to sign a waiver. Confidential exposure follow-ups are performed in the event of an exposure to a BBP.

# Chapter 9 Recombinant DNA

The University of Delaware complies with the NIH *Guidelines*. Any research involving recombinant DNA must be registered with the UBC. A copy of the *Guidelines* is available on the EHS web page. The *Registration Form for Recombinant DNA Research* is also available on the web page or through EHS, as are the procedures to have a protocol reviewed and approved. The form is also available through WebForms. Appendix E of this manual has a copy of the registration form and procedures.

# Chapter 10 Select Agents and Dual Use Research of Concern

## 10.1 Select Agents

The CDC enacted the "Antiterrorism and Effective Death Penalty Act of 1996" on April 15, 1997. The regulation required facilities that ship or receive certain microorganisms and toxins to be registered. In 2001 the USA PATRIOT Act was released, and then in 2002 the "Public Health Security and Bioterrorism Preparedness and Response Act" was released. These made it a criminal offense to possess select agents unless registered for bona fide purposes, and regulated their use and transport. The CDC and USDA regulate these agents and have certain requirements for working with them.

If anyone at the University of Delaware wishes to receive or work with any select agent, they must first contact the Biosafety Officer regarding registration requirements. The regulations are available on the EHS web page. The agents in this regulation include bacteria, viruses, rickettsiae, fungi, and some toxins. Complete lists are available at our web site and in Appendix D of this manual.

Certain toxins are exempt from the regulatory requirements when maintained below a certain quantity. The university has requirements in place to work with these exempt quantity toxins. Contact the Biosafety Officer for further information regarding this program.

## 10.2 Dual Use Research of Concern

Dual use research of concern is life sciences research that could be reasonably anticipated to provide knowledge, products, or technology that could be directly misused to pose a significant threat to public health, agriculture, or national security. The United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern applies to research that involves certain select agents. The categories of experiments that are covered include:

### 10.2.1 Enhances the harmful consequences of the agent or toxin

### 10.2.2 Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification

### 10.2.3 Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies

### 10.2.4 Increases the stability, transmissibility, or the ability to disseminate the agent or toxin

### 10.2.5 Alters the host range or tropism of the agent or toxin

10.2.6 Enhances the susceptibility of a host population to the agent or toxin

10.2.7 Generates or reconstitutes an eradicated or extinct agent or toxin from the list of covered select agents

There is no work taking place at the University of Delaware that falls into the above categories. If a researcher at the university wishes to work with select agents and may perform any of the above covered categories of experiments, they must first contact the Biosafety Officer and the University Biosafety Committee. An institutional review entity would be appointed to review the research and work with the researcher to draft a risk mitigation plan if needed.

# Chapter 11 Toxins

Toxins may be of biological origin or be used in biological research. For guidance on the safe handling of toxins, refer to Chapter 7 of the university's Chemical Hygiene Plan. There is a registration requirement for Highly Toxic/ Carcinogenic Materials. Any toxin with an LD50 of less than 50 mg/kg body weight must be registered through the Chemical Hygiene Committee.

Certain toxins are also considered Select Agents. Some of these are exempt from the Select Agent program if maintained below a certain quantity. A list of these is available in Appendix D of this manual. The university has requirements in place to work with these exempt quantity toxins. Contact the Biosafety Officer for further information regarding this program.

# Chapter 12 Packaging and Transportation

## 12.1 Introduction

The CDC, Department of Transportation (DOT), and International Air Transport Association (IATA) regulate transportation of biological materials. Each group has different definitions and regulations for these materials. Shipments to or from foreign countries may be subject to special importation or exportation requirements. Shipment of the materials must be performed according to the appropriate regulations. The transportation, or driving, of materials may also be regulated depending on the materials. Below are procedures for both shipping and transporting biologicals.

## 12.2 Procedures for Shipping Biological Materials

These procedures are for shipping biological materials through a carrier such as FedEx. For information regarding transporting (driving) materials, refer to the "Transporting Biological Materials" procedures. These procedures are only for biological materials. If the shipment contains chemicals follow the Chemical Shipment Procedures. If the shipment is radioactive, contact the Radiation Safety Officer at 831-1434.

### 12.2.1 Preparing for a shipment:

To begin the shipping process, you must complete the Hazardous Material Shipping Request Form. This is available on WebForms. Please submit the form a week prior to the desired shipping date in order to allow enough time to classify the materials and acquire the proper shipping materials if needed.

EHS will then determine whether the shipment meets the definition of hazardous materials per the DOT and/or IATA. You will be contacted via email or phone to inform you of the next step.

### 12.2.2 If the material is considered hazardous:

If your shipment meets the definition of a hazardous material, you will be contacted to schedule a time for EHS to perform the shipment for you.

### 12.2.3 If the material is NOT considered hazardous:

If EHS informs you the material itself is not hazardous, and it does not contain any chemicals or radioactive materials, you may ship it yourself. You will receive an email from EHS stating it is not hazardous and that you may ship it. This authorization is valid to use for shipments of the material stated, to the same recipient, under the same conditions for up to one year. You do not need to submit a new form for the exact same shipment during that year. If any of the conditions change, however, a new approval is needed.

Follow these guidelines if dry ice is NOT being used:

- Assure primary container is tightly sealed. Secure the cap with tape or parafilm. If the sample is liquid, ensure there is sufficient headspace in the container to allow for expansion.

- Wrap primary container in sufficient absorbent material to absorb the entire sample if the container were to break.
- Place the primary container and absorbent into a secondary container such as another screw-top tube or a heavy duty ziplock bag.
- Use a sturdy shipping box in good condition. Add padding as needed.
- Include a piece of paper inside the box stating that the samples are not regulated per DOT or IATA. Describe the samples on this sheet. A form will be provided for you to use, or a copy is available in Appendix E.

If the non-hazardous material is to be shipped on dry ice, follow these guidelines:

- You must have completed the DOT Dry Ice Shipping training within the previous 2 years. The training is available online through BioRAFT at https://delaware.bioraft.com.
- EHS will verify you have current DOT dry ice shipping training, then will contact you to authorize the shipment. We will send you a checklist to assist you in packaging the materials and will provide the necessary stickers and information on acceptable packaging materials.
- Complete the shipment per your training and the checklist.

12.2.4 Materials that are NOT regulated for shipping:
The following materials are NOT currently regulated by DOT or IATA for shipping purposes. You do not need to complete a Hazardous Material Shipping Request Form in order to ship these materials in quantities less than 100ml or 100g:

DNA samples from Biosafety Level 1 organisms
RNA samples from Biosafety Level 1 organisms
Proteins from Biosafety Level 1 organisms

As long as they do NOT contain any chemicals or radioactive materials, and they are NOT being shipped on dry ice, you may follow these procedures and perform the shipment yourself:

- Assure primary container is tightly sealed. Secure the cap with tape or parafilm. If the sample is liquid, ensure there is sufficient headspace in the container to allow for expansion.
- Wrap primary container in sufficient absorbent material to absorb the entire sample if the container were to break.
- Place the primary container and absorbent into a secondary container such as another screw-top tube or a heavy duty ziplock bag.
- Use a sturdy shipping box in good condition. Add padding as needed.
- Include a piece of paper inside the box stating that the samples are not regulated per DOT or IATA. Describe the samples on this sheet, including contact information for the shipper and recipient, and the emergency contact number for UD Public Safety- 302-831-2222. A form to use for this is available in Appendix E.

12.2.5 Any samples being shipped on dry ice are considered regulated and you must follow the dry ice procedures in Section 12.2.3. If you have any questions

or concerns about how your samples should be classified either complete the Hazardous Material Shipping Request Form or contact the Biosafety Officer at 831-1433.

12.3 Procedures for Transporting Biological Materials

These procedures are for driving or transporting biological materials by university personnel. For information regarding shipping biological materials through a carrier such as FedEx, refer to the "Shipping Biological Materials" procedures. These procedures are only for biological materials. If the samples contain chemicals contact the Chemical Hygiene Officer at 831-2103. If the samples are radioactive, contact the Radiation Safety Officer at 831-1434.

12.3.1 Are your samples considered hazardous?

The Department of Transportation (DOT) regulates the transportation of hazardous materials by road in the United States.

**The following categories of materials are considered hazardous according to the DOT (2019 edition):**

- Dry ice
- Infectious substances: material known to contain or suspected of containing a pathogen. A pathogen is a microorganism (including its bacteria, viruses, rickettsiae, parasites, or fungi) or a prion that can cause disease in humans or animals
- Patient specimens: human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue, tissue swabs, body parts, and specimens in transport media being transported for diagnosis, investigational activities, or disease treatment or prevention related to infectious disease. Diagnostic specimens that do NOT contain a pathogen or that contain a Risk Group 1 pathogen are not considered hazardous
- Cultures: material prepared and maintained for growth and storage and containing a Risk Group 2, 3, or 4 infectious substance
- Sharps: any object contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and also capable of cutting or penetrating skin or a packaging material. This includes needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires
- Materials which require a permit from USDA or CDC: contact EHS to verify transportation requirements

**The following materials are NOT considered hazardous for purposes of ground transportation:**

- Diagnostic specimens that do not contain a pathogen or that contain a Risk Group 1 pathogen
- Biological products that do not contain a pathogen or that contain a Risk Group 1 pathogen

- Blood or organs collected for transfusion or transplant
- A material that previously contained an infectious substance that has been treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance
- Environmental microbiological samples collected to evaluate occupational and residential exposure risks
- DNA, RNA, or protein samples from biosafety level 1 organisms
- Cell lines which are not known to be infected with Risk Group 2 or 3 agents

12.3.2 If the material is NOT considered hazardous per DOT:
Use the following procedures to transport samples which do NOT meet the DOT definition of hazardous materials:

- All materials must be transported and stored in a secondary container to prevent breakage. A secondary container must be capable of containing the materials if the primary container breaks or leaks. Absorbent materials must be included in the secondary container to absorb any liquids. Cushion the materials to prevent container breakage.

- Small amounts of biological materials in sealed containers can be transported in a cooler with a latching lid. The cooler will act as the approved secondary container. Inside this cooler must be enough absorbent or cushioning to prevent shifting during transport. The cooler must also be secured to prevent it from sliding or toppling during transport.

- Include on the cooler or container a sheet listing the materials being transported and the below-listed emergency phone numbers. Keep a copy with the driver as well. A form to use for this is available in Appendix E.

- It is best if the materials can be transported within the trunk if the vehicle has one. It is also recommended, though not required, that a university vehicle be used for the transportation. For security and safety purposes minimize stops along the route.

- It is prudent to carry a cell phone in case of any problems or emergencies along the way. If there is a problem during transport, contact EHS during normal business hours at 302-831-8475. After normal hours contact EHS via Public Safety at 302-831-2222.

12.3.3 If the material is considered hazardous per DOT:
A state agency or local jurisdiction that transports biological materials for its own use, using its own personnel and state-owned vehicles, is exempt from the DOT regulations as long as the material is not shipped for commerce, it remains within the state, and it is packaged according to these procedures. The University of Delaware must comply with the DOT regulations if it offers biological materials to a non-governmental carrier (by motor vehicle, aircraft, rail, or vessel) or transports these materials in “furtherance of a commercial enterprise”.

This procedure states the requirements for the packaging and transport of biologicals in a manner that will minimize the threat of release via container breakage during transport. Biological materials which are considered hazardous cannot be transported in privately owned or personal vehicles. All transport must be in a University of Delaware vehicle by a university employee. Biological materials can only be transported for the purposes of conducting research, field investigations, educational purposes and other official university business.

- All materials must be transported and stored in a secondary container to prevent breakage. A secondary container is capable of containing the materials if the primary container breaks or leaks. Absorbent materials must be included in the secondary container to absorb any liquids. Cushion the materials to prevent container breakage.

- Small amounts of biological materials in sealed containers can be transported in a cooler with a latching lid. The cooler will act as the approved secondary container. Inside this cooler must be enough absorbent or cushioning to prevent shifting during transport. The cooler must also be secured to prevent it from sliding or toppling during transport.

- Include on the cooler or container a sheet listing the name of the suspected infectious agent(s) or materials being transported and the below-listed emergency phone numbers. Keep a copy with the driver as well. A form to use for this is available in Appendix E.

- To transport materials on dry ice, you must have completed the DOT Dry Ice Shipping training within the previous 2 years. The training is available online through BioRAFT at https://delaware.bioraft.com. Package the samples as listed above in a sealed primary container and a secondary container which will contain the material if the original container were to break or leak. Place the samples, in their secondary container, in a Styrofoam lined sturdy cardboard box containing the dry ice. Tape the box shut.

  - It is best if the materials can be transported within the trunk if the vehicle has one. Samples containing dry ice should be transported in a truck. For security and safety purposes minimize stops along the route.

  - It is prudent to carry a cell phone in case of any problems or emergencies along the way. If there is a problem during transport, contact EHS during normal business hours at 302-831-8475. After normal hours contact EHS via Public Safety at 302-831-2222.

12.4 Resources

For questions regarding shipping or transporting biological materials please contact EHS. The following resources may also be helpful:

- International Air Transport Association. Dangerous Goods Information Hotline
514-390-6770
http://www.iata.org/whatwedo/cargo/dangerous_goods

- US Department of Transportation Office of Hazardous Materials Safety
800-467-4922
http://hazmat.dot.gov

- Centers for Disease Control and Prevention 404-639-3235
  - Importation Permits for Etiologic Agents and Packaging Guidelines
  http://www.cdc.gov/od/eaipp/

- US Department of Agriculture- Animal and Plant Health Inspection Service- Veterinary Services Import/Export
http://www.aphis.usda.gov/import_export/index.shtml

- Hazardous Materials Advisory Council
http://www.hmac.org

- Federal Express- Dangerous Goods
800-GO-FED-EX
http://www.fedex.com/us/services/options/dangerousgoods/

# Chapter 13 Infectious Waste Guidelines

EHS Protocol L-05 addresses the management of infectious waste at the university. The university's program meets the requirements of the State of Delaware's Department of Natural Resources and Environmental Control (DNREC). A copy of the policy is available in Appendix A.

## 13.1 Introduction

The following guidelines are to be used for the safe handling and disposal of infectious waste generated at the University of Delaware. No radioactive or hazardous waste will be handled through these guidelines. Consult the Radiation Safety Manual or your Department Chemical Hygiene Plan for the proper disposal of those respective wastes. For additional information regarding the Infectious Waste Disposal Program contact EHS at extension 8475 or consult the EHS web page.

## 13.2 Infectious Waste Management Guidelines

The responsibility for infectious waste identification, segregation, and packaging rests with the PI or area supervisor. The PI or area supervisor shall follow all of the procedures in the guidelines and provide proper instruction to personnel under their supervision.

All infectious waste generated at the university must be properly segregated from all other wastes. EHS will supply the appropriate boxes, bags, and sharps containers for segregation and disposal. A waste is infectious if it meets the following definition of infectious waste as written in the State of Delaware's Regulations Governing Solid Waste, Section 11, Part 1:

**Infectious Waste**- means those solid wastes which may cause human disease and may reasonably be suspected of harboring human pathogenic organisms, or may pose a substantial threat or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of or otherwise managed. Types of solid waste designated as infectious include, but are not necessarily limited to, the following:

### 13.2.1 **Biological wastes:**

a. **Biological liquid waste** means blood and blood products, excretions, exudates, secretions, suctionings, and other body fluids including liquid wastes from renal dialysis.

b. **Pathological waste** means all human tissues and anatomical remains, including human fetal remains, which emanate from surgery, obstetrical procedures, autopsy and laboratory procedures.

c. **Culture and stocks** of etiologic agents and associated biological wastes means, but is not limited to, specimen cultures and stocks of etiologic agents, and wastes from production of biologicals and serums.

d. **Laboratory wastes** means those wastes that have come in contact with pathogenic organisms or blood or body fluids. Such wastes include, but are not limited to, disposable materials; culture dishes; devices used to transfer, inoculate, and mix cultures; paper and cloth which has come in contact with specimens or cultures which have not been sterilized or rendered noninfectious; or laboratory wastes, including cultures of etiologic agents, which pose a substantial threat to health due to their volume and virulence.

e. **Animal tissue, bedding and other wastes from animals** known or suspected to be infected with a pathogen which also causes human disease, provided that prevailing evidence indicates that such tissue, bedding or other waste may act as a vehicle of transmission to humans.

f. **Human dialysis waste** materials including blood lines and dialysate membranes.

13.2.2 **Sharps** means any discarded article that may cause punctures or cuts. Such wastes include, but are not limited to, needles, intravenous (IV) tubing with needles attached, scalpel blades, glass slides, glassware, and syringes that have been removed from their original sterile containers.

13.2.3 **Discarded biologicals** means serums and vaccines produced by pharmaceutical companies for human or veterinary use. These products may be discarded because of a bad manufacturing lot (i.e., off-specification material that does not pass quality control or that is recalled), out-dating or removal of the product from the market or other reasons. Because of the possible presence of etiologic agents in these products, the discarded material constitutes infectious waste.

13.2.4 **Other infectious waste means** any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill of any infectious waste.

13.2.5 The NIH requires that all waste from recombinant microorganism work be decontaminated prior to disposal. Certain permits for work, such as from the USDA, may require that waste be handled as infectious or be disinfected prior to leaving the lab. An example of this is USDA and NIH requirements that all recombinant plant work be handled as infectious waste.

13.2.6 **Infectious waste** that has been sterilized or disinfected by autoclaving or chemical treatment **must** still be disposed of following the procedures outlined in these guidelines.

13.3 Segregation and Packaging Requirements

Liquid infectious waste may be discarded into the sanitary sewer system, if appropriate, following treatment with an appropriate disinfectant. Do not place large quantities (greater than 20 ml) of liquid infectious waste into the boxes supplied by EHS.

All waste, except sharps (see definition) and infectious animal carcasses and/or tissues, that is determined to be infectious must be placed into an infectious waste box which is lined with two red infectious waste bags. Make sure the bottom of the box is secured with packing tape. The bags and boxes are supplied by EHS.

All BSL3 waste must be autoclaved prior to disposal in the infectious waste container. Waste at a lower biosafety level should be autoclaved prior to placing in an infectious waste container if it presents a risk to individuals handling it or if it could harm animals or the environment if it is accidentally released prior to incineration. Some departments may require that all infectious waste be autoclaved prior to disposal in the infectious waste containers.

The waste vendor will not accept boxes over 45lb. When the infectious waste box is full or 45lb, seal each of the red infectious waste bags individually. Each bag is to be sealed by twisting the top of the bag into a gooseneck and wrapping with a sufficient amount of strong tape (ex. duct tape, packaging tape). **NOTE:** Do not overfill the box. The flaps to the top of the box must be able to close without obstruction.

If exterior contamination of the infectious waste container occurs, it shall be placed in a second container meeting the same requirements as the original container.

Sharps are to be placed into rigid, puncture-resistant containers supplied or approved by EHS. Clipping, breaking and recapping of needles and resheathing of scalpels is not permitted in order to prevent aerosol generation and accidental punctures or cuts. Under no circumstances shall a discarded sharp (used or unused) be removed from a sharps container. Do not overfill the container. The container should be discarded when it is 3/4 full. When the sharps container is 3/4 full, tightly seal the container and place into a properly lined infectious waste disposal box. Please use the following guidelines for disposal of sharps:

- Syringes with or without a needle attached must all go into a sharps container. This is a state regulation.

- Contaminated micropipettes, pipette tips, and Pasteur pipettes must be treated as sharps. They shall be discarded in a puncture-resistant container or a sharps container for disposal through the infectious waste program. Large contaminated pipettes may go into an infectious waste box if care is used to prevent them from puncturing the box and bags, or they may be discarded into the original cardboard or fiberboard box after the original container has been lined with plastic to contain any liquid. This container is then discarded through the infectious waste program.

- Razor blades, lancets, scalpels, broken contaminated glassware and any other contaminated items that could cut or pierce the skin will go into a sharps container.

When the infectious waste box is full and the box has been sealed, either place it in your department's designated storage location or contact EHS for a pick-up if your facility is on the Newark campus. The EHS website has a form to request an infectious waste pickup (http://www.udel.edu/ehs/waste/infectious-waste-pick-up.html). Infectious waste will be picked up on a weekly basis. The following information will be required at the time of your request for service:

a. Name
b. Building
c. Laboratory room number
d. Number of boxes to be picked up
e. Packaging supplies needed (number of boxes and/or sharps containers)

Departments may be authorized by EHS to establish a local storage area for waste prior to collection by the disposal contractor.

Infectious animal carcasses and/or tissues will be handled separately. All infectious animal carcasses and/or tissues should be double-bagged using 3 mil red infectious waste bags supplied by EHS. Small animal carcasses can be individually wrapped and collected together in a larger bag. Store carcasses in your freezer or your department's designated cold storage area. Call EHS (ext. 8475) for pick up.

Containers for sharps disposal and for infectious waste at any satellite campus or research facility shall be available from a vendor approved by EHS. Collection of filled containers shall also be done by a vendor approved by EHS.

13.4 Gel Waste Disposal

Because gels are used by so many biological labs, their disposal procedures have been included here.

13.4.1 Ethidium bromide and agarose solid gels can be collected in a sealed bag and placed in the infectious waste box for disposal. Acrylamide gels must be collected in a sealed bag or container and managed as chemical waste

if they were made at the University by research staff. Acrylamide gels which were purchased pre-cast, ready to use, and came with a manufacturer certification that they contain no free acrylamide can be collected in a bag and placed in the infectious waste.

13.4.2 Acrylamide and ethidium bromide reagents must be managed as chemical waste. Liquid acrylamide and ethidium bromide must be managed as non-corrosive aqueous chemical waste. Liquid agarose can be poured down the sink drain with copious amounts of water, or packaged in a sealed container and placed in an infectious waste box.

13.4.3 Some waste buffers can be poured down the drain with copious amounts of water. However, they must be uncontaminated. If they are used as a running solution with ethidium bromide, run the solution through an ethidium bromide filter first and then place the used filter in the infectious waste box. An example of an acceptable filter available through VWR is the Schleicher & Schuell Extractor Ethidium Bromide Waste Reduction System. If a buffer was used as a running solution for acrylamide gels, it must be managed as a non-corrosive aqueous chemical waste. Buffers that can be poured down the drain include phosphate buffers and SDS. Contact EHS for guidance on other buffers.

13.4.4 Staining and de-staining solutions must be managed as non-corrosive aqueous chemical waste.

# Chapter 14 Disinfectants and Decontamination

For the safety of employees and the environment, it is very important that work surfaces and materials be properly cleaned when a spill occurs and at the conclusion of a work period. There is specific terminology to indicate the level of cleaning to be achieved. Certain agents only work against certain microorganisms, so it is crucial that the appropriate agent be used for the application.

## 14.1 Terminology

14.1.1 Decontamination- destruction or removal of microorganisms to some lower level, but not necessarily zero.

14.1.2 Sanitization- reduction of microbial load on an inanimate surface to an acceptable level.

14.1.3 Disinfection- chemical or physical treatment that destroys most resistant vegetative microbes or viruses, but not the spores, on inanimate objects.

14.1.4 Sterilization- complete destruction of all viable organisms.

## 14.2 Types of Disinfectants/ Sterilants

14.2.1 Formaldehyde gas is used to decontaminate biosafety cabinets, HEPA filters, and the BSL3 facilities.

14.2.2 Most other disinfectants/ sterilants are liquids. Below is a listing of the compounds and some of their properties.

## 14.3 Decontamination Information

It is important to make sure the appropriate disinfectant is used for the work being performed. The instructions on the agent must be followed. Dilution, shelf life, and contact time are all vital to assuring an effective kill. Care must be used to ensure mixing of incompatible materials does not occur.

## 14.4 Laboratory Decommissioning Procedures

Chemical, biological and radioactive materials are used and stored within designated areas for teaching and research purposes throughout the University of Delaware. These designated areas can become contaminated with residues over a period of time and use. Contamination typically results from spills, splashes, failed containers, uncontrolled chemical reactions, storage of incompatible chemicals next to each other and simply using the areas for their intended purposes.

If a laboratory needs to be decommissioned for renovation, transfer to another principal investigator or any other reason these steps must be followed:

14.4.1 The department requesting the cleaning must contact EHS at 831-8475 to evaluate the laboratory.

14.4.2 EHS will review the historical use of chemical, biological and radioactive materials within the laboratory.

14.4.3 EHS will inspect the laboratory.

14.4.4 EHS will determine whether the area needs to be decontaminated by a qualified contractor or simply cleaned by Custodial Services. Custodial Services personnel are not trained or equipped to clean areas that are contaminated with chemical, biological and radiological residues; therefore, they cannot clean contaminated areas.

14.4.5 EHS will coordinate with a qualified contractor to schedule and perform the cleaning, if needed.

14.4.6 EHS will confirm that the contractor adequately cleaned the laboratory and will provide written confirmation to the requesting department contact.

14.4.7 Laboratories may not be renovated or reoccupied until EHS has confirmed that the area is adequately cleaned.

14.4.8 All costs associated with the cleaning of a laboratory will be charged back to the requesting department if it is necessary to hire a qualified contractor.

Laboratories for the purpose of this procedure are defined as entire rooms or as designated areas within rooms such as fume hoods and associated ductwork, photographic darkrooms, glove-boxes, sinks, biosafety cabinets, storage cabinets and shelves, closets, refrigerators, freezers and lab equipment where chemical, biological and radiological materials are used and stored.

## DISINFECTANTS

| Compound | Example | Effective Against: | | | | Used On: | | | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | Bact. | Virus | Spores | TB | Skin | Instr. | Env. | |
| Alcohols | Ethanol, isopropanol | Good | Mod. | No | Good | X | X | | |
| Chlorine | Sodium hypochlorite (bleach) | Good | Good | Mod. | Good | | X | X | Corrosive to metal, bleach fabric |
| Glutaraldehyde | Cidex | Good | Good | Good | Good | | X | | |
| Iodine | Betadine, Wescodyne | Good | Good | Mod. | Good | X | | X | May be corrosive |
| Phenol | Wexcide, Vesphene, Amphyl spray | Good | Mod. | No | Good | | X | X | |
| Quaternary Ammonium | Roccal, Virex Disinfectant, Saniplex | Good | Mod. | No | No | | X | X | |

Notes:
Bact. = Bacteria
TB = Tuberculosis
Instr. = Instruments
Env. = Environmental surfaces
Mod. = Moderate action

# Chapter 15 Spill Protocols

## 15.1 BSL2 Spills

15.1.1 Small spills: Wipe up spill with a disinfectant-soaked paper towel and clean the surface with a suitable disinfectant.

15.1.2 Larger spills within a BSC

15.1.2.1 Cabinet must run during cleanup to contain aerosols and HEPA-filter exhaust air.

15.1.2.2 Don appropriate personal protective equipment before initiating cleanup.

15.1.2.3 Initiate cleanup as soon as possible using a germicidal disinfectant (phenolic or iodophor). Alcohol is <u>not</u> recommended. Large quantities may create the risk of fire.

15.1.2.4 If the spill is contained on a bench diaper, remove the contaminated bench diaper and discard as infectious waste.

15.1.2.5 If the spill is on the work surface, cover spilled material with disinfectant-soaked towels. Allow 20 minutes contact time then remove the contaminated towels and discard as infectious waste.

15.1.2.6 Wipe down the interior of the cabinet and any splatter on items within the cabinet with a disinfectant-soaked towel.

15.1.2.7 Wipe down non-autoclavable materials with disinfectant. Allow 20 minutes of contact time with disinfectant before any items are removed from cabinet.

15.1.2.8 Place items designated as <u>contaminated used sharps</u> in a sharps container *using tongs/forceps*. Place other contaminated disposable materials used in the cleanup process in an infectious waste bag. Process as infectious waste.

15.1.2.9 Place contaminated re-usable items in biohazard bags or autoclavable pans with lids. Sterilize, preferably by autoclaving, then clean for re-use.

15.1.2.10 If the cabinet has a catch basin beneath the work surface and the spill resulted in liquids flowing into this area, more extensive decontamination is required.

-Ensure the drain valve under the cabinet is closed.

-Pour disinfectant onto the work surface and through the front and rear grilles into the drain pan. Allow 20-30 minutes contact time.

-Absorb spilled fluid-disinfectant from work surface with paper towels and discard in biohazard bag.

15.1.2.11 Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving. Wash hands whenever gloves are removed.

15.1.2.12 Notify PI or supervisor and EHS. Consult with EHS to determine whether formaldehyde decontamination of the cabinet and filters is necessary, especially if a high-risk agent or a major spill of a moderate-risk agent occurred.

15.1.2.13 Run BSC at least 10 minutes after cleanup, before resuming activity in the cabinet.

15.1.3 Large spills inside the laboratory

15.1.3.1 If a spill occurs in a BSL2 facility, outside the BSC, notify other individuals in the laboratory to evacuate.

15.1.3.2 Exit the laboratory, closing the door behind you.

15.1.3.3 Remove any contaminated clothing and place it in an autoclave bag.

15.1.3.4 Wash all exposed skin.

15.1.3.5 Place signs on door(s) to the laboratory warning individuals who may want to enter that a spill occurred and access is denied.

15.1.3.6 Allow aerosols to settle for 30 minutes before re-entering the laboratory.

15.1.3.7 Assemble supplies (disinfectant, sharps containers, towels, tongs, autoclave bags, etc.) before entering the laboratory.

15.1.3.8 Don appropriate personal protective equipment (i.e. disposable gown, protective eyewear, gloves, shoe coverings and respiratory protection if needed).

15.1.3.9 Clean up spill with a suitable disinfectant as follows:

-Surround spill area with disinfectant or diking material that is soaked in disinfectant.
-Place paper towels soaked in a disinfectant over the entire spill area.
-Allow 20 minute contact time with the disinfectant to ensure adequate germicidal action.
-Wipe down non-autoclavable materials with germicidal disinfectant.
-Place items designated as <u>contaminated used sharps</u> in a sharps container. Place other disposable materials used in the cleanup process in an infectious waste bag. Process as infectious waste.
-Place contaminated re-usable items in biohazard bags or autoclavable pans with lids. Sterilize, preferably by autoclaving, then clean for re-use.

15.1.3.10 Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving.

15.1.3.11 Wash hands whenever gloves are removed.

15.1.3.12 Notify PI or supervisor and EHS.

15.1.4 Large spills inside a centrifuge

The potential for multiple infections from a single centrifuge accident is great. Aerosols are created when fluid escapes from the rotor or cup while the centrifuge is operating at high speed. All opening of centrifuges must be performed slowly.

If a centrifuge tube breaks while the centrifuge is running, turn off the motor. Allow the machine to be at rest for 30 minutes before opening. DO NOT OPEN THE CENTRIFUGE. If breakage is discovered after the machine has stopped, re-close the lid immediately and allow the unit to be at rest for 30 minutes. Have all personnel leave the lab and call EHS for guidance on how to proceed.

15.2 BSL3 Spills

15.2.1 Spills within a BSC

15.2.1.1 Cabinet must run during cleanup to contain aerosols and HEPA-filter exhaust air.

15.2.1.2 Don appropriate personal protective equipment before initiating cleanup (disposable gown, double gloves, safety glasses).

15.2.1.3 Initiate clean-up as soon as possible using a germicidal disinfectant (phenolic or iodophor). Alcohol is <u>not</u> recommended. Large quantities may create risk of fire.

15.2.1.4 If the spill is small and contained on a bench diaper, remove the contaminated bench diaper, and discard as infectious waste.

15.2.1.5 If the spill is small and on the work surface, cover spilled material with disinfectant-soaked towels. Allow 20 minutes contact time then remove the contaminated towels and discard as infectious waste.

15.2.1.6 Wipe down the interior of the cabinet and any splatter on items within the cabinet with a disinfectant-soaked towel.

15.2.1.7 Wipe down non-autoclavable materials with disinfectant. Allow 20 minutes of contact time with disinfectant before any items are removed from cabinet.

15.2.1.8 Place items designated as contaminated used sharps in a sharps container *using tongs/forceps*. Place other contaminated disposable materials used in the cleanup process in an autoclave bag. Process as infectious waste.

15.2.1.9 Place contaminated re-usable items in biohazard bags or autoclavable pans with lids. Sterilize, preferably by autoclaving, then clean for re-use.

15.2.1.10 If the cabinet has a catch basin beneath the work surface and the spill resulted in liquids flowing into this area, more extensive decontamination is required.
-Ensure the drain valve under the cabinet is closed.
-Pour disinfectant onto the work surface and through the front and rear grilles into the drain pan. Allow 20-30 minutes contact time.
-Absorb spilled fluid-disinfectant from work surface with paper towels and discard in biohazard bag.

15.2.1.11 Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving. Wash hands after removing gloves.

15.2.1.12 Notify PI or supervisor and EHS. Consult with EHS to determine whether formaldehyde decontamination of the cabinet and filters is necessary.

15.2.1.13 Run BSC at least 10 minutes after cleanup, before resuming activity in the cabinet.

15.2.2 Spills inside the laboratory

15.2.2.1 Notify other individuals in the laboratory to evacuate the laboratory immediately.

15.2.2.2 Hold your breath and exit the laboratory to the anteroom.

15.2.2.3 Remove contaminated clothing (place into autoclave bag). Wash hands after gloves are removed.

15.2.2.4 Wash all exposed skin with germicidal soap. If eyes were splashed, flush at eyewash station for 15 minutes then contact EHS.

15.2.2.5 Notify PI or supervisor and EHS. EHS will consult with the PI to determine the appropriate method of decontamination and spill cleanup (personnel spill response or formaldehyde decontamination of the entire facility).

15.2.2.6 Place a sign on the door to the BSL3 lab, to warn individuals of the spill and advise them keep out of the lab.

If personnel spill response is required, do the following:

15.2.2.7 Allow aerosols to settle for a minimum of 30 minutes before re-entering the laboratory.

15.2.2.8 Assemble supplies (disinfectant, sharps containers, towels, tongs, autoclave bags and protective equipment [disposable Tyvek suit/back-closing gown, protective eyewear, gloves, shoe coverings, respiratory protection], etc.) before initiating spill cleanup.

15.2.2.9 Don appropriate PPE. Double gloving is recommended.

15.2.2.10 Clean up spill with a suitable disinfectant as follows:
- -Surround spill area with disinfectant or diking material that is soaked in disinfectant.
- -Place paper towels soaked in a disinfectant over the entire spill area.
- -Allow a minimum 20 minute contact time with the disinfectant to ensure adequate germicidal action.
- -Wipe down non-autoclavable materials with germicidal disinfectant, allowing 20 minute contact time.
- -Place items designated as <u>contaminated used sharps</u> in a sharps container *using tongs/forceps*. Place other contaminated disposable materials used in the cleanup process in an autoclave bag. Process as infectious waste.
- -Place contaminated autoclavable re-usable items in biohazard bags or autoclavable pans with lids. Sterilize, preferably by autoclaving, then clean for re-use.
- -Repeat decontamination of spill area (floor and work surfaces) after contaminated materials are removed.

15.2.2.11 Remove outer gloves before exiting laboratory to the anteroom.

15.2.2.12 Remove protective clothing used during cleanup in the following order: shoe coverings, gown/suit, respiratory protection, and gloves last. If reusable, wipe down respirator with disinfectant. Place disposable PPE in a biohazard bag for autoclaving.

15.2.2.13 Wash hands with germicidal soap after gloves are removed; showering is recommended.

15.2.3 Spills inside a centrifuge

The potential for multiple infections from a single centrifuge accident is great. Aerosols are created when fluid escapes from the rotor or cup while the centrifuge is operating at high speed. All opening of centrifuges must be performed slowly.

If a centrifuge tube breaks while the centrifuge is running, turn off motor. Allow the machine to be at rest for 30 minutes before opening. DO NOT OPEN THE CENTRIFUGE. If breakage is discovered after the machine has stopped, re-close the

lid immediately and allow the unit to be at rest for 30 minutes. Have all personnel leave the lab and call EHS for guidance on how to proceed.

# Chapter 16 Exposure Follow-ups

Even when precautions are followed an accidental exposure may occur. If an exposure occurs, administer first aid if needed. In the event of a major injury, contact UDPD by dialing 911 or picking up a red phone. If it is not a major injury, wash the contaminated area thoroughly with soap and water. A splash to the face should be flushed thoroughly with water. If the material or substance involved in the exposure can be identified do not dispose of it. It may be possible to test the material for certain pathogens. Notify EHS of the exposure so any necessary medical follow-up that is indicated may be implemented. After hours, or when university offices are closed, Public Safety can contact EHS. When the immediate needs of the patient have been met, the appropriate accident documentation must be completed. EHS can advise regarding what forms must be completed.

# Chapter 17 Training Requirements

Biosafety training is required for anyone working with biological materials. The subjects to be covered are dependent on the biosafety level of the labs. All employees and research staff working with biological materials must attend initial biosafety training prior to initiating biological research then refresher training every two years. More in-depth training is provided for individuals working at BSL3.

Bloodborne pathogens training is required annually for any employees or students who will be exposed to blood or other potentially infectious materials, as defined in the BBP ECP, through their work or studies at the university. Recombinant DNA Research Training is required for anyone participating in a research project covered by the NIH *Guidelines*. The training must be completed prior to initiation of the work, then every three years. Autoclave safety training is available for anyone operating an autoclave.

There are several options for receiving training. Sessions are provided at EHS on a regular basis. The schedule is available on the EHS web page. Sessions can be scheduled for individual groups by contacting EHS. All of these trainings are also available through online training in the BioRAFT program. Completion of an online training is recorded in BioRAFT automatically.

# Chapter 18 Procedures for Regulatory Inspections at the University of Delaware

On occasion the University may be visited by federal or state regulatory inspectors. This could include, but is not limited to, representatives from the Nuclear Regulatory Commission, Delaware Department of Natural Resources and Environmental Control, US Department of Agriculture, the Environmental Protection Agency, Delaware Department of Agriculture, US Department of Transportation, the Federal Aviation Administration, Centers for Disease Control and Prevention, or the Department of Health and Human Services. Some of these groups may contact the Department of Environmental Health and Safety (EHS) or the Research Office to initiate an inspection, but others may just present themselves at a lab or building. If this occurs, it is recommended that you follow these procedures:

- Request identification or credentials from the inspector. Write down the inspector's name and affiliation. If satisfactory credentials are not provided, do not offer any further assistance and contact Public Safety immediately.
- Contact EHS at x8475 to inform them of the inspection. Provide the affiliation of the inspector when calling to assure the proper response from EHS.
- As per your lab or department's policy, contact your PI, department chair and/or building manager to inform them of the inspector's presence. The department chair and the director of EHS should advise the administration that the inspector is on site and arrange for any close-out conferences requested.
- Do not decline the inspection, however ask the inspector if they can wait until one or more of the above individuals can join the inspection. At a minimum, the PI or EHS representative should be present before proceeding. If EHS is not present before the inspection starts, please take notes of what is said and/or visited until they arrive.
- Answer the inspector's questions, but only provide the information or files that are specifically requested. Do not volunteer information. If the inspector asks to take pictures, do not allow it unless you are able to also take the same pictures for the university's records or verify that they will make them available to the university as well.
- The inspector's status does not authorize him/her to handle any hazardous material in your facility so do not permit this.
- The inspector must always be accompanied by you or other University personnel during the inspection so do not allow them unescorted access to your facility.
- Assure that the inspector wears all appropriate or required personal protective equipment.

If you are contacted to schedule an inspection, please inform EHS and allow the appropriate personnel to be present to assist with the inspection. If you have any questions regarding these procedures, please contact EHS at 831-8475.

# Chapter 19 References

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# Appendix B Classification of Infectious Agents*

## Risk Group 1 (RG1) Agents

RG1 agents are not associated with disease in healthy adult humans. Examples of RG1 agents include asporogenic *Bacillus subtilis* or *Bacillus licheniformis*; adeno- associated virus (AAV – all serotypes); and recombinant or synthetic AAV constructs, in which the transgene does not encode either a potentially tumorigenic gene product or a toxin molecule and are produced in the absence of a helper virus. A strain of *Escherichia coli* is an RG1 agent if it (1) does not possess a complete lipopolysaccharide (*i.e.*, lacks the O antigen); and (2) does not carry any active virulence factor (*e.g.*, toxins) or colonization factors and does not carry any genes encoding these factors.

Those agents not listed in Risk Groups (RGs) 2, 3 and 4 are not automatically or implicitly classified in RG1; a risk assessment must be conducted based on the known and potential properties of the agents and their relationship to agents that are listed.

## Risk Group 2 (RG2) Agents

RG2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

<u>Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia</u>

--Acinetobacter baumannii (formerly Acinetobacter calcoaceticus)
--Actinobacillus
--Actinomyces pyogenes (formerly Corynebacterium pyogenes)
--Aeromonas hydrophila
--Amycolata autotrophica
--Archanobacterium haemolyticum (formerly Corynebacterium haemolyticum)
--Arizona hinshawii - all serotypes
--Bacillus anthracis
--Bartonella henselae, B. quintana, B. vinsonii
--Bordetella including B. pertussis
--Borrelia recurrentis, B. burgdorferi
--Burkholderia (formerly Pseudomonas species) except those listed in Risk Group 3
--Campylobacter coli, C. fetus, C. jejuni
--Chlamydia psittaci, C. trachomatis, C. pneumoniae
--Clostridium botulinum, C. chauvoei, C. haemolyticum, C. histolyticum, C. novyi, C. septicum, C. tetani
--Corynebacterium diphtheriae, C. pseudotuberculosis, C. renale
--Coxiella burnetii- specifically the Phase II, Nine Mile strain, plaque purified, clone 4
--Dermatophilus congolensis
--Edwardsiella tarda
--Erysipelothrix rhusiopathiae

--Escherichia coli - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including E. coli O157:H7
--Francisella tularensis, specifically F. tularensis subspecies novocida strain Utah 112; F. tularensis subspecies holarctica LVS; F. tularensis biovar tularensis strain ATCC 6223 (aka strain B38) *For research involving high concentrations, BSL3 practices should be considered.
--Haemophilus ducreyi, H. influenzae
--Helicobacter pylori
--Klebsiella - all species except K. oxytoca (RG1)
--Legionella including L. pneumophila
--Leptospira interrogans - all serotypes
--Listeria
--Moraxella
--Mycobacterium (except those listed in RG3) including M. avium complex, M. asiaticum, M. bovis BCG vaccine strain, M. chelonae, M. fortuitum, M. kansasii, M. leprae, M. malmoense, M. marinum, M. paratuberculosis, M. scrofulaceum, M. simiae, M. szulgai, M. ulcerans, M. xenopi
--Mycoplasma, except M. mycoides and M. agalactiae which are restricted animal pathogens
--Neisseria gonorrhoeae, N. meningitidis
--Nocardia asteroides, N. brasiliensis, N. otitidiscaviarum, N. transvalensis
--Pseudomonas aeruginosa
--Rhodococcus equi
--Salmonella including S. arizonae, S. choleraesuis, S. enteritidis, S. gallinarum-pullorum, S. meleagridis, S. paratyphi, A, B, C, S. typhi, S. typhimurium
--Shigella including S. boydii, S. dysenteriae, type 1, S. flexneri, S. sonnei
--Sphaerophorus necrophorus
--Staphylococcus aureus
--Streptobacillus moniliformis
--Streptococcus including S. pneumoniae, S. pyogenes
--Treponema pallidum, T. carateum
--Vibrio cholerae, V. parahaemolyticus, V. vulnificus
--Yersinia enterocolitica
--Yersinia pestis specifically pgm(-) strains and lcr(-) strains

Risk Group 2 (RG2) - Fungal Agents

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

--Penicillium marneffei
--Sporothrix schenckii
--Trichophyton

Risk Group 2 (RG2) - Parasitic Agents

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

Risk Group 2 (RG2) - Viruses

Adenoviruses, human - all types

Alphaviruses (Togaviruses) - Group A Arboviruses
--Chikungunya vaccine strain 181/25
--Eastern equine encephalomyelitis virus
--Venezuelan equine encephalomyelitis vaccine strain TC-83 and V3526
--Western equine encephalomyelitis virus

Arenaviruses
--Junin virus candid #1 vaccine strain
--Lymphocytic choriomeningitis virus (non-neurotropic strains)
--Tacaribe virus complex
--Other viruses as listed in "Biosafety in Microbiological and Biomedical Laboratories"

Bunyaviruses
--Bunyamwera virus
--Rift Valley fever virus vaccine strain MP-12
--Other viruses as listed in "Biosafety in Microbiological and Biomedical Laboratories"

Caliciviruses

Coronaviruses

Flaviviruses - Group B Arboviruses
--Dengue virus serotypes 1, 2, 3, and 4
--Japanese encephalitis virus strain SA 14-14-2
--Yellow fever virus vaccine strain 17D
--Other viruses as listed in "Biosafety in Microbiological and Biomedical Laboratories"

Hepatitis A, B, C, D, and E viruses

Herpesviruses - except Herpesvirus simiae (Monkey B virus) (see Risk Group 4 (RG4) - Viral Agents)
--Cytomegalovirus
--Epstein Barr virus
--Herpes simplex types 1 and 2
--Herpes zoster
--Human herpesvirus types 6 and 7

Orthomyxoviruses
--Influenza viruses types A, B, and C (except those listed in Risk Group 3 (RG3)- Viruses and Prions)
--Tick-borne orthomyxoviruses

Papilloma viruses
--All human papilloma viruses

Paramyxoviruses

--Newcastle disease virus
--Measles virus
--Mumps virus
--Parainfluenza viruses types 1, 2, 3, and 4
--Respiratory syncytial virus

Parvoviruses
--Human parvovirus (B19)

Picornaviruses
--Coxsackie viruses types A and B
--Echoviruses - all types
--Polioviruses - all types, wild and attenuated
--Rhinoviruses - all types

Poxviruses - all types except Monkeypox virus (see Risk Group 3 (RG3) - Viruses and Prions) and restricted poxviruses including Alastrim, Smallpox, and Whitepox

Reoviruses - all types including Coltivirus, human Rotavirus, and Orbivirus (Colorado tick fever virus)

Rhabdoviruses
--Rabies virus - all strains
--Vesicular stomatitis virus non-exotic strains: VSV-Indiana 1 serotype strains (e.g. Glasgow, Mudd-Summers, Orsay, San Juan) and VSV-New Jersey serotype strains (e.g. Ogden, Hazelhurst)

Rubivirus (Togaviruses)
--Rubella virus

**Risk Group 3 (RG3) Agents**

RG3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions *may* be available.

Risk Group 3 (RG3) - Bacterial Agents Including Rickettsia

--Bartonella
--Brucella including B. abortus, B. canis, B. suis
--Burkholderia (Pseudomonas) mallei, B. pseudomallei
--Coxiella burnetii (except the Phase II, Nine Mile strain listed in Risk Group 2 (RG2) – Bacterial Agents including Chlamydia)
--Francisella tularensis (except those strains listed in Risk Group 2 (RG2) – Bacterial Agents including Chlamydia)

--Mycobacterium bovis (except BCG strain, see RG2 - Bacterial Agents Including Chlamydia), M. tuberculosis
--Orientia tsutsugamushi (was R. tsutsugamushi)
--Pasteurella multocida type B -"buffalo" and other virulent strains
--Rickettsia akari, R. australis, R. canada, R. conorii, R. prowazekii, R. rickettsii, R, siberica, R. typhi (R. mooseri)
--Yersinia pestis (except those strains listed in Risk Group 2 (RG2) – Bacterial Agents including Chlamydia)

Risk Group 3 (RG3) - Fungal Agents

--Coccidioides immitis (sporulating cultures; contaminated soil)
--Histoplasma capsulatum, H. capsulatum var. duboisii

Risk Group 3 (RG3) - Parasitic Agents

None

Risk Group 3 (RG3) - Viruses and Prions

Alphaviruses (Togaviruses) - Group A Arboviruses
--Chikungunya virus (except the vaccine strain 181/25 listed in Risk Group 2 (RG2) - Viruses
--Semliki Forest virus
--St. Louis encephalitis virus
--Venezuelan equine encephalomyelitis virus (except the vaccine strain TC-83 and V3526, see Risk Group 2 (RG2) – Viruses)
--Other viruses as listed in "Biosafety in Microbiological and Biomedical Laboratories"

Arenaviruses
--Flexal
--Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)

Bunyaviruses
--Hantaviruses including Hantaan virus
--Rift Valley fever virus

Coronaviruses
--SARS-associated coronavirus (SARS-CoV)
--Middle East respiratory syndrome coronavirus (MERS-CoV)

Flaviviruses - Group B Arboviruses
--Japanese encephalitis virus (except those strains listed in Risk Group 2 (RG2) – Viruses)
--West Nile virus (WNV)

--Yellow fever virus
--Other viruses as listed in "Biosafety in Microbiological and Biomedical Laboratories"

Orthomyxoviruses
--Influenza viruses 1918-1919 H1N1 (1918 H1N1), human H2N2 (1957-1968), and highly pathogenic avian influenza H5N1 strains within the Goose/Guangdong/96-like H5 lineage (HPAI H5N1)

Poxviruses
--Monkeypox virus

Prions
--Transmissible spongiform encephalopathies (TSE) agents (Creutzfeldt-Jacob disease and kuru agents)(see "Biosafety in Microbiological and Biomedical Laboratories" for containment instruction)

Retroviruses
--Human immunodeficiency virus (HIV) types 1 and 2
--Human T cell lymphotropic virus (HTLV) types 1 and 2
--Simian immunodeficiency virus (SIV)

Rhabdoviruses
--Vesicular stomatitis virus (except those strains listed in Risk Group 2 (RG2) – Viruses)

**Risk Group 4 (RG4) Agents**

RG4 agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available.

Risk Group 4 (RG4) - Bacterial Agents

None

Risk Group 4 (RG4) - Fungal Agents

None

Risk Group 4 (RG4) - Parasitic Agents

None

Risk Group 4 (RG4) - Viral Agents

Arenaviruses
--Guanarito virus
--Lassa virus

--Junin virus (except the candid #1 vaccine strain listed in Risk Group 2 (RG2) - Viruses
--Machupo virus
--Sabia

Bunyaviruses (Nairovirus)
--Crimean-Congo hemorrhagic fever virus

Filoviruses
--Ebola virus
--Marburg virus

Flaviruses - Group B Arboviruses
--Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring-summer encephalitis viruses

Herpesviruses (alpha)
--Herpesvirus simiae (Herpes B or Monkey B virus)

Paramyxoviruses
--Equine morbillivirus (Hendra virus)

Hemorrhagic fever agents and viruses as yet undefined

**Animal Viral Etiologic Agents in Common Use**

The following list of animal etiologic agents is appended to the list of human etiologic agents. None of these agents is associated with disease in healthy adult humans; they are commonly used in laboratory experimental work.

A containment level appropriate for RG1 human agents is recommended for their use. For agents that are infectious to human cells, e.g., amphotropic and xenotropic strains of murine leukemia virus, a containment level appropriate for RG2 human agents is recommended.

Baculoviruses

Herpesviruses
--Herpesvirus ateles
--Herpesvirus saimiri
--Marek's disease virus
--Murine cytomegalovirus

Papilloma viruses
--Bovine papilloma virus
--Shope papilloma virus

Polyoma viruses
--Polyoma virus
--Simian virus 40 (SV40)

Retroviruses
--Avian leukosis virus
--Avian sarcoma virus
--Bovine leukemia virus
--Feline leukemia virus
--Feline sarcoma virus
--Gibbon leukemia virus
--Mason-Pfizer monkey virus
--Mouse mammary tumor virus
--Murine leukemia virus
--Murine sarcoma virus
--Rat leukemia virus

Murine Retroviral Vectors

Murine retroviral vectors to be used for human transfer experiments (less than 10 liters) that contain less than 50% of their respective parental viral genome and that have been demonstrated to be free of detectable replication competent retrovirus can be maintained, handled, and administered, under BL1 containment.

*List taken from April 2019 NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*. See the most current NIH *Guidelines* for current classifications, or the American Biological Safety Association International *Risk Group Classification for Infectious Agents*.

# Appendix F Glossary

ABSA- American Biological Safety Association International

ABSL- Animal biosafety level

APHIS- Animal and Plant Health Inspection Service

BBP- Bloodborne pathogen

Biohazard- agent that is biological in nature, capable of self-replication, and capable of producing deleterious effects upon other biological organisms, particularly humans

BMBL- *Biosafety in Microbiological and Biomedical Laboratories*

BSC- Biosafety cabinet

BSL- Biosafety level

CDC- Centers for Disease Control and Prevention

DNA- Deoxyribonucleic acid

DNREC- Department of Natural Resources and Environmental Control

DOT- Department of Transportation

ECP- Exposure control plan

EHS- Department of Environmental Health and Safety

*Guidelines- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*

HBV- Hepatitis B virus

HEPA- High efficiency particulate air

HIV- Human immunodeficiency virus

IATA- International Air Transport Association

LFB- Laminar flow clean bench

NIH- National Institutes of Health

NIOSH- National Institute for Occupational Safety and Health

OSHA- Occupational Safety and Health Administration

PI- Principal Investigator

PPE- Personal protective equipment

Primary containment- protection of the personnel and the immediate lab environment from exposure to infectious agents

RG- Risk group

Secondary containment- protection of the environment external to the laboratory

Sharps- any discarded contaminated article that may cause punctures or cuts. Includes, but is not limited to, needles, syringes, intravenous tubing with needles attached, scalpel blades, glass slides, glassware, razor blades, Pasteur pipettes, and pipette tips

UBC- University Biosafety Committee

USDA- United States Department of Agriculture

VS- Veterinary Services