The UW-Madison Researchers' Biosafety Manual

UW-Madison Institutional Biosafety Committee and Office of Biological Safety Policies, Requirements, and Recommendations Manual

Institutional Biosafety Committee (IBC)
Office of Biological Safety (OBS)
University of Wisconsin–Madison
https://ehs.wisc.edu/office-of-biosafety/

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THE UW-MADISON RESEARCHERS' BIOSAFETY MANUAL

The Institutional Biosafety Committee (IBC) at UW-Madison originated in 1972 when Chancellor Edwin Young established the Biological Safety Committee. The stated purpose of the committee was to address general concerns about the "increased use in research of biological materials that may result in inadvertent exposure of laboratory personnel and the general public to potentially dangerous infectious agents which either occur naturally or are the result of laboratory manipulations…" The goal of the committee was to identify potential hazards and to assure that adequate precautions are taken. In 1979, Chancellor Irving Shain delegated further authority to the committee to assure compliance with the NIH *Guidelines for Activities Involving Recombinant DNA Molecules* and to promote biological safety for all activities which involve the use of biological materials.

The current charge of the committee was issued in 2015 by Chancellor Rebecca Blank. Chancellor Blank clarified that the IBC is charged with responsibility for oversight of research using biological materials that entails a potential risk to humans, animals, plants, or the environment. This research includes, but is not necessarily limited to, studies involving recombinant DNA, infectious agents, toxic chemicals used to elicit a biological response, or other substances that may be toxic to living organisms. The IBC is authorized to approve, require modifications to secure approval, or disapprove these proposed research activities. The IBC is further authorized to suspend or revoke authorization for previously approved research that is not being conducted in accordance with the approved protocol, the IBC's requirements, federal or state laws or regulations, or institutional policies applicable to biological research. The IBC may also suspend or revoke authorization for previously approved research when the research or its conduct creates an unexpected serious potential threat to safety, health, or the environment. In addition, the IBC is authorized to draft and implement policy and to set other requirements related to the use of biological materials in research or teaching, and to conduct assessments of potential Dual Use Research of Concern.

The Office of Biosafety (OBS) mission is to provide biosafety guidance to the UW –Madison research community and serve the IBC in an administrative role. OBS promulgates biological aspects of safety through laboratory visits, consultations, training as well as following regulations regarding biosafety in laboratory spaces.

The IBC is mandated by the U.S Department of Health and Human Services, National Institutes of Health (NIH) - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (https://osp.od.nih.gov/biotechnology/nih-guidelines/). The responsibilities of this committee extend beyond recombinant DNA activities to all biohazardous materials. In addition to the Guidelines, the recommendations of the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) - Biosafety in Microbiological and Biomedical Laboratories (BMBL), current edition, (http://www.cdc.gov/biosafety/publications/index.htm) are adopted as standards of conduct.

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PRINCIPAL INVESTIGATOR (PI) RESPONSIBILITIES

Biological Safety Protocol

The UW-Madison Office of Biological Safety (OBS) monitors research on campus involving any of the following:

- Recombinant (transgenic) or synthetic DNA/RNA materials, including human gene therapy
- Microbes and disease-causing agents including bacteria, viruses, fungi, prions, protozoa, and parasites
- Large scale propagation consisting of a volume greater than 10L or more in one vessel
- Human cells and cell culture, organs or tissues, or biological samples
- Non-human cells and cell culture, organ or tissues, or biological samples that are infectious, potentially infectious or recombinant
- Animals (vertebrate and/or invertebrate) that are recombinant (transgenic), exotic, and/or grown in association with pathogens and/or recombinant materials
- Plants that are recombinant (transgenic), exotic, and/or grown in association with pathogenic or recombinant microbes and/or pathogenic or recombinant small animals (insects, etc.)
- Biological Toxins (this does not include toxic chemicals or antibiotics)

Training

All faculty and staff working with biohazardous and/or recombinant materials must complete the three required biosafety training modules. In addition, laboratory specific training should be provided for all staff.

Principal Investigator Assurance Statement

The Principal Investigator (PI) is responsible for the scientific research within a laboratory, training of laboratory personnel, and must abide by and adhere to all UW-Madison IBC policies, NIH Guidelines, Biosafety in Microbiological and Biomedical Laboratories, and any other applicable requirements. The PI must understand, adhere to and sign the UW-Madison IBC assurance statement included below.

Assurance Statement

I certify that the information contained in this application is accurate and complete. I am familiar with and agree to abide by *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, current ed.* and *Biosafety in Microbiological and Biomedical Laboratories, current ed.*

Also I agree to abide by the following requirements:

a. I will not initiate any biological research subject to the guidance and guidelines mentioned above until that research has been registered, reviewed, and approved by the UW-Madison Institutional Biosafety Committee (IBC). The purview of the UW-Madison IBC includes biological research involving recombinant nucleic acids; biological agents and pathogens; human cells, tissues, materials and embryonic stem cells; select agents and toxins, biological toxins, synthetic nucleic acids and the use of any of these in animal or plant research.

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b. I will assure that personnel, including animal care staff or other laboratory support staff, have received appropriate information including signage, about the biological hazards of the research outlined in this registration by making available copies of approved protocols, Biosafety Manuals, and Biological Research Registrations that describe the potential biohazards and precautions to be taken to prevent exposures or release to the laboratory or the environment.

c. I will ensure that laboratory personnel understand the procedures for dealing with incidents and spills of biological materials and know the appropriate waste management procedures.

d. I will comply with all training and shipping requirements for the transport of hazardous biological materials according to the US Dept. of Transportation (DOT) 49 CFR 171-178, International Civil Aviation Organization (ICAO) and International Air Transport Association (IATA).

e. I will comply with the OSHA/DOC Bloodborne Pathogen Standard 29 CRF 1910.1030 if my research includes human cells, tissues, materials and embryonic stem cells.

f. I will ensure that all laboratory personnel working with biological materials are listed on this registration.

g. I will assure that I along with all laboratory personnel have completed all required biosafety training and that their training records are up to date.

h. I assure that all laboratory spaces associated with the research described in this registration are listed.

i. I am familiar with and understand my responsibilities as a Principal Investigator as outlined in Section IV-B-7 of the NIH Guidelines.

j. I will assure adequate supervision of personnel, and will correct work errors and conditions that could result in breaches of the guidelines and regulations pertaining to this research as listed above.

k. I will immediately inform the UW-Madison Biosafety Office of any spills outside containment, potential exposures or breaches of the guidelines and regulations listed above and will submit the *First Report of Biological Exposure or Release Form* within 24 hours.

Principal Investigator:_____

Signature:_____ Date:_____

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IBC POLICIES

Policies and Procedures Adopted by the IBC

Note: This section will be updated as the IBC continues to approve policies
The IBC sets the date effective on a case-by case basis for each policy.

IBC-Policy-001_Conduct of Meetings in Open Session

IBC-Policy-002_Access to IBC Meeting Minutes & Records

IBC-Policy-003_Receipt & Transmission of Public Comments

IBC-Policy-004_Transgenic Animals

IBC-Policy-005_Incident Reporting

IBC-Policy-006_Protocol Review

IBC-Policy-007_PI-Research Service and Core Unit Responsibilities

IBC-Policy-008_Shared Use of BSL-2 Facilities

IBC-Policy-009_IBC Member Training

IBC-Policy-010_IBC Policy for Compulsory Biosafety Training

IBC-Policy-011_Principal Investigator for a Biosafety Protocol

IBC-Policy-012_Reporting of Lab-Acquired Infections to PH Authorities

IBC-Policy-013_Vaccinia Policy and Form

IBC-Policy-014_Dengue Policy and Form

IBC-Policy-015_IBC Policy for Suspension of Previously Approved Research

IBC-Policy-016_IBC Policy for PI Request for Reconsideration Process

IBC-Policy-017_IBC Member Conflict of Interest Policy

IBC Policy-018_IBC BSC Policy

IBC-Policy-019_IBC Policy for Select Opportunistic Pathogens

IBC-Policy-020_IBC Policy for Animal Waste and Carcass Disposal

IBC-Policy-021_IBC Policy for Reporting Biosafety Concerns

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IBC-Policy-022_IBC Policy for Expired Biosafety Protocols

GENERAL PRINCIPLES OF BIOLOGICAL SAFETY

Risk Assessment

Risk assessment is the rational application of safety principles to available options for handling hazardous materials. The following characteristics are considered when evaluating a potential pathogen:

- The agent's biological and physical nature
- The concentration and suspension volume of the agent
- The sources likely to harbor the agent
- Host susceptibility
- The procedures that may disseminate the agent
- The best method to effectively inactivate the agent

Risk Groups

Microorganisms that are human pathogens can be categorized into risk groups (RG) based on the transmissibility, invasiveness, virulence (i.e., ability to cause disease), and the lethality of the specific pathogen. Risk groupings of infectious agents (RG1 through RG4) approximately correspond to biosafety levels (BSL1 through BSL4), which describe containment practices, safety equipment, and facility design features recommended for safe handling of these microorganisms. A parallel series of animal biosafety levels (ABSL1 through ABSL4) applies to handling of infected or potentially infected animals.

Beginning with RG1 agents, which are nonpathogenic for healthy human adults, the scheme ascends in order of increasing hazard to RG4. The risk group listing of the NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (see website) is an accepted standard, even when recombinant DNA technology is not used. The American Biological Safety Association (ABSA) also provides a comprehensive risk group listing that references agencies globally. The Pathogen Safety Data Sheets (PSDSs) available through the Public Health Agency of Canada website are an excellent source of information about pathogens.

RISK GROUP 1 agents are not associated with disease in healthy adult humans. Examples: *E. coli* K-12, *Saccharomyces cerevisiae.*

RISK GROUP 2 agents are associated with human disease that is rarely serious and for which preventive or therapeutic interventions are often available. Examples: enteropathogenic *E. coli* strains, *Salmonella, Cryptosporidium, Staphylococcus aureus.*

RISK GROUP 3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk). Examples: human immunodeficiency virus, *Brucella abortus*, *Mycobacterium tuberculosis.*

RISK GROUP 4 agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk). Examples: Ebola virus, Macacine herpesvirus 1 (Herpes B or Monkey B virus).

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Consideration of the risk group assignment, however, merely is a starting point for the comprehensive risk assessment. Further attention must be given to the circumstances, such as the planned procedures and the available safety equipment. Then, the recommended precautions may be increased or decreased relative to those based solely on the risk group assignment and adjusted to reflect the specific situation in which the pathogen will be used.

Microorganisms in RG1 require use of standard basic biological laboratory facilities and microbiological practices, whereas those in RG4 require maximum containment facilities and practices. Some of the agents likely to be handled experimentally at UW-Madison are RG2 or RG3 pathogens; designated as moderate and high hazard, respectively. These agents typically require more sophisticated engineering controls (e.g., facilities and equipment) than are available in standard laboratories, as well as special handling and decontamination procedures.

Consideration also is extended to microorganisms that cause diseases in animals and/or plants, which are not categorized into risk groups as are human pathogens. The desired containment for animal and plant pathogens is based on the severity of the disease, its ability to disseminate and become established in the local environment, and the availability of prophylactic treatment. The relationship between Risk Groups and Biosafety Levels, practices, facilities, and equipment is provided in Table 1.

The progression from invasion to infection to disease following contact with an infectious agent depends upon the dose, route of transmission, invasive characteristics of the agent, virulence and resistance of the exposed host. Not all contacts result in infection and even fewer develop into clinical disease. Even when disease occurs, severity can vary considerably. Attenuated strains should be handled with the same precautions as the virulent strain unless the reduced pathogenicity is well documented and is irreversible. Viral vectors, even if rendered replication defective, still may pose a threat of recombination with wild-type strains and/or unintentional delivery of their foreign genes. It is prudent to assume virulence and to handle such agents with precautions appropriate for the virulent parental organism.

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Table 1. Relationship of Risk Groups to Biosafety Levels, Practices, Facilities, and Equipment

Risk Group (RG)	Biosafety Level (BSL)	Examples of Laboratories	Laboratory Practices	Facilities and Equipment[a]
RG 1	BSL 1	Basic teaching and research	Good microbiological technique (GMT)	None required; open bench work; directional air flow
RG 2	BSL 2	Primary health services; research; diagnostic, teaching and public health	BSL 1 practices plus protective clothing; biohazard sign	Open bench plus biological safety cabinet (BSC) for potential aerosols; directional air flow
RG 3	BSL 3	Special diagnostic and research	BSL 2 practices plus special clothing, controlled access, directional airflow	BSC and/or other primary containment devices for all activities; directional air flow
RG 4	BSL 4	Dangerous pathogen unit	BSL 3 practices plus airlock entry, shower exit, special waste disposal	Class III BSC or positive pressure suits, double-door autoclave, filtered exhaust air

[a] Additional facility requirements listed in Table 2 of this document.

Routes of Infection

Pathogens can be transmitted via several different routes in the laboratory. The most common routes of infection are inhalation of infectious aerosols or dusts, exposure of mucous membranes to infectious droplets, ingestion from contaminated hands or utensils, animal bites, or percutaneous self-inoculation (injection or incision). Increased risk is associated with pathogens that are aerosol transmitted and when high concentrations or large volumes are used. Appropriate precautions can be implemented to avoid such exposures.

Inhalation of infectious aerosols is implicated as the cause of many laboratory-acquired infections. Even pathogens that normally do not cause infections by inhalation route present a danger when aerosolized. Aerosols can spread throughout the laboratory by traveling along air currents and can contaminate areas considered to be “clean.” This creates the potential for indirect laboratory acquired infections to occur. This is a problem for both infectious material and recombinant material. Activities that have the potential to create aerosols should be performed in a biological safety cabinet (BSC) whenever possible (or a fume hood when working with biological toxins). The BSC captures aerosols on a HEPA filter, protecting the worker and the work environment. If the activity cannot be performed in a BSC, additional personal protective equipment (PPE) such as a respirator should be considered.

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Some situations warrant special considerations or measures to prevent infection of laboratory personnel by certain microorganisms. For example, organisms which are not known to cause infection in healthy individuals but are known pathogens of persons who have been compromised in various ways including, open wounds, cuts, antibiotic therapy, persons with immune systems rendered deficient via infection, acquired or congenital condition or via therapy (e.g., HIV+, diabetes, complement deficiencies, severe asthma, organ transplant, chemotherapy or long-term steroid treatment) and persons with immunocompromised, immunosuppressed or susceptible immune status (e.g., pregnant women, very young or old, diabetes, individuals on steroid therapy).If any of these conditions apply to you, inform your personal physician/health care professional of your work.

Clinical and Pathological Specimens

Every specimen from humans or animals may contain infectious agents. Human specimens should be considered especially hazardous. Personnel in laboratories and clinical areas handling human blood or body fluids should practice Universal Precautions, an approach to infection control wherein all human blood and certain human body fluids are treated as if known to be infectious for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens. Such personnel are required by OSHA to complete bloodborne pathogen training. The Office of Biological Safety offers researchers bloodborne pathogen training and makes HBV immunization available.

A written exposure control plan must be prepared by laboratories that handle human blood or other potentially infectious materials (PIM), defined in the regulations as semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, and any body fluids in situations where it is difficult or impossible to differentiate between body fluids. Any unfixed human tissue, organ, or primary cell cultures, and HIV- or HBV-containing culture media or other solutions are also subject to oversight. Blood, organs, human established cell lines, human stem cells, or other tissues from experimental animals infected with HIV or HBV are also included. Contact the Office of Biological Safety for more information on precautions and regulatory requirements.

Cultures

Routine manipulations of cultures may also release microorganisms via aerosol formation:

- Popping stoppers from culture vessels
- Opening vessels after vigorous shaking or vortexing
- Flame-sterilizing utensils, which causes spatter
- Electroporation
- Centrifugation
- Sonicating, homogenizing, blending or grinding tissues
- Expelling the final drop from a pipette

Manipulate cultures of infectious material carefully to avoid aerosols. Centrifugation should involve the use of gasket-sealable tubes and rotors. Seal microplate lids with tape or replace the lids with adhesive-backed Mylar film. Load, remove, and open tubes, plates, and rotors within a BSC or fume hood. Accidental spilling of liquid infectious cultures is an obvious hazard due to the generation of aerosols (airborne droplets containing microorganisms).

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Equipment used for manipulations of infectious materials, such as sonicators, flow cytometers, cell sorters, and automated harvesting equipment, must be evaluated to determine the need for secondary containment and to consider decontamination issues. When preparing aliquots of infectious material for long-term storage, consider that viable lyophilized cultures may release high concentrations of dispersed particles if ampoules are not properly sealed. Breakage of ampoules in liquid nitrogen freezers may also present hazards because pathogens may survive and disperse in the liquid phase.

Use of human or animal cell cultures in laboratories requires special consideration. Cell or tissue cultures in general present few biohazards, as evidenced by their extensive use and lack of infection transmitted to laboratory personnel. Clearly, when a cell culture is inoculated with or known to contain a pathogen, it should be classified and handled at the same biosafety level as the agent. BSL2 containment conditions are used for cell lines of human origin, even those that are well established, such as HeLa and Hep-2, and for all human clinical material (e.g., tissues and fluids obtained from surgery or autopsy). Cell lines exposed to or transformed by an oncogenic virus, primate cell cultures derived from lymphoid or tumor tissue, and all nonhuman primate tissues are handled using BSL2 practices. A BSC, not a laminar flow clean bench, should be used for manipulations that have potential to create aerosols. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory.

Animals

Exercise care and thoughtfulness when using animals in research. Numerous risks may be present when animals are used in studies of microorganisms, as well as studies of hazardous chemicals. Use containment and PPE that protects against both the biological and chemical hazards. Precautions commonly include use of a lab coat, gloves and eye protection when handling animals and their bedding; respiratory protection may be recommended when specific conditions present a concern.

There are some inherent risks in working with animals (e.g., allergenicity, bites, and scratches). Laboratory and wild-trapped animals may harbor microorganisms that can produce human diseases following bites, scratches, or exposure to excreted microorganisms. Rhesus macaques present a significant potential for hazards, requiring that stringent procedures be followed to guard against Herpes B virus (Macacine herpesvirus 1). Even in the absence of known hazards, animal care providers should use precautions to avoid exposure to animal allergens.

In the process of inoculating animals, an investigator can be exposed to infectious material by accidental self-inoculation or inhalation of infectious aerosols. During surgical procedures, necropsies, and processing of tissues, aerosols can be produced inadvertently, or the operator can inflict self-injury with contaminated instruments. Since animal excreta can also be a source of infectious microorganisms, investigators should take precautions to minimize aerosols and dust when changing bedding and cleaning cages. Containment equipment such as a fume hood or biosafety cabinet is sometimes appropriate for performing cage changes. Bedding from animals infected or potentially infected with pathogens must be decontaminated prior to disposal, typically by autoclaving.

Transfer of human cells, primate cells or opportunistic microbes, whether newly isolated or well-established, into immunocompromised animals could result in propagation of pathogens that would be suppressed in the normal host. BSL2 containment must be applied to militate against such risks and also to prevent spread of animal pathogens within a research colony.

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Mixed waste disposal methods require thorough risk assessment. Please contact the Office of Biological Safety for assistance.

Plant Biocontainment

Biosafety principles are applied to activities involving plants that are exotic, recombinant, and/or grown in association with pathogenic or recombinant microbes and/or pathogenic or recombinant small animals (insects, etc.). Under special circumstances, which typically require explicit approval from USDA-APHIS (U.S. Department of Agriculture-Animal and Plant Health Inspection), it is possible to conduct field trials. Otherwise, release to the environment must be prevented.

The goal is to protect the environment, not the researcher. The risk assessment considers the specific organism(s), geographic/ecological setting, and available mechanical barriers; the selected practices are tailored to the specific situation. It becomes especially difficult to prescribe containment when genetic modifications lead to uncertainty in characteristics such as host range and competitiveness. Containment may be achieved by a combination of physical and biological means. Containment for transgenic plants and their associated plant pathogens relies more heavily on biological factors than is the norm for human and animal infectious agents. Preventing the spread or release of transgenic pollen is a form of biological containment which can be achieved by using sterile lines, altering day length to prevent flowering, and other strategies.

For research involving plants, four biosafety levels (BSL1-P through BSL4-P) are utilized (see Appendix P, NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*). BSL1-P is designed to provide a moderate level of containment for experiments for which there is convincing biological evidence that precludes the possibility of survival, transfer, or dissemination of recombinant DNA into the environment, or in which there is no recognizable and predictable risk to the environment in the event of accidental release. BSL2-P is designed to provide a greater level of containment for experiments involving plants and certain associated organisms for which there is a recognized possibility of survival, transmission, or dissemination of recombinant DNA–containing organisms, but the consequence of an inadvertent release has a predictably minimal biological impact. BSL3-P and BSL4-P describe additional containment conditions for research with plants and certain pathogens and other organisms that require special containment because of their recognized potential for significant detrimental impact on managed or natural ecosystems.

BSL1-P relies upon accepted scientific practices for conducting research in most ordinary greenhouse or growth chamber facilities and incorporates accepted procedures for good pest control and horticultural practices. BSL1-P facilities and procedures provide a modified and protected environment for the propagation of plants and microorganisms associated with the plants and a degree of containment that adequately controls the potential for release of biologically viable plants, plant parts, and microorganisms associated with them. BSL2-P and BSL3-P rely upon accepted scientific practices for conducting research in greenhouses with organisms infecting or infesting plants in a manner that minimizes or prevents inadvertent contamination of plants within or surrounding the greenhouse. Additional facility requirements are also implemented for BSL2-P and BSL3-P containment.

When conducting work in greenhouse space, it is important to communicate the risks and proper precautions required for your project to facility personnel and other researchers sharing the

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space. Greenhouses in which BSL2-P or higher work is conducted are required to have a facility specific greenhouse practices manual. The manual must advise personnel of potential consequences if such practices are not followed and it must outline contingency plans to be implemented in the event of an unintentional release of organisms. The PI must also keep a record of experimental plants, microorganism or small animals that are brought into or removed from the greenhouse facility.

Biohazard Containment
Although the most important aspect of biohazard control is the awareness and care used by personnel in handling infectious materials, certain features of laboratory design, ventilation, and safety equipment can prevent dissemination of pathogens and exposure of personnel should an accidental release occur.

Practices and Procedures
The following practices are important not only for preventing laboratory infection and disease, but also for reducing contamination of experimental material.

Standard microbiological practices are common to all laboratories. Special microbiological practices enhance worker safety, environmental protection, and address the risk of handling agents requiring increasing levels of containment. Please also see the CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL) website at http://www.cdc.gov/biosafety/publications/index.htm (Section IV) regarding information on Laboratory Biosafety Level criteria, etc. It is the responsibility of all laboratory staff to effectively decontaminate equipment before it is removed from the laboratory for maintenance, relocation, sale, or disposal.

These standardized practices and procedures provide the foundation for the more restrictive containment of RG3 organisms, which are not covered in this manual. Specialized facilities and rigorous attention to procedures that control the biohazards are required for the conduct of research under BSL3 containment, which must be described in a biosafety manual that is specific to the agents, facilities, and activities. Requirements for the BSL3 manual are described in Appendix B.

Good Microbiological Technique and Personal Hygiene: Biosafety Level 1
- ✓ Do not eat, drink, chew gum, use tobacco, apply cosmetics, or handle contact lenses in the work area.
- ✓ Do not store food for human consumption in the work area.
- ✓ Do not store items such as coats, handbags, dishes or other personal items in the laboratory.
- ✓ Wash hands frequently after handling infectious materials, after removing gloves and protective clothing, and always before leaving the laboratory.
- ✓ Keep hands away from mouth, nose, eyes, face, and hair.
- ✓ Use mechanical pipetting devices; never mouth-pipette.
- ✓ Wear pants (or other clothing that covers legs) and close-toed shoes.
- ✓ Wear appropriate Personal Protective Equipment. A lab coat and eye protection is the minimum required PPE to enter the laboratory, with gloves, respiratory protection, face protection, etc. added as required to suit the activities.
- ✓ Keep laboratory doors closed.
- ✓ Aerosol generating procedures should not be performed in equipment corridors not located with research suites.

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- ✓ Plants and animals not associated with the work being performed should not be permitted in the laboratory.

Laboratory Procedures for Handling Infectious Microorganisms: Biosafety Level 2

- ✓ Prepare a site-specific laboratory safety manual outlining activities and defining standard operating procedures.
- ✓ Train employees and ensure that all personnel are informed of hazards.
- ✓ Plan and organize materials/equipment before starting work.
- ✓ Keep laboratory doors closed; limit access to personnel who have a need to be in the laboratory.
- ✓ Post a biohazard sign at the laboratory entrance when RG2 pathogens are used. Identify the agents in use and the appropriate emergency contact personnel. Biohazard signs and laboratory information signs are available from the Office of Biological Safety.
- ✓ A lab coat and eye protection is the minimum required PPE to enter the laboratory. A fully fastened lab coat, gloves, and eye protection must be worn when working with infectious agents or potentially hazardous materials, including human blood, body fluids, tissue and cells.
- ✓ Remove all protective clothing, including gloves, and leave within the laboratory before exiting.
- ✓ When practical, perform all aerosol-producing procedures such as shaking flasks, grinding tissue, sonicating, mixing, and blending in a certified biological safety cabinet. Note that some equipment may compromise cabinet function by disturbing the air curtain.
- ✓ Centrifuge materials containing infectious agents in unbreakable, closable tubes. Use a rotor with a sealed head or safety cups, and load it in a biological safety cabinet. After centrifugation, open the rotor and tubes in a biological safety cabinet.
- ✓ Avoid using hypodermic needles whenever possible. If it is necessary to use them, discard used syringe-needle units in a sharps container without removing or re-capping the needles.
- ✓ Cover counter tops where hazardous materials are used with plastic-backed disposable paper to absorb spills; discard it at the end of the work session.
- ✓ Routinely wipe work surfaces with an appropriate disinfectant after experiments and immediately after spills.
- ✓ Routinely decontaminate all infected materials by appropriate methods before disposal.
- ✓ Report all accidents and spills to the laboratory supervisor. All laboratory personnel should be familiar with the emergency spill protocol, the location of cleanup equipment and the First Report of Biological Exposure or Release Form (https://ehs.wisc.edu/emergencies/).
- ✓ Good housekeeping practices are essential in laboratories engaged in work with infectious microorganisms. Establish the habit of weekly cleaning.
- ✓ Be sure to advise custodial staff of hazardous areas and places they are not to enter. Use appropriate warning signs.

Laboratory Procedures for Handling Infectious Microorganisms: Biosafety Level 3

Details for BSL3 laboratories may be found in the Biosafety in Microbiological and Biomedical Laboratories (BMBL). Briefly, some points include:

- ✓ Special consideration for all sharps required.
- ✓ Elimination or reduction of the use of glassware in the laboratory.
- ✓ Hazard communication and training for microbes handled in the laboratory.
- ✓ Laboratory BSL3 manual is required.
- ✓ All procedures for infectious materials must be conducted within a BSC.

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- ✓ Researchers wear protective clothing with solid-front gowns, scrub suits or coveralls. This is not worn outside of the laboratory.
- ✓ Eye and face protection is worn for anticipated splashes.
- ✓ Gloves must be worn and not be worn outside of the laboratory.
- ✓ Laboratory doors must be self-closing and access restricted.
- ✓ Laboratory must have a ducted ventilation system and laboratory must be able to identify the direction of the airflow.
- ✓ Facility design including decontamination, engineering controls, operational parameters, SOPs and manuals are specific to each laboratory space. Please contact OBS for more detailed information.

BSL3 Manual: Required Elements for High-Containment Laboratories
The purpose of a BSL3 Manual is to provide detailed procedures and policies for staff to follow while working in your facility under BSL3 containment. The manual is required to be specific to your laboratory, facility, agents and procedures used. These details provide a basic understanding for OBS and the UW-Madison Institutional Biosafety Committee (IBC) to evaluate a risk assessment for your laboratory. It also serves as a valuable tool for training and reference for your staff.

Details and instructions within this manual are specific and it is important that the manual and the biosafety protocol be reviewed and updated to reflect any changes in the laboratory. OBS should also receive a copy of any amended BSL3 Manual. The BSL3 Manual also serves to meet the Biosafety in Microbiological and Biomedical Laboratories (BMBL) recommendation for a manual specific to the agents/procedures/facilities to be prepared and should also satisfy the UW-Madison IBC that hazard risks are mitigated. The IBC reviews the BSL3 manual along with the biosafety protocol.

Although this list is not inclusive, all elements below must be addressed in the BSL3 manual. Some of the elements may not be applicable to your laboratory and are *italicized* in the list below:

1. Title, date of current revision, table of Contents
2. Emergency Contacts
3. Biosafety Level 3 (BSL3) Description:
    a. Standard Microbiological Practices
    b. Special practices
    c. Safety Equipment
    d. Laboratory Facilities
4. *Animal Biosafety Level 3 (ABSL3)Description:*
    a. Standard Microbiological Practices
    b. Special practices
    c. Safety Equipment
    d. Laboratory Facilities
5. Microbes
    a. List agent and describe brief history, host range, route of transmission, biosafety level practices recommended, genetic manipulation performed on the agent (how

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that affects the risk assessment), other important information to understand the risk of manipulating the agent

b. May also develop a laboratory specific medical response sheet

6. Facility Design and Specifications
    a. How many rooms, location of suite.
    b. Engineering controls (e.g. filters, exhaust, air handling systems, pressure gauges)
    c. Generator for power outages
    d. Security description (e.g. fingerprint scanners, ID card scanners, high security keys)
    e. Waste collection system
7. Facility Certification
    a. Annual certification, work stoppage, certifications performed (BSC, Fume hoods, filters, air handling, showers, HVAC, regular maintenance
8. Facility Decontamination
    a. Yearly requirements
    b. At the end of facility use
    c. When significant repairs are needed
9. Pest Control
    a. Insect and Post Control Program written and in place, reviewed annually
    b. Describe regulation requirements
10. Plants, Pets
    a. Describe regulation requirements
11. Personnel Requirements
    a. List specific requirements for staff
        i. Training
        ii. Any applicable background checks, clearances, evaluations
        iii. Understanding of hazards
        iv. Understanding health and medical requirements
        v. Describe fit testing of respirators (testing, medical clearance, refer to detailed SOP for respirator use)
        vi. Understand and comply with any agent specific programs (quarantine, allergy etc.)
    b. List specific requirements for visitors:
        i. Escort
        ii. Use of PPE
        iii. Visitor training
        iv. Visitor log
        v. Vaccination requirements
    c. Special Maintenance staff requirements as applicable
12. Personnel Training
    a. Describe training procedures
    b. List SOPs required proficiency

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    c. Specify responsibility of staff
13. Entrance and Exit Requirements and Personal Protective Equipment (PPE)
    a. List step by step what staff need to do, wear, sign referencing a more detailed SOPs used for training. This list should be specific enough for readers to understand steps, but does not have to be as detailed as the SOPs for Exit and Entry.
    b. If separate animal areas are also used, there needs to be a description of exit and entry for those as well and detailed training SOPs.
14. Removal of equipment from the BSL-3 area (e.g. maintenance, repair, replacement)
    a. Detail decontamination procedures and documentation
15. Decontamination of Laboratory Waste
    a. Autoclave use
    b. Documentation
    c. Efficacy testing
    d. Equipment decontamination (large and small) procedures
    e. Animal waste decontamination (cages, waste, bedding, animals)
    f. Sharps handling
16. Laboratory Research Practices
    a. List specific practices beyond the already required inherent BSL1 and BSl2 practices required to work at BSL3
    b. Describe any special practices for specific agents (agent A may not be worked on when agent B is being worked on)
    c. Experimental procedures must be well thought out and described in separate SOP's. These may be referenced, but give brief descriptions (e.g. use of BSCs, movement of samples from BSL3 to BSL2, maintenance of vacuum lines)
    d. Cleaning and maintaining equipment and surfaces (e.g. frequency, disinfectant exposure time and concentration, eye wash maintenance)
    e. Animal experimental procedures describe briefly and reference specific SOPs. (cleaning, housing, monitoring, PPE, who performs tasks)
    f. Procedures for waste removal
17. Special Practices
    a. Consider regulations as applicable to DURC
18. Spill Protocols and Response
    a. Detail Spill protocol with emergency contacts listed and reporting procedures
        i. Inside and outside containment
19. Health and Medical Monitoring
    a. Depending on the agent, certain restrictions, vaccinations or monitoring may need to be in place for BSL3 work.
    b. Outline as applicable to your agent (symptoms for each agent, reporting, what to do when you are sick, emergency procedures, contact numbers, testing requirements)
    c. Types of accidental exposure list:

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i. Needle stick
ii. *Animal Bite*
iii. Break in PPE
iv. Broken vessel outside BSC
v. Unknown exposure with symptoms

20. Emergency Response
    a. Accident/Fire/Weather Emergency
    b. Exposure procedures
    c. Breech of containment
    d. Theft/missing agents
21. Shipping and Receiving Requirements
    a. Detail training for shipping and receiving materials
22. SOP's and Training
23. Policy Documentation
    a. Signature signifying that the BSL3 manual has been read and understood and all questions and concerns have been addressed.
24. Revision history
    a. Specific changes made, who made the changes, date and signature of PI

Personal Protective Equipment

Laboratory coats provide a barrier that protects the worker from hazardous materials contacted in the laboratory. Note that it is not possible to see residues of many hazardous materials; they could have been left behind on various surfaces by another worker. By removing your lab coat when exiting the laboratory, contaminants remain in the laboratory. It follows logically then that protective clothing should not be taken home for cleaning. Depending on the nature of the work, protective clothing also could include disposable sleeves, coats that close in back, disposable protective suits (e.g., Tyvek) and hair and shoe covers.

Gloves should be worn whenever there is the potential for contact with hazardous materials. They further serve to maintain the integrity of the material being handled. Many different types of gloves are available, and the choice depends on the nature of the hazard. Gloves must be removed in a prescribed manner before exiting the laboratory. Material that is transported outside the laboratory that poses a risk to personnel should be surface decontaminated and placed in a clean secondary container so that a lab coat and gloves need not be worn outside the laboratory.

The eyes and mucous membranes are vulnerable routes of exposure. Eye protection should always be worn in the laboratory. Contact lenses may be worn with discretion and in combination with eye protection. Depending on the activities, it may be appropriate to use safety glasses with side shields, goggles, and/or a splash shield. University Health Services (UHS) offers prescription safety glasses at minimal or no cost to help employees comply with the OSHA Lab Standard.

Respiratory protection should be considered carefully and used only when there is risk of aerosol exposure that cannot be mitigated through the use of alternative procedures or containment equipment. The background level of microbes in the research laboratory should be negligible when good microbiological techniques are employed. Selection of a respirator to guard against pathogens is not as simple as for chemical hazards where tables of permissible exposure limits

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are available and background levels are factored into the decision. Recommendations for respirators are not documented for work with pathogens with the exception of clinical specimens containing *Mycobacterium tuberculosis* since acceptable exposure levels have not been determined.

An issue regarding respiratory protection is that, if used improperly, the user has a false sense of security. A surgical mask or common dust mask, have poor fit to the contours of the face, provide minimal protection against large particles and are inappropriate for work with infectious agents.

A HEPA (high efficiency particulate air) filtered face piece (e.g., N95 or N100) is appropriate for many situations where protection against animal allergens and microbes is desired, but the protection will only be as good as the respirator's fit to the face. Furthermore, HEPA filtration is ineffective against volatile chemicals. A full head cover with a Powered Air Purifying Respirator (PAPR) is used when respiratory protection is critical for work with highly pathogenic microbes or in situations where a biological safety cabinet cannot be used. A medical evaluation to wear a respirator, fit testing, and training in proper use are mandatory if respiratory protection is required by the employer. Contact the Occupational Health Office at UHS for guidance on appropriate respiratory protection.

Engineering Controls
Table 2 describes the relationship between biosafety levels and engineering controls, which include laboratory design, laboratory ventilation, and biological safety cabinets.

Laboratory Design
The more virulent an organism, the greater the degree of physical containment required. Proper safety equipment provides primary containment; laboratory design provides secondary containment. The Office of Biological Safety and Engineering and Technical Services are available for consultation and should be contacted when changes (i.e., addition, deletion, or relocation) of protective equipment occurs or renovations projects that affect laboratory ventilation.

Laboratory Ventilation
For containment in a laboratory to be effective, it is important that laboratory air pressure be lower than that in the adjacent spaces. This negative air pressure differential ensures that air will enter the laboratory and not egress to the hallway or adjacent rooms. **To maintain negative room pressure, laboratory doors must be kept closed.** Exhaust air from biohazardous laboratories should not be recirculated in the building. It should be ducted to the outside and released from a stack remote from the building air intake. In certain special situations, air exhausting from a hazardous facility should be filtered through certified HEPA (high efficiency particulate air) filters that are tested at least annually and verified to retain microorganisms.

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Table 2. Summary of Facility Standards Recommended for Biosafety Levels

	BSL 1	BSL 2	BSL 3
Laboratory visit by Office of Biological Safety	Desirable	Yes	Yes
Isolation of laboratory from public areas	---	---	Desirable
Eyewash, plumbed	Desirable	Yes	Yes
Interior surfaces (impervious, cleanable):	Yes	Yes	Yes
Bench tops	Yes	Yes	Yes
Laboratory furniture	Yes	Yes	Yes
Floors, conventional (no carpet)	Yes	Yes	---
Floors, seamless, integral cove base	---	Desirable	Yes
Ceiling, conventional	Yes	Yes	---
Ceiling, permanent	---	---	Yes
Sinks in laboratory	Yes	Yes	Yes
Hands-free	---	---	Yes
Water supply protected	---	---	Yes
Windows allowed	Yes	Yes	Yes
May be opened	No	No	No
Must be sealed	No	No	Yes
Room penetrations sealed for gas decontamination (pressure decay testing)	No	No	Desirable
Ventilation (single-pass supply/exhaust)	Yes	Yes	Yes
Inward air flow (negative pressure)	Yes	Yes	Yes
Mechanical, centralized system	Yes	Yes	Yes
Mechanical, independent system	No	No	Desirable
Filtered exhaust required	No	No	Desirable
Interlocked supply required	No	No	Yes
Annually test filters/HVAC systems	No	No	Yes
Annually test controls/alarms	No	No	Yes
Doors (self-closing):	Desirable	Desirable	Yes
Double-door entry required	No	No	Yes
Airlock with shower required	No	No	Desirable
Autoclave on site	Desirable	Yes	Yes
In laboratory room	---	---	Desirable
Pass-through (double-ended)	---	---	Desirable
Biological safety cabinets			
Annual certification	Desirable	Yes	Yes
Class I or Class II	---	Desirable	Yes
Class III	---	---	Desirable
Vacuum lines should be protected with liquid trap or in-line HEPA filter	Desirable	Yes	Yes[a]
Waste effluent treatment	---	---	Desirable
Centrifuge with sealed rotors	---	Desirable	Yes

-- not applicable or needed

[a] HEPA filter required

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Existing facilities that do not meet these recommendations may need to address deficiencies during future maintenance or remodeling. Contact the Office of Biological Safety for assistance.

Types of Ventilation Equipment

Be sure you know the differences between chemical fume hoods, clean benches, biological safety cabinets, and isolators. These provide three basic types of protection:

- **Personal protection** is the protection of the people working in the laboratory.
- **Product protection** is the protection of the product or experiment.
- **Environmental protection** is the protection of the environment outside the laboratory.

Different types of ventilation equipment provide different types of protection (see Table 3).

Chemical Fume Hoods

Characteristics of chemical fume hoods are that they:

- Offer only protection of personnel.
- Always exhaust air to the outside.
- Do not offer protection to the product or the environment, as there is no filtration of intake and exhaust air; sometimes air cleaning treatment is added to the exhaust.
- Directly draw air from the laboratory over the product in the hood.

Chemical fume hood applications:

- Used for work with chemical hazards; also used to prevent laboratory exposure to biological materials when product protection (sterility) is not a concern.

Clean Benches, Clean Air Devices

Characteristics of clean benches and clean air devices are that they:

- Provide product protection only.
- Create a unidirectional airflow generated through a HEPA filter to provide product protection.
- Discharge air goes across the work surface and directly into workroom.

Clean bench and clean air device applications:

- Any application where the product is not hazardous but must be kept contaminant free.
- Preparation of nonhazardous mixtures and media.
- Particulate-free assembly of sterile equipment and electronic devices.

Biological Safety Cabinet (BSC)

Characteristics of BSCs are that they:

- Are designed to contain biological hazards and to allow products to be handled in a clean environment.
- Have an inward airflow for personal protection.
- HEPA-filter exhaust air for environmental protection.
- HEPA-filter supply air for product protection (except Class I).

BSCs are separated into classes and types: Class I, Class II (Type A1/A2/B1/B2), Class III (glove box, isolator).

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BSC applications:

- Microbiological studies.
- Cell culture research and procedures.
- Protection against hazardous chemicals varies according to the class and type.
- Pharmaceutical research, manufacturing, and quality control testing.

Biological Safety Cabinets

Biological safety cabinets (BSCs) are the primary means of containment developed for working safely with infectious microorganisms. When certified and used correctly in conjunction with good microbiological techniques, they can control infectious aerosols. BSCs are designed to provide personal, environmental, and product protection when appropriate practices and procedures are followed. An excellent reference is *Primary Containment for Biohazards: Selection, Installation, and Use of Biological Safety Cabinets*, published by the CDC and NIH. **Clean air devices are not biological safety cabinets and should never be used for work with potentially hazardous biological or chemical materials.** These devices protect the material in the cabinet but not the worker or the environment.

BSC Types

Three kinds of biological safety cabinets, designated as Class I, II, and III, have been developed to meet varying research and clinical needs. Table 3 summarizes the major characteristics of the various types. Four varieties of Class II biological safety cabinets are used on campus. All are adequate for manipulations of pathogens in RG2 or RG3.

Please note that because of the greater safety margin, small amounts of volatile chemical toxins or radioactive materials can be used in Type B cabinets. Type A cabinets, however, recirculate a high percentage of air and therefore cannot be used with toxic, explosive, flammable, or radioactive substances. Class III cabinets and isolators are totally enclosed glove boxes, which are used for the most hazardous biological operations and for super-clean manufacturing. These enclosures should not be confused with anaerobic chambers.

Purchasing a BSC or Other Workstations

A contract is maintained by the UW-Madison for the purchase of all types of biological safety cabinets (BSC) and clean air devices (CAD). Before ordering one, consult the Office of Biological Safety (OBS) and Engineering and Technical Services for an evaluation, selection and approval of BSC suitability for the intended work and of the available space. To ensure the adequacy of the installed mechanical ventilation and to facilitate coordination with the Physical Plant Remodeling group, exhausted biological safety cabinets (type B1 or B2) must be approved by the Engineering Department, UW Facilities Planning & Management, prior to purchase.

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Table 3. Ventilation Equipment

Device	Protection	Airflow Direction (feet/min)	Application/Airflow Pattern	Use of Volatile Toxic Chemicals and Radionuclides
Chemical fume hood	Personnel	Inward (100)	A completely exhausted, unfiltered device used for work with chemical hazards, minimizing exposure to personnel.	Acceptable
Clean air device, Clean bench	Product	Outward (100)	Any application where the product is not hazardous, but must be kept contaminant free. A laminar flow clean bench provides HEPA filtered supply to the work surface and a particulate-free work area. Preparation of nonhazardous intravenous mixtures and media. Particulate-free assembly of sterile equipment and electronic devices. Polymerase chain reaction (PCR).	Not Acceptable
Animal transfer station	Product	Inward	A HEPA-filtered device used to transfer animals from dirty to clean cage, minimizing exposure to animal and personnel.	Not Acceptable
Bedding dump station	Personnel and environment	Inward	A HEPA-filtered device used to capture airborne particulates when disposing of waste bedding from animals, minimizing exposure to personnel.	Not Acceptable
BSC Class I	Personnel and environment	Inward	Effectively a fume hood with filtered exhaust. HEPA filtered exhaust air passes through a dedicated duct system to the outside	Acceptable if connected to exhaust[1]
BSC Class II–A1	Product, personnel, and environment	Inward (75)	A laminar flow device that recirculates 70% of its airflow to the work surface through a HEPA filter and exhausts the 30% balance through a HEPA filter back into the room or to the outside through a thimble connection via building exhaust system. Plenums are under positive pressure.	Minute amounts only if thimble connected to exhaust[1]
BSC Class II–A2	Product, personnel, and environment	Inward (100)	A laminar flow device that recirculates 70% of its airflow to the work surface through a HEPA filter and exhausts the 30% balance through a HEPA filter back into the room or to the outside through a thimble connection via building exhaust system. Plenums are under negative pressure.	Minute amounts only if thimble connected to exhaust[1]
BSC Class II–B1	Product, personnel, and environment	Inward (100)	A laminar flow device that recirculates 30-40% of its airflow to the work surface through a HEPA filter and exhausts the 60-70% balance through a HEPA filter to the outside via building exhaust system. Exhaust connection must be hard ducted to the outside.	Limited amounts[1]
BSC Class II–B2	Product, personnel,	Inward (100)	A laminar flow device that has a dedicated HEPA filtered supply to the work surface and a dedicated HEPA filtered exhaust to the outside via building	Acceptable

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	and environment		exhaust system. No recirculated supply, and exhaust connection must be hard ducted to the outside.	
BSC Class III, Isolator , Glove box	Maximum product, personnel, and environment	Inward	A laminar flow device with dedicated HEPA filtered supply to the work surface and dual dedicated HEPA filtered exhausted to the outside via building exhaust system. No recirculated supply, and exhaust connection must be hard ducted to the outside. (e.g., pharmaceutical quality control testing, super-clean manufacturing without creating clean room, pharmaceutical manufacturing of potent compounds, BL4 agents).	Limited amounts[1]

[1] In no circumstances should the chemical concentration approach the lower explosion limits of the compound.

Sources: Adapted from NSF Standard 49 and Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, Current Edition. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention and National Institutes of Health

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Overview for Proper Use of a BSC

Loading Materials/Equipment and BSC Startup

- ✓ Always close doors to laboratory when working with any biohazardous materials.
- ✓ Turn on blower at least 10 minutes before use and make sure drain valve is closed.
- ✓ Check pressure gauge(s) to ensure proper operating conditions are within range of those indicated on the annual certification label on the BSC.
- ✓ Check grilles for obstructions.
- ✓ Disinfect all interior work surfaces with a disinfectant appropriate for the agent in use.
- ✓ Disinfect the exterior of all containers prior to placing them in the cabinet.
- ✓ Load only items needed for the procedure.
- ✓ Arrange materials so that movement within the cabinet is minimized; flow of procedure is from clean to dirty. Never place non-sterile items upstream of sterile items. Check that rear and front grilles are unobstructed. Never hang articles from the interior walls or interior ceiling grid.
- ✓ Once the cabinet is loaded, adjust the view screen to proper position and wait 4 minutes before commencing procedures. Never use the view screen above the mark specified by the certification agency (common opening is 8-inches and up to 12" for animal facilities)
- ✓ Restrict traffic in the vicinity of the BSC.

Recommended Work Techniques

- ✓ Wash hands thoroughly with soap before and after procedures.
- ✓ Wear sterile gloves and lab coat/gown and eye protection; use aseptic technique.
- ✓ Avoid blocking front grille. Work only on or over a solid surface and adjust the chair so your armpits are at the level of the lower window edge.
- ✓ Avoid rapid movement during procedures, particularly within the BSC, but also in the vicinity of the BSC.
- ✓ Move hands and arms straight into and out of the work area; never rotate hand/arm out of work area during procedure. Move laterally in work area.
- ✓ Do not use a Bunsen burner that burns gas continuously since the flame causes air turbulence and could cause a fire or explosion. Consider using alternative equipment, such as flameless instrument sterilizers or heat plates.
- ✓ Place contaminated items such as pipettes in a waste receptacle located within the BSC.

Final Purging and Wipe-Down

- ✓ After completing work, run the BSC blower for at least 10 minutes before unloading materials from the cabinet.
- ✓ Disinfect the exterior of all containers before removing them from the work zone.
- ✓ Decontaminate interior work surfaces of the BSC with an appropriate disinfectant effective against the agent used.
- ✓ Routinely check the drip pan beneath the work surface for cleanliness, and if a spill has occurred, clean and disinfect it.
- ✓ Take care to prevent towelettes from being sucked into exhaust plenums.
- ✓ When closing the sash, the BSC blower needs to be turned off unless the BSC is labeled 'Energy efficient engineered'.

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Decontamination and Spills
All containers and equipment should be surface decontaminated and removed from the cabinet when work is completed. The final surface decontamination of the cabinet should include a wipe-down of the work zone. Investigators should remove their gloves and gowns and wash their hands as the final step in safe microbiological practices.

Small spills within the cabinet can be handled immediately by placing the contaminated absorbent paper toweling into the biohazard waste container. Any splatter onto items within the cabinet, as well as the cabinet interior, should be immediately wiped with a towel dampened with decontaminating solution. Gloves should be changed after the work surface is decontaminated and before clean absorbent toweling is placed in the cabinet. Hands should be washed whenever gloves are changed or removed.

Spills large enough to result in liquids flowing through the front or rear grilles require more extensive decontamination. All items within the cabinet should be surface decontaminated and removed. Beneath the BSC work surface is a drip pan to collect large spills. After ensuring that the drain valve is closed, decontaminating solution can be poured onto the work surface, grilles, and the drain pan. Twenty to thirty minutes is generally considered an appropriate contact time for decontamination, but this varies with the disinfectant and the microbiological agent. The drain pan should be emptied into a collection vessel containing disinfectant. If the drain pan is accessible, wipe it down to remove remaining debris. Should the spilled liquid contain radioactive material, Radiation Safety personnel should be contacted for specific instructions on conducting a similar procedure.

Maintenance
To function adequately, the cabinet airflow must be closely regulated and the HEPA filters must be certified**.** All biological safety cabinets should be certified annually. **Annual certification is required for work at BSL2 and BSL3**. **Annual risk assessment through OBS is required for work at BSL1 to determine certification needs**. It is highly recommended that all BSL1 BSCs be annually certified (IBC-POL-018). Certification services are available for a fee through Engineering and Technical Services at Environment, Health & Safety (EH&S) or through an EH&S approved vendor. All BSC service, maintenance and certification must be either approved by or provided by EH&S - BSC Program.

All BSCs must be either surface or gas decontaminated prior to being moved from one space to another. Before a unit is removed from the lab for maintenance, opened up for maintenance or repair, relocated, or disposed, laboratory staff are responsible for arranging surface or gas decontamination with Engineering and Technical Services. Gas decontamination is always required prior to disposal of a BSC. Gas decontamination must be done by trained personnel; through Engineering and Technical Services. BSCs to be decommissioned must be disposed by campus metal recycler. BSCs should not be sent to UW-Madison's Surplus With a Purpose (SWAP) to be sold. Prior to the disposal or removal from campus the Principal Investigator must determine if the BSC is listed by Property Control as an inventory (capital) asset by their department. If so, the BSC must be removed from the inventory list. The Department's Property Administrator will be able to help with the list and inventory removal.

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Disposal of Wastes from Biological Laboratories
The following biohazardous waste disposal guidelines are designed to protect not only the public and the environment, but also laboratory and custodial personnel, waste haulers, and landfill/incinerator operators at each stage of the waste-handling process. Workers who generate biohazardous waste in the laboratory must assure that the labeling, packaging, and intermediate disposal of waste conform to these guidelines. The appropriate packaging of all waste is fundamental for assuring protection of the handler and proper disposal. A display poster that summarizes sharps and glass disposal is available at the EH&S website and upon request.

Decontamination means a process of reducing the number of disease-producing microorganisms and rendering an object safe for handling.
Disinfection means a process that kills or destroys most disease-producing microorganisms, except spores.
Sterilization means a process by which all forms of microbial life, including spores, viruses, and fungi, are destroyed.

Biohazardous Waste
The following items require decontamination prior to disposal:

- Microbiological laboratory wastes such as cultures derived from clinical specimens and pathogenic microorganisms, and laboratory equipment that has come into contact with them
- Tissues, liquid blood, cells and body fluids from humans
- Tissues, liquid blood, cells and body fluids from an animal that is carrying an infectious agent that can be transmitted to humans
- Recombinant organisms
- Exotic or virulent plant and animal pathogens
- Contaminated sharps
- Bedding/waste from animals as per risk assessment

Other categories of waste that require decontamination before disposal are regulated materials. For mixed waste, the hazardous chemical and radioactive materials take precedence over the biological hazards, and special handling may be required.

Infectious and Medical Waste
Contaminated materials from laboratories and animal facilities, such as cultures, tissues, media, plastics, glassware, instruments, and laboratory coats, must be decontaminated before disposal or washing for re-use. Collect contaminated materials in leak-proof containers labeled with the universal biohazard symbol; autoclavable biohazard bags are recommended. After autoclaving, deface the biohazard symbols on containers. Additionally, you should add a green “OK to Trash” sticker to the bags to show the material is decontaminated and safe to handle by UW custodial/waste disposal personnel.

Effective 07/2011, UW’s waste contractor will NOT accept any red biohazard waste bag or container because they consider these waste items to be Medical Waste which has NOT been autoclaved and is therefore still biohazardous. This is in effect regardless of whether a red bag has been autoclaved and/or biohazard symbol defaced or covered. Furthermore, the contractor will not accept the UW “OK to Trash” sticker as proof of non-hazardous status on a red bag.

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All units that generate biohazard waste must put autoclaved waste in EITHER **CLEAR** OR **ORANGE** biohazard autoclave bags. Both clear and orange colored biohazard bags are available via MDS.

Laboratories shall continue to use a green "OK to Trash" sticker on autoclaved waste in clear or orange biohazard bags. The green sticker informs custodial personnel that the bag only contains autoclaved material and does NOT contain sharps. Custodians will no longer handle red biohazard bags, even if labeled with a green "OK to Trash" sticker.

Sharps are instruments designed to cut or penetrate skin. Examples include syringes with needles, lancets, and razor blades, regardless of their actual use. Collect these items in an approved medical sharps container to prevent wounding of coworkers and waste handlers. Sharps require special handling and may not go directly to the landfill. A contractor, MERI (Madison Environmental Resourcing, Inc.), collects and processes medical sharps, disinfecting and grinding them prior to final disposal. Medical sharps need not be autoclaved prior to disposal by MERI unless generated by a BSL3 or Select Agent facility. If your facility is off the main UW-Madison campus, be sure to verify disposition procedures for your sharps and infectious waste as they may differ from buildings on the main campus; building managers may be your best resource. If you plan to autoclave the sharps container, make sure it is made from heat resistant material. Please note that general building custodial personnel are instructed not to handle or transport sharps containers as part of their safety training.

Be aware that there are buildings on campus (such as UW Hospital and Clinics) which may have different waste pick-up policies than those stated here for custodial personnel. Be aware of your building policies and contact the facilities manager in your building.

Liquid Waste

Liquid waste that is contaminated with infectious agents or biological toxins must be rendered safe by chemical or autoclave treatment before sewer disposal. Care must be taken to avoid splashing and generating aerosols. Sewer lines should be decontaminated by flushing with hypochlorite (1:10 dilution of household bleach containing 5.25%-6.15% sodium hypochlorite) prior to servicing.

Waste from Animal Experiments

Animal waste (bedding, feces, urine, etc.) may require disinfection/inactivation by methods as described in the biosafety protocol followed by disposal via trash or sanitary sewer. Animal carcasses are disposed by incineration or via chemical digestion. Disposal outside of these regular routes must be reviewed and approved.

Animal waste which does not require disinfection/inactivation as described in the biosafety protocol is disposed via trash or sanitary sewer. Disposal outside of these regular routes must be reviewed and approved.

All animal carcasses from animals covered under Appendix Q (containing recombinant or synthetic nucleic acid molecules or a recombinant or synthetic nucleic acid molecule-derived organism) shall be disposed of to avoid its use as food for human beings or animals unless food use is specifically authorized by an approved Federal agency. (NIH Guidelines Appendix Q-I-B-1)

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Noninfectious Waste

The following are usually not included in the definition of infectious waste, but should be placed in containers such as plastic bags prior to disposal to contain the waste. If these items have been mixed with infectious wastes, they have to be managed as though they are infectious. Non-infectious waste may include:

- Items soiled or spotted, but not saturated, with human blood or body fluids. Examples: blood-spotted gloves, gowns, dressings, and surgical drapes.
- Containers, packages, non-fragile waste glass, laboratory equipment, and other materials that have had no contact with blood, body fluids, clinical cultures, or infectious agents.
- Noninfectious animal waste such as manure and bedding, and tissue, blood, body fluids, or cultures from an animal that is not known or suspected to be carrying an infectious agent transmissible to humans.

As a general rule, materials that can cut, but are not intended to do so, should be disposed in a manner that prevents harm. Examples of such materials include fragile glass, glass slides and cover slips, and pipettes and pipette tips. If a bag is apt to be punctured because of sharp-edged contents, double bagging and boxing may be necessary. Furthermore, the material must be decontaminated prior to disposal if it harbors infectious agents or recombinant materials.

Methods of Decontamination

Choosing the right method to eliminate or inactivate a biohazard is not always simple; it is difficult to prescribe methods that meet every contingency. Decisions are best left to the personnel directly involved, provided they are well informed and prepared to verify the effectiveness of the treatment. The choice depends largely on the treatment equipment available, the target organism, and the presence of interfering substances (e.g., high organic content) that may protect the organism from decontamination. Other common factors that influence the efficacy of disinfection are contact time, temperature, water hardness, and relative humidity.

Various treatment techniques are available, but practicality and effectiveness govern which is most appropriate. For example, there is a practical limit to the time that can be spent autoclaving waste, and alternative methods might be more effective and economical. The efficacy of the selected method against the particular biohazard must be documented by reference to accepted procedures or quantitative testing.

Use extreme caution when treating waste that is co-contaminated with volatile, toxic, or carcinogenic chemicals, radioisotopes, or explosive substances. Autoclaving this type of waste may release dangerous gases (e.g., chlorine from bleach) into the air. Such waste should be chemically decontaminated or picked up by the Safety Department for special disposal.

Ideally, biohazardous waste should be decontaminated before the end of each working day unless it is to be picked up for special waste treatment. Biohazardous waste should never be compacted. Ordinary laboratory wastes should be disposed of routinely as much as possible to reduce the amount requiring special handling.

Steam Sterilization

Decontamination is best accomplished by steam sterilization in a properly functioning autoclave that is monitored monthly with biological (i.e., *Bacillus stearothermophilus* spore testing) or chemical (i.e., 3M™ Comply™ SteriGage™) indicators that verify adequate temperatures and

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times have been reached inside the material/load to kill microorganisms. Efficacy test results must be recorded and retained. Indicator tape provides assurance only that a high temperature was reached; it does not indicate it was heated for the proper time. The tops of autoclavable biohazard bags should be opened to allow steam entry. For dry materials, it may be necessary to add water to the package prior to autoclaving.

Although we recommend autoclaving all biohazardous wastes for at least one hour, the nature of the waste in a load should determine cycle duration. For example, if the waste contains a dense organic substrate such as animal bedding or manure, one hour may be insufficient to inactivate certain pathogens buried within. A considerably longer exposure time (e.g., 8 to 12 hours) may be required to effectively decontaminate such waste. General autoclave safety and use guidelines are available through the OBS website.

Chemical Disinfection
Where autoclaving is not appropriate or feasible, an accepted alternative is to treat material with a chemical disinfectant, freshly prepared at a concentration known to be effective against the microorganisms in use. The disinfectant of choice should be one that quickly and effectively kills the target pathogen at the lowest concentration and with minimal risk to the user. Allow sufficient exposure time to ensure complete inactivation. Other considerations such as economy and shelf life are also important. The susceptibility to chemical disinfection generally is greater for enveloped viruses than for non-lipid viruses, and greater for vegetative bacteria and fungi than for spores. Mycobacteria are more resistant to inactivation than most bacteria, while prions are notably resistant to most chemicals.

The following brief overview cannot do justice to the complexity of this subject. Additional references should be consulted and testing done to verify the efficacy for the given usage.

Alcohol (ethanol, isopropanol) is effective against vegetative forms of bacteria, including mycobacteria and fungi, and hydrophobic (enveloped) viruses, but will not destroy spores or hydrophilic viruses. The recommended strength is 70–90%; higher levels actually may be less efficacious. Alcohol typically is used for disinfection of instruments or surfaces that have low organic burden. Characteristics limiting its usefulness are flammability, poor penetration of protein-rich materials, and rapid evaporation making extended contact time difficult to achieve. Alcohol-based hand-rubs may be used for the decontamination of lightly soiled hands in situations where proper hand-washing is inconvenient or impossible.

Aldehydes (formaldehyde, glutaraldehyde) have broad germicidal activity, but toxicity to humans limits their usefulness as laboratory disinfectants. Example products: Cidex, Wavicide-01.

Peroxygen compounds provide a wide range of bactericidal, viricidal, and fungicidal activity, although activity is variable against bacterial spores and mycobacteria. Corrosivity varies with different products but is less problematic than with hypochlorite disinfectants. Their good detergent properties combine cleaning with disinfection. Example product: Virkon.
Ethylene oxide sterilizers can provide effective treatment of heat sensitive equipment. Ethylene oxide is a human carcinogen. **Release of ethylene oxide gas is restricted under federal and state regulations. You must consult with the EH&S Department prior to purchasing this equipment.**

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Halogens such as hypochlorite, the active ingredient in household bleach, are inexpensive and are also highly effective in decontaminating large spills. Their drawbacks include short shelf life, easy binding to nontarget organic substances, and corrosiveness, even when diluted. Household bleach typically contains 5.25%-6.15% NaOCl Solutions should be stored in an opaque bottle to reduce decay during storage. A freshly prepared solution should be used for sanitary purposes such as cleaning a blood spill. Solutions containing bleach should not be autoclaved. Also be aware that using chlorine compounds to disinfect substances co-contaminated with radioiodine may cause gaseous release of the isotope. Contact with skin should be avoided. Example products: Clidox, Clorox, or other household bleach.

Iodophors, complexes of iodine and carrier, have good germicidal properties with relatively low toxicity and irritancy. Efficacy has been demonstrated against bacteria including mycobacteria, viruses, and fungi; prolonged contact time may be needed to kill certain fungi and bacterial spores. Example products: Povidine, Betadine.

Phenolic compounds are effective against vegetative bacteria, particularly gram positive species, and enveloped viruses but not against spores. Phenolics may be used in combination with detergents for one-step cleaning and disinfection of surfaces. Phenolic disinfectants maintain their activity in the presence of organic material and are generally considered safe, although prolonged exposure of skin may cause irritation. Example products: Vesphene, LpH.

Quaternary ammonia disinfectants kill most fungi and vegetative gram positive bacteria but lack efficacy against mycobacteria, spores, and some viruses including adenovirus. Quaternary ammonium compounds generally have low toxicity and irritancy and are relatively inexpensive. Example products: CaviCide, HB Quat, Roccal, Solucide.

It is important to be aware that common laboratory disinfectants can pose hazards to users. Ethanol and quaternary ammonium compounds may cause contact dermatitis. Chlorine in high concentrations irritates the mucous membranes, eyes, and skin. The toxicity of aldehydes limits their usefulness.

Large-volume areas such as fume hoods, biological safety cabinets, or rooms may be decontaminated using gases such as formaldehyde, ethylene oxide, or peracetic acid. These gases, however, must be applied with extreme care. **Only experienced personnel who have the specialized equipment and protective devices to do it effectively and safely should perform gas decontamination.**

Incineration
The optimal method of disposal for some types of waste is incineration. Animal carcasses are routinely picked up by the EH&S Department for disposal by this method. Bedding, plastic, and metallic objects must be excluded from packages of animal carcasses. Consult the EH&S Department for more information.

UV Treatment
The efficacy of UV light for disinfection is limited by a number of factors and thus is not recommended as the primary method of disinfection. The light is only effective on surfaces it contacts, has little ability to penetrate organic material, and the UV output decreases as the lamp

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ages. Personnel should avoid exposure to light in this wavelength region since brief exposure can cause erythema (sunburn), and/or eye injury.

EMERGENCY PLANS

Emergency plans should be tailored for the laboratory. The laboratory supervisor should prepare instructions specifying immediate steps to be taken and all personnel should understand basic emergency measures. It is recommended the instructions be displayed prominently in the laboratory and annually reviewed with personnel. No single plan will apply to all situations, but the following general principles should be considered:

- Always know the location of emergency response materials, such as spill kits, fire extinguishers, eyewashes, safety showers, first aid kits, automated exterior defibrillators (AED), contact numbers or first aid kit.
- In the event of a spill outside of containment, everyone should leave the affected area immediately. Even for apparently small spills, evacuation is important if aerosols were generated. Clothing, if contaminated, should be removed. Exposed skin should be washed for at least 15 minutes with soap and water. A splash to the eyes should be treated by flushing with water at a plumbed eyewash for at least 15 minutes.
- If a spill presents immediate danger to people and exceeds the ability of local staff to control it, the event should be reported as an emergency to UW Police.
- Close the laboratory door and post a "No Entry" sign indicating the hazard. Notify the laboratory supervisor and the Office of Biological Safety.
- Seek medical treatment for persons exposed.
- Personnel accidentally exposed via ingestion, skin puncture, or obvious inhalation should be given appropriate first aid and then seek immediate medical assessment.
- If necessary, call 9-1-1 or UW Police for transportation to the University Hospital emergency room at any hour.
- Complete a First Report of Biological Exposure or Release Form online at the OBS website within 24 hours.
- Do not reenter the room until aerosols have settled (30 minutes minimum), and the extent of the hazard and its dissemination has been determined.
- Each person who enters the laboratory for cleanup should wear at a minimum a lab coat, gloves and eye protection.
- Use an appropriately concentrated disinfectant to decontaminate the area. A supply of stock disinfectants should always be available.
- Decontaminate all materials used in cleanup procedures.

In any emergency situation, attention to immediate personal danger overrides containment considerations. With the exception of BSL3 laboratories, properly garbed and masked fire or security personnel are adequately prepared to enter any biological laboratory in an emergency. Reporting is an additional required step in emergency management. The supervisor should always be notified and a First Report of Biological Exposure or Release Form prepared even in situations that do not involve emergency responders or require immediate medical care. Notify the Biological Safety Officer of any spills outside containment, potential exposures, violations of the NIH Guidelines, or any research-related accidents and illnesses.

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Exposure Response

PIs are asked in the context of the biosafety protocol to consider the consequences of an accidental exposure to the microbes used in their research and prepare an appropriate response procedure. At times it is difficult to ascertain whether an illness is laboratory or community acquired, and you should not discount the possibility that an illness could be related to research activities. For any possible or identifiable exposure to a hazardous substance, individuals must seek immediate medical assessment.

- For non-emergency assessments Monday through Friday, 9:00 a.m. to 5:00 p.m., UW employees must go to University Health Service at 333 East Campus Mall.
- UW Hospital employees may seek non-emergency assessment at University Hospital Employee Health Service.
- For after-hours non-emergency exposure contact University Hospital Emergency Department for assessment
- For emergency medical attention go directly to University Hospital Emergency Department; be sure to communicate the exposure event related to the emergency.

Be prepared to respond to an accidental exposure. The best approach is to have a well-prepared exposure response plan and to provide training to personnel according to this plan. Following are the basic elements of a plan:

- A description of the microbe(s) and the signs and symptoms of infection.
- Distinct characteristics of the laboratory strain(s), such as known antibiotic resistance, transmissibility, atypical tissue tropism, foreign genes that alter pathogenicity, and so forth.
- Recommendations for treatment regarding effective drugs, quarantine, and so forth.
- A test to establish a history of exposure at the start of employment and periodically thereafter may be appropriate for work with a few pathogens such as *Mycobacterium tuberculosis*.
- Completion of a First Report of Biological Exposure or Release Form, located online at the OBS website, within 24 hours.

Biohazardous Spills

Laboratories should be prepared to immediately address biohazardous spills by training personnel in advance and having appropriate spill-control materials in place. Note that biohazardous materials being transported outside of laboratories, including to autoclaves, should be in secondary containment capable of completely containing the spills.

In addition to spill-prevention procedures, information regarding spill-control procedures should be displayed in laboratories and periodically reviewed with personnel. In the event of emergency, do not hesitate to call 911 if necessary. The UW-Madison Office of Biological Safety (OBS) is available for additional assistance and information at 263-2037.More emergency contact information is available at https://ehs.wisc.edu/emergencies/

All spills or releases of biohazardous or recombinant materials must be reported to the Principal Investigator (PI) and also to the Office of Biological Safety (OBS) and University Health Services (UHS) within 24 hours through the use of the First Report of Biological Exposure or Release Event Form, available on the EHS Website: https://ehs.wisc.edu/first-report-of-biological-exposure-or-release-event/

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Recommended Supplies

Appropriate materials to handle biohazardous spills should be prepared in advance, placed in strategic locations inside or outside the laboratory, and all laboratory personnel informed of the location(s).

Disinfectant(s):

- Disinfectant(s) appropriate to the agent(s) used in the lab should be available.
- If dilutions are made in advance (i.e. 10% bleach), fresh solutions should be made (and dated) on a specific schedule depending on the materials and manufacturer's instructions.

Absorbent materials:

- Sufficient absorbent materials should be available to absorb the maximum volume of biohazardous materials handled in the laboratory.
- Paper towels or other absorbent laboratory wipes are commonly utilized, and spill-specific materials are available through laboratory supply companies.

PPE:

- PPE may vary depending on the biosafety level, route of infection of agents, etc., but minimally should include disposable gloves, eye protection, and laboratory coats or gowns.

Other:

- Signage to post the area as off-limits until potential aerosols have settled.

Decontamination Procedures

General spill cleanup procedures are provided below, and may be modified to meet the specific needs of your laboratory. A sample procedure suitable for posting in the laboratory can be found at: https://ehs.wiscweb.wisc.edu/wp-content/uploads/sites/25/2017/01/BioHazSpillProtocolSample.pdf

Spills Inside a BSC

- Properly functioning BSCs should contain potentially dangerous aerosols from spills within the units.
- Immediate Response:
    - Immediately stop all work, but leave BSC blower on during clean-up.
    - Notify others in the area.
    - Determine if first aid and/or medical attention is needed (injury, direct or potential exposure). Call 911 if necessary.
    - Remove potentially contaminated PPE and dispose of them in biohazard waste containers inside the BSC.
    - Wash hands thoroughly with soap/antimicrobial agent and water.
- Clean-up Response:
    - Don new PPE (at minimum, gloves, lab coat, eye protection)
    - Completely cover spill with absorbent material and pour an appropriate disinfectant solution onto absorbent material.
    - Flood drain pan (Type II BSC) with disinfectant.
    - Using paper towels and disinfectant, wipe down walls, work surfaces, and equipment.
    - Let disinfectant stand for an adequate length of time (up to several hours).

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        - Proper disinfection time is dependent on specific disinfectants, organic load, and type of microbe. Consult your disinfectant documentation for further guidance.
    - Flush drain pan with water and remove drain tube.
    - Transfer all contaminated disposable materials into an autoclave bag.
    - Wipe down exterior of autoclave bag, disinfectant container, and other contact surfaces with disinfectant.
- Wrap-up:
    - Remove PPE and dispose of them in biohazard waste containers inside the BSC (autoclave prior to disposal).
    - Wash hands thoroughly with soap/antimicrobial agent and water.
    - Autoclave all contaminated materials.
    - Report incident to PI (if not already notified).

Spills Outside of a BSC

- Immediate Response:
    - Immediately stop all work and notify others in the area.
    - For material infectious via aerosols:
        - Evacuate everyone from the laboratory area
        - Remove potentially contaminated PPE (and potentially contaminated clothing) and dispose of them in biohazard waste containers.
        - Determine if first aid and/or medical attention is needed (injury, direct or potential exposure). Call 911 if necessary.
        - In a secondary location, wash hands thoroughly with soap/antimicrobial agent and water.
        - Post all laboratory doors with "Spill: Do not enter" signage.
        - Wait at least 30 minutes before re-entry to allow potentially dangerous aerosols to dissipate.
    - For materials not infectious via aerosols:
        - Determine if first aid and/or medical attention is needed (injury, direct or potential exposure). Call 911 if necessary.
        - Remove potentially contaminated disposable PPE and dispose of them in biohazard waste containers.
        - Wash hands thoroughly with soap/antimicrobial agent and water.

- Clean-up Response:
    - Put on new/clean PPE (at minimum, gloves, lab coat, eye protection)
    - Completely cover spill area and area in immediate proximity to the spill with absorbent material and pour an appropriate disinfectant solution onto absorbent material. Pour disinfectant in a controlled fashion in order to minimize aerosols.
    - With disinfectant and absorbent material. Wipe down any equipment or furniture in the spill area that may have been splashed with material.
    - Transfer all contaminated disposable materials into an autoclave bag.
- Wrap-up:
    - Remove and discard disposable PPE (autoclave prior to disposal).
    - Wash hands thoroughly with soap/antimicrobial agent and water.
    - Autoclave all contaminated materials.
    - Report incident to PI (if not already notified).

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- Report incident to UW-Madison Environment, Health and Safety (EHS) through the use of the First Report of Exposure/Release Form within 24 hours.

Spills in BSL3 Laboratories
Laboratories handling materials at BSL3 or ABSL3 can use the above protocols as a starting point, but should work closely with OBS to develop specific spill protocols for their agents for each area. These protocols must be included in their laboratory BSL3 and ABSL3 manuals.

TRANSPORT OF HAZARDOUS MATERIALS

Transport of hazardous materials on campus, in a campus vehicle or by a commercial carrier (such as FedEx or UPS) requires special attention to particular safety containment and regulations.

To protect the public at large, hazardous materials transportation by commercial carrier is regulated by the US Department of Transportation (DOT) as well as by the International Air Cargo Organization (ICAO) and International Air Transport Association (IATA). The US Department of Transportation (DOT) regulates the shipping and transportation of hazardous materials in commerce on United States' roadways, airways and vessels as described in the Code of Federal Regulations Title 49, Parts 171 to 178 (49CFR §171-178). Air transport and international transport of Dangerous Goods (aka Hazardous Materials) in commerce is regulated by International Air Cargo Organization (ICAO) and International Air Transport Association (IATA). International and DOT regulations are similar but can vary on some substances; therefore it is crucial to become trained and certified according to both regulatory bodies.

A hazardous material is defined as "a substance or material that the Secretary of Transportation has determined is capable of posing an unreasonable risk to health, safety, and property when transported in commerce." All DOT hazardous materials regulated in transport are listed in the 49CFR §172.101 Hazardous Materials Table.

The regulations for shipping hazardous materials apply to all individuals involved in the shipping process, including individuals who:

- Arrange for transport
- Package materials
- Mark and label packages
- Prepare shipping papers
- Handle, load, secure or segregate packages within a transport vehicle.

The Regulations require the individual to receive training in order to become certified to ship hazardous materials. Training must be refreshed at least every 2-3 years (3 years US DOT; 2 years ICAO/IATA) or when regulations significantly change. Regulatory updates commonly occur at the beginning of each year and may or may not be significant; individuals who have completed training must be cognizant of changes.

OBS provides Bio-Hazardous Materials Shipping certification training through a combination of online and in-person courses. Training through OBS is good for 2 years. See the EH&S website

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Hazmat Shipping page, https://ehs.wisc.edu/hazmat-shipping-transportation/, or contact OBS for additional information.

Many materials and shipment situations may require a permit and/or a materials transfer agreement (MTA). OBS is not a resource for acquiring permits or MTAs. Information on MTAs can be found at https://kb.wisc.edu/gradsch/page.php?id=33011. To determine if your material movement requires a permit, you and the shipment recipient will need to contact permitting agencies in the country and state of origin and destination. Permitting agencies in the United States include: Centers For Disease Control & Prevention (CDC), US Department of Agriculture (USDA), State Department of Agriculture, US Department of Commerce, US Fish & Wildlife Department, and Convention on International Trade in Endangered Species (CITES).

There are times when it is practical and reasonable for UW-Madison employees to transport biological materials, some of which meet the regulatory definition of a hazardous material, between buildings on the main campus or to outlying campus areas in an institutional vehicle. This activity does not meet the regulatory definition of transportation in commerce because the UW is a government agency and current regulations allow an exemption from the Hazardous Materials transportation standard (49CFR §171.1(d)(5)). This means that UW employees transporting hazardous materials (except hazardous waste) from building to building and/or on public roadways in a UW vehicle are not subject to the US DOT regulations for personnel training & certification and materials packaging, documentation and labeling.

Although UW is exempt from US DOT Hazardous Materials transportation regulations (CFR49) when moving materials on campus or in a campus vehicle on roadways, we must still adhere to safety guidelines which essentially mimic the HazMat regulations. OBS and EH&S published guidelines for transport of biologicals and other hazardous materials on campus or by campus vehicle: https://ehs.wisc.edu/hazmat-shipping-transportation/

OBS and EH&S strongly advise against individuals transporting hazardous materials in a personal vehicle, as your personal insurance may not cover incidences occurring while moving these materials (materials include but are not limited to pathogenic specimens, dry ice, liquid nitrogen, chemical preservatives or other laboratory chemicals). It is also recommended that hazardous materials are not transported via taxi, city bus, bicycle or scooter either on or off campus by personnel.

Transport of Hazardous Material for Disposal
Movement of hazardous materials for disposal (aka waste) on campus must only be performed by UW EH&S employees or approved contractors. Hazardous waste is regulated by the US Environmental Protection Agency (EPA) and requires specialized training to perform appropriate handling, marking and documentation. UW EH&S has designated employees trained for handling, transporting and disposal of hazardous materials. For additional information or to request disposal services https://ehs.wisc.edu/disposal-services/.

LABORATORY SECURITY AND PUBLIC AREAS

Security commonly refers to safeguarding electronic equipment and personal belongings. Security also needs to be considered in terms of preventing theft of materials from our facilities that have the potential to harm our community.

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The UW-Madison Police Department recommends several basic precautions:

- Do not prop doors open; lock doors when no one is present
- Wear visible identification
- Remove sensitive data from the Web
- Report suspicious activities and unauthorized individuals

The degree to which laboratory security is implemented should be commensurate with risk. All laboratories, including those handling only low-risk biological materials under BSL1 containment practices, must maintain a basic level of security. You should make an effort to know all the people who work in your area, and to greet unknown persons who enter laboratories and to ask their purpose. According to CDC's guidance for BSL1 laboratories, "Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments or work with cultures and specimens is in progress." Translated into common practice, this statement means that everyone entering a laboratory should have the supervisor's explicit approval to be there.

Security concerns also extend to all laboratory materials in storage. Unauthorized persons should not be able to access it. Inventory records are instrumental to determining if there is a discrepancy due to misuse or a security lapse. An easy way to prevent unauthorized access is to lock the laboratory door when the room is unoccupied. Equipment should be located in the laboratory to prevent theft and release of materials. For materials stored outside of the laboratory, such as in a freezer located in a hallway or shared equipment space, the equipment must be locked at all times.

DURC (DUAL USE RESEARCH OF CONCERN)

The University of Wisconsin-Madison is subject to the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC). As a result the University of Wisconsin-Madison must review all potential dual use research to determine whether or not it meets the criteria outlined in this policy for DURC. Dual use research is research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that could be utilized for both benevolent and harmful purposes.

Currently this policy covers 15 agents, but the University of Wisconsin-Madison will not limit its review to just these agents. If you work with one of these 15 agents OR you feel your research could potentially be dual use research **fill out the** form found on our website (https://ehs.wisc.edu/notification-of-potential-durc-form/). For additional information, contact the Institutional Contact for Dual Use Research (ICDUR).

Avian influenza virus (highly pathogenic)
Bacillus anthracis
Botulinum neurotoxin (all amounts)
Burkholderia mallei
Burkholderia pseudomallei
Ebola virus

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Foot-and-mouth disease virus
Francisella tularensis
Marburg virus
Reconstructed 1918 Influenza virus
Rinderpest virus
Toxin-producing strains of *Clostridium botulinum*
Variola major virus
Variola minor virus
Yersinia pestis

RESEARCH WITH SELECT AGENTS

Biological Select Agents or Toxins (BSATs) are biological agents that have been declared by the U.S. Department of Health and Human Services (HHS) or by the U.S. Department of Agriculture (USDA) to have the "potential to pose severe threat to public health and safety." The U.S. Centers for Disease Control and Prevention (CDC) regulates the laboratories which may possess, use, or transfer select agents within the United States in its Federal Select Agent Program. To acquire more information on the federal select agent program including a complete list of biological agents and toxins which fall under these regulations go to www.selectagents.gov.

UW- Madison has oversight of research conducted with select agents on UW-Madison's campus. If you are considering starting work with select agents, please contact the UW-Madison SA program.

Select Agent Toxins (Subthreshold Amounts)
UW-Madison requires that you maintain an accurate inventory of Select Agent (SA) toxins and secure the toxins in your laboratory. Inventory reports should be submitted quarterly to the SA program manager. For additional information, contact the UW-Madison SA Program.

Abrin
Botulinum neurotoxins
Clostridium perfringens epsilon toxin
Conotoxin
Diacetoxyscirpenol (DAS)
Ricin
Saxitoxin
Shiga-like ribosome inactivating proteins
Shigatoxin
Staphylococcal enterotoxins
T-2 toxin
Tetrodotoxin

MINORS

In general, physical, chemical, and biological laboratories and animal facilities are unsuitable for entry by children or by adults with precarious health status. Department chairs/committees,

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laboratory directors, or PIs should clearly discourage laboratory entry except for scheduled educational activities supervised by an authorized host. In certain circumstances of high hazard potential, the appropriate safety committee may limit laboratory access to program personnel or support staff. Laboratory door signs will be posted to that effect.

Minors can be granted access to a biological laboratory for educational activities unless the activity is deemed to have high hazard potential. In order for a minor to be granted access to a laboratory:

- An appropriate form of parental permission is required (in writing). For assistance with release/authorization forms, contact the Office of Risk Management/Business Services.
- Appropriate PPE (lab coat, gloves, and eye protection) and laboratory specific safety instruction must be provided prior to any laboratory work performed by the minor or in the direct presence of the minor.
- Minors must complete the three required biosafety training modules on Learn@UW and be listed in the personnel section of the Biosafety Protocol if the laboratory work performed is part of a registered Biosafety Protocol.
- Minors must be supervised in the laboratory at all times by the PI or a senior laboratory staff member.
- Minors cannot handle (and should not be in the presence of) Risk Group 3 pathogens or Select Agents.

RESPONSIBILITIES OF THE INSTITUTIONAL BIOSAFETY COMMITTEE

The Institutional Biosafety Committee (IBC) serves as the Institutional Biosafety Committee required under the NIH Guidelines. The committee consists of university and community representatives. University representatives will remain in the majority.
The IBC will support and critically evaluate University of Wisconsin–Madison biological safety activities intended to protect the health and safety of the university community, visitors, and neighbors, and ensure compliance with applicable regulations and guidelines. As part of fulfilling its charge, the IBC will:

- Review protocols that involve biological materials for safety, regulatory compliance and protection of human health and the environment. Collaborate with other committees, including but not limited to the Chemical and Environmental Safety Committee, Animal Care and Use Committees, Radiation Safety Committee, Biosecurity Task Force, and Institutional Review Boards to assure that biological safety issues are properly addressed. Periodically review criteria for mutual referral of protocols. Collaborate with the Chemical and Environmental Safety Committee to review protocols and to review respiratory protection policies and programs.
- Give advice and counsel to the UW-Madison EH&S Office of Biological Safety, the Graduate School, and the Chancellor concerning safe use and management of biological materials and compliance with regulations to support and achieve excellence in biological safety.
- In conjunction with OBS, adopt policies that guide and support the work of OBS and promote high standards of safety, regulatory compliance and protection of human health and the environment in work involving biological materials.

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- Review biological safety issues in the OBS publications and on its web site. Perform annual reviews of campus biological safety programs and biological safety aspects of regulatory compliance documents that require annual review.
- Review biological safety training programs, records, plans, and priorities as needed to help ensure optimum availability of needed and required training.
- Review proposed regulatory changes and prepare comments to agencies as judged appropriate.
- Provide a forum for the campus community to raise concerns regarding the safe use and handling of biological materials and advise the chancellor in the resolution of disputes regarding biological safety issues.
- Suspend research and/or revoke a protocol in instances where necessary according to the IBC charge and responsibilities.

The IBC will receive administrative support from the UW-Madison, Environment, Health and Safety (EH&S) Department, Office of Biological Safety.

Administrative support for the functions of this committee is provided by the UW-Madison Office of Biological Safety (OBS), described below:

Evaluations of the protocols are transmitted to the investigators and to Research and Sponsored Programs in order to satisfy the funding clearance requirements. The direct linkage between review and registration of biosafety protocols and the release of awards is an important aspect of ensuring safe and compliant conduct of research at this institution.

Confidentiality and Conduct
The IBC members shall read, sign and understand the UW-Madison IBC non-disclosure agreement (NDA). Failure to sign or abide by this agreement may lead to direct dismissal from the IBC. During meetings subject to state of Wisconsin open meetings law, IBC members shall provide opinions and review consistent with the charge of the IBC under the NIH Guidelines. Significant deviation from the charge of the IBC may result in direct dismissal from the IBC. Due to Wisconsin open meetings law requirements, IBC members are required to refrain from e-mail communications among IBC members regarding IBC business.

Consultants with the following expertise serve on the committee:

- Physical aspects of containment (equipment and ventilation)
- Legal affairs
- Human subjects
- Occupational health

Appointment Process and Length of Service
The IBC members are appointed by the Chancellor at UW-Madison. The BSO provides an annual update of the roster and recommendations to the Associate Vice Chancellor for Research Policy. Regular members serve a 3-year term starting at the beginning of the fall term. At the conclusion of the 3 year term, they may elect to continue for an additional 3-year term or to rotate off the committee (IBC Members will be limited to 3 consecutive 3-year terms). The length of service for public members is indeterminate. *Ex officio* members serve as long as they are in their respective positions. The committee chairperson, a faculty member, usually serves in this capacity for at least 1 year.

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APPOINTMENT DISMISSAL PROCEDURES

Dismissal from the IBC may occur prior to appointment end for adequate cause related to:

- the person's deviation from the charge of the IBC
- breach in confidentiality
- any other significant cause (e.g., not following or disregarding IBC policies, UW-Madison policies or other governing entity policies, person deemed to be in violation of the NIH Guidelines or has had past violations or noncompliance, which the person refuses to correct, and actions that threaten or have the potential to threaten UW-Madison accreditations, registrations (e.g., the Select Agent Program) and/or memberships.)

The IBC chair shall form a dismissal review committee made up of three IBC members plus the chair. The dismissal committee shall review charges and determine if dismissal is appropriate. The IBC chair will communicate, prior to the dismissal committee meeting, to the person in question, and allow a written explanation and/or in person explanation of the cause for dismissal. After a decision is reached by the full IBC, the IBC chair will communicate the decision and any actions required to the person in question. Serving on the IBC is a voluntary position without compensation and there is no appeals process for any person dismissed by the IBC. The Chancellor will be informed by the IBC chair with regards to any dismissal decision.

If the chair is believed to be in violation of any of the above grounds for dismissal, a review committee will instead be formed by the current *ex officio* members of the IBC plus three IBC members of their selection. Dismissal procedures will continue as outlined above, with the exception that the *ex officio* members will be charged with the duties related to dismissal procedure communication normally held by the IBC chair.

Ex officio members of the IBC cannot be dismissed by a review committee, due to the nature of their position. Any and all decisions relating to improper conduct of these members will be handled by their respective office of origin.

MAKE-UP OF THE IBC

The IBC is composed of faculty, a laboratorian, 2 public members, *ex officio* members, and consultants as per NIH guidelines section IV. The committee typically has 18 voting members; consultants are not voting members. With the exception of the Associate Dean for Research Policy, there is no provision for designation of alternates to serve when a member cannot attend. Regular members are selected for their expertise in subjects for which the committee will review protocols, as follows (see also IBC-POL-006):

- All areas of microbiology including virology, parasitology, bacteriology, and mycology.
- Recombinant techniques involving microbes, plants, and animals that are subject to the NIH Guidelines, particularly Section III-D.
- Exotic organisms, particularly those regulated by U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) and Veterinary Services (VS), http://www.aphis.usda.gov/, for which escape from containment would have

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significant consequences for the environment.
- Experience working under Biosafety Level 2 (BSL-2) and Biosafety Level 3 (BSL-3) containment in laboratory and animal facilities.
- Human gene transfer (Section III-C of the NIH Guidelines).
- Toxicology, to assess biological toxins.
- A minimum of 2 public members from the community are sought. It is helpful if the public members have some background in the biological sciences, but this is not critical since their main role is to represent the community. It is important that public members do not have a conflict of interest with the research that is conducted at this institution, such as a vested interest with financial gains at stake.

Ex officio members may be selected from the following areas:
- Associate Vice Chancellor for Research Policy in the Office of the Vice Chancellor for Research and Graduate Education (VCRGE), or designee
- Campus Veterinarian or designee
- Biological Safety Officer (BSO)

*Note: An **ex officio** member is a member of a body (a board, committee, council, etc.) who is part of it by virtue of holding another office.*

MEETING PROCEDURES AND PROTOCOL REVIEWS

Reviews of biosafety protocols focus on the risks of the materials and the mitigating measures, and are very different from grant proposal reviews. The IBC does not judge the merits of the scientific inquiry, traditional ethical considerations (unless it pertains to elements of public safety under the IBC review purview as per NIH Guidelines), or review the scientific approach of the research itself but reviews for the purpose of risk assessment in accordance with the NIH Guidelines.

Actions by the IBC on a protocol typically involve one or a combination of the following decisions.
- Approve. The protocol is accepted as provided to the committee.
- Approve with contingency(s). The investigator is required to take additional steps before the protocol will be approved. The protocol must be revised to the satisfaction of the OBS and/or the reviewers.
- Table. The protocol has significant deficiencies that must be addressed before the committee will reconsider it.
- Reject. This action is indicative of significant problems with the protocol. The BSO, and/or reviewers, or designee sends a memo to the investigator explaining the action taken by the IBC.

The following criteria generally are used for selection of full protocols to be reviewed by the IBC:
- Projects involving organisms that could have a significant impact on the environment if accidentally released from the laboratory (e.g., exotic plants, non-indigenous plant pathogens or regulated insects).
- Projects involving activities that are subject to the NIH Guidelines, section III-A through

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III-D, and require containment under BSL-2, BSL-3, or involve large scale production under BSL1-LS or BSL2-LS.
- Human gene therapy trials, subject to NIH Guidelines, section III-C.
- Select Agents and toxins
- Protocols involving an issue that OBS is not able to resolve.

A brief summary of all III-E protocols are reviewed. Any IBC member can call for the full IBC review of an III-E protocol prior to the next meeting. During the meeting, the committee will vote for approval of all posted III-E protocols.

Protocols submitted to OBS that do not require full IBC review (e.g., personnel amendments, non-recombinant DNA protocols, protocols which are exempt from the NIH Guidelines, and grant additions) are processed and reviewed by OBS staff.

Previously approved protocols will be submitted to OBS for review at least every three years (Note: the entire protocol will be review by the OBS and by the IBC, as applicable). In addition, any changes to the experiment to which the NIH Guidelines apply and/or that differ from the existing, approved experiment, will be reviewed by the IBC. Finally, protocol changes that require significant changes in safety precautions (addition or reduction of PPE, administrative controls, engineering controls) will be reviewed by the IBC.

OBS has the discretion to withhold protocols from the agenda if the protocol is deemed not ready for review. Principal Investigators may be asked to attend the meeting in order to help clarify points and answer questions when their protocol is being reviewed.

Meetings are conducted according to Robert's Rules of Order. Thus, the IBC cannot act on a protocol without a quorum present, which is defined as one more than half of the voting members. Attendance of meetings by voting members is critical. Committee members will be polled in advance of the meeting to ensure that we will have a quorum; otherwise, the meeting will be canceled. It is recognized, however, that members will not be able to make every meeting.

Meetings may be digitally recorded by OBS staff for the purpose of having an accurate record of the deliberations to assist in preparation of minutes. There is no requirement that the meetings are recorded.

Open Meetings Law
The committee is subject to the Wisconsin Open Meetings Law. Actions may be taken only at meetings that are announced and open to the public. A notice of the meeting is publically posted. Specific statutory exceptions from the requirement to meet in open session allow the conduct of certain business in closed session.

Closed Session
Protocols may contain information that must be protected due to confidentiality agreements and/or impact of disclosure on competitive positioning or the ability to obtain a patent and/or to ensure the safety and security of research facilities, especially in the case of work involving Select Agents and Toxins or research subject to Dual Use Research of Concern (DURC). Such protocols will be discussed in closed session pursuant to Wisconsin Statutes sections 19.85(1)(d) and 19.85(1)(e).
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Committee members and consultants are asked to sign a nondisclosure agreement (NDA) when their term begins. Guests who represent particular campus offices are also asked to sign the NDA. Visiting members of the public will not be asked to sign, and they will not be given copies of the protocols. Every protocol is assumed to contain confidential information and release of copies to an individual outside of the committee may be done only with the permission of the PI. If an external person or entity requests a copy of the protocol, the University's records custodian should be contacted so that the request can be handled pursuant to the University's standard processes. Copies of protocols may not be retained by committee members and consultants, but they must be destroyed (e.g., shredded) prior to disposal.

Meeting Schedule and Location
Meetings of the IBC are tentatively scheduled each month. Unless otherwise noted, IBC meetings usually are held on campus and typically last 1 to 3 hours. Meetings may be cancelled if it is unlikely that a quorum will be present or if there is not enough business to be conducted. Committee members will be notified when this is the case.

The Role of the Office of Biological Safety in Support of the IBC
The Office of Biological Safety (OBS) supports the functions of the IBC and acts on its behalf to ensure safety and compliance with regard to recombinant DNA and biohazardous materials used in research.

Protocol Processing
The "Biological Safety Protocol" form serves as a tool to gather relevant information about research that involves the criteria for which a protocol must be submitted. The protocol template is available at the OBS web site. There are several different types of submissions:

- **New** protocols are the first submission for a given project.
- **Renewals** of existing protocols are required every 3 years.
- **Amendments** must be submitted for changes in research elements, microbes utilized, and/or locations.
- **Administrative Amendments** serve to change personnel or grant awards to the protocol.

RESPONSIBILITIES OF THE OFFICE OF BIOLOGICAL SAFETY

The Office of Biological Safety (OBS) fosters safe laboratory practices and ensures compliance with or implementation of policies, guidelines, or regulations set forth by university administration, the Institutional Biosafety Committee (IBC), and regulatory agencies. This office, under the direction of the Biological Safety Officer, provides many services, including:

- Advises faculty and staff in biosafety matters.
- Provides guidance on recombinant DNA (rDNA) regulations or other aspects of genetic engineering.
- Recommends safe procedures, containment devices, and equipment for all campus activities (research, teaching, diagnostic, and building services) involving biohazards.
- Recommends methods of handling, transporting, decontaminating, and disposing of biohazardous materials.
- Provides advice regarding the disposal of biohazardous waste and biological toxins.

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- Provides consultation for containment laboratory/ventilation system design.
- Provides consultation concerning the purchase of biological safety cabinets (BSCs) through the Engineering and Technical Services Department at EH&S, which offers a BSC certification program.
- Provides biological safety education and training aids; develops educational and training programs designed to meet the specific biological safety needs of a variety of departments and staff.
- Provides a variety of biological safety references, resources and guidance materials online or in the Office of Biological Safety
- Provides biohazard signs, BSL signs and emergency door cards.
- Provides training and certification for compliance with U.S. Department of Transportation and international regulations for shipping hazardous biological materials.
- Provides administrative support to the Institutional Biosafety Committee (IBC)
- Print and distribute reviewer comments at the meeting.
- Take notes during the meeting to develop an accurate record of the deliberations.
- The BSO facilitates the discussion, as needed.
- Prepare the minutes of the meeting.
- Provide information to PIs explaining the committee's action on their protocol.
- Follow up on any action requested by the committee.
- Draft policies for the committee's consideration, as appropriate.
- Report incidents, such as significant laboratory accidents and laboratory acquired infections, and violations of the NIH Guidelines and institutional policies.
- Provide information to the IBC as relevant issues come to light.
- Keep the IBC apprised of regulatory and scientific developments that pertain to biosafety.

OBS staff performs a review of all biosafety protocols. The Principal Investigator (PI) or designee is contacted if additional information or clarification is needed for completion of the risk assessment. Protocols must be submitted well in advance of the IBC meeting, typically by the previous meeting, to allow time to address outstanding issues. Protocols that require review by the IBC usually cannot be expedited.

Protocols are valid for 3 years and must be kept up-to-date during that period through submission of amendments, as applicable.

The final step in processing protocols is to issue the registration form (see Appendix 1). Once the final version of a protocol (new, renewal, or amendment) has been reviewed and approved by OBS (e.g., OBS ensures IBC contingencies are met, as applicable, etc.), the registration form is then forwarded to the PI and to college and departmental administrators.

Biosafety Administration

- **Federal Guidelines:** Certain research is subject to federal guidelines and regulations prescribed by the NIH, CDC, the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency, and the U.S. Food and Drug Administration. Investigators utilizing human blood and other potentially infectious human materials must meet certain requirements. The Occupational Health Officer (263-2177) can assist you in this area.

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- **State Law Regarding rDNA Field Studies:** The State of Wisconsin has enacted a law requiring that the Wisconsin Department of Natural Resources or Department of Agriculture, Trade and Consumer Protection (DATCP) be notified of intended field studies of genetically engineered organisms.
- **Wisconsin Department of Natural Resources Guidelines for Waste Disposal:** The DNR has established regulations for the decontamination and elimination of infectious and medical wastes. Appropriate disposal of these wastes is an important aspect of a comprehensive safety program. WI Administrative Codes Chapter NR 526 Medical Waste Management, 2006.
- **Wisconsin Department of Commerce Regulations/OSHA Bloodborne Pathogens Standard:** As a public institution, the university must also comply with regulations prescribed by the Wisconsin Department of Commerce, including the Bloodborne Pathogens Standard mandated by the Occupational Safety and Health Administration (OSHA).

Biosafety Training
Biological safety training is offered by OBS through Learn@UW online courses, in-person classes and online reference materials. Most training courses are optional based on your laboratory needs or work position; however some are required. Required courses are clearly marked in the list below and on the OBS website Training pages https://ehs.wisc.edu/biosafety-training/

Individuals should maintain a record of training activities (Training Record), including not just formal classroom sessions but also topics covered during staff meetings and one-on-one mentoring.

Required Training
The OBS offers biological safety training courses designed to inform and prepare you for work in campus biological research laboratories in compliance with standards set forth by the NIH and CDC. Courses are offered online through Learn@UW.

The Biosafety Required Training course is required training for any person working in a biological laboratory in accordance with a registered biosafety protocol and must be renewed every 5 years. Individuals who completed Biosafety 101, Biosafety 104, and Biosafety 201 will need to complete the Biosafety Required Training course when training expires for Biosafety 101, Biosafety 104, or Biosafety 201. Biosafety 102 is required for any laboratory staff working with human-derived materials and must be renewed annually. Dual Use Research of Concern (DURC) training is required for personnel listed on a biosafety protocol that includes research activities with any of the 15 agents covered by the DURC policy and must be renewed every 3 years.

All other Biosafety trainings are not required by OBS but may be required by individual laboratories, PI's, Lab Managers or departments.

Biosafety Required Training
Required for all personnel working in laboratories with biohazardous materials.
Renew training every 5 years.

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Biosafety 102: Bloodborne Pathogens for Lab and Research
Meets Bloodborne Pathogen (BBP) training requirement for staff working with human source materials in the laboratory.
The Bloodborne Pathogen Program is administered by the Research Safety Program. Contact OBS for BBP course options and requirements.
Renew training every year.

Biosafety 105: Building Biosafety into Your Research - Biosafety Cabinet Use
Guidance training for any personnel working in laboratories using Biological Safety Cabinets (BSCs).

Biosafety 106: Autoclave Use
Guidance training for any personnel working in laboratoties using autoclaves.

Biosafety 107: Centrifuge Safety
Guidance training for any personnel working in laboratories using laboratory centrifuges.

Biological Hazardous Materials (Bio HazMat) Shipping Certification Training: Biosafety 205, 206, 207
The OBS training modules Biosafety 205 (on Learn@UW) and 206 (a hands-on workshop) provide initial certification training according to the Dangerous Goods/Hazardous Materials Regulations of the IATA and US DOT, focused specifically on shipping infectious substances and other biological materials, as well dry ice.

Renewal is required every 2 years for individuals who choose to complete this training. Renewal can be accomplished by completion of a shorter Recertification course, Biosafety 207, also available on Learn@UW.

Note: UW-Madison employees may receive shipping training from outside training agencies and are not obligated to receive the training from UW-Madison. Trained employees are obligated to keep track of training expiration, regulatory updates and accomplish renewal on time as designated by the training agency and regulatory requirements.

Biosafety 205: Hazardous Materials Shipping: Infectious and Biological substances (Bio-HazMat) - Required for Initial Certification UW Madison Personnel who ship and receive infectious and biological substances.

Biosafety 206: Hazardous Materials Shipping: Packaging Workshop
Required for Initial Certification for UW Madison Personnel who ship and receive infectious and biological substances.

Biosafety 207: Recertification for Bio Hazardous Materials Shipping
Required for Renewal of Certification of UW Madison Personnel who ship and receive infectious and biological substances.

DURC: Dual Use Research of Concern

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Dual Use Research of Concern (DURC) training is required for personnel listed on a biosafety protocol that includes research activities with any listing one of the 15 agents covered by the DURC policy.
Renew training every 3 years.

Biosafety Training Materials for Select Agent Labs
Individuals in the Select Agent Program will be notified of required training and access is by invitation only. Direct any questions regarding the types and frequency of required training to the UW-Madison Select Agent Program.

Additional trainings are presented by OBS trainers and staff on request. Our trainings may cover specialized topics, discussions or address specific audiences (e.g. first year graduate student biosafety orientation, summer science interns, emergency lab drills).

Laboratory Visits
Visits to facilities are conducted to ensure safe and compliant conduct of biological research. Additional goals include:

- to meet the needs of researchers for guidance on biosafety and regulatory issues.
- to facilitate communication between staff and OBS.
- to discuss facility issues.
- to ensure that our records accurately reflect ongoing research activities.

These visits are designed to be informational, instructional and collegial. The goal for OBS laboratory visits is to develop a relationship with our laboratory PIs, graduate students, technicians and laboratory staff and support staff. Through this relationship the OBS can be a resource for biosafety protocols, laboratory safety practices, regulatory information and updates, training and guidance. These elements are essential to foster growth in our exemplary research institution.

USEFUL REFERENCES

Note: URLs of remote sites change frequently. The OBS website has a more current set of links, or you may need to search from the root directory of each organization.

American Biological Safety Association (ABSA) list of risk groups:
http://www.absa.org/riskgroups/index.html

Arthropod Containment Guidelines. Version 3.1 (12/01), A project of the American Committee of Medical entomology of the American Society of Tropical Medicine and Hygiene:
http://www.astmh.org/subgroup/archive/ACGv31.pdf

Biosafety in Microbiological and Biomedical Laboratories, CDC/NIH. Current Edition:
http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.ht

Public Health Agency of Canada, Material Safety Data Sheets (MSDS) for Infectious Substances:
http://www.phac-aspc.gc.ca/msds-ftss/index-eng.php

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National Sanitation Foundation Standard (NSF) 49, Biological Safety Cabinets, 2002:
http://www.nsf.org/business/biosafety_cabinetry/index.asp

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules:
https://osp.od.nih.gov/biotechnology/nih-guidelines/

NTP Report on Carcinogens. National Toxicology Program, Department of Health and Human Services:
http://ntp.niehs.nih.gov/?objectid=03C9B512-ACF8-C1F3-ADBA53CAE848F635

OSHA Lab Standard. Occupational exposure to hazardous chemicals in laboratories. 29 CFR 1910.1450 Appendix A – National Research Council Recommendations Concerning Chemical Hygiene in Laboratories (Non-Mandatory):
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10106

Public Health Service, U.S. Department of Health and Human Services, CDC/NIH. Primary Containment for Biohazards: Selection, Installation, and Use of Biological Safety Cabinets, Current Edition:
http://www.cdc.gov/biosafety/publications/

TOXNET, a cluster of databases on toxicology, hazardous chemicals, and related areas. The National Library of Medicine:
http://toxnet.nlm.nih.gov/

Traynor et al. 2001. A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes. Information Systems for Biotechnology:
http://www.isb.vt.edu/Containment-guide.aspx

World Health Organization (WHO) Laboratory Biosafety Manual. 3rd Ed. revised. Geneva, 2004:
http://www.who.int/csr/delibepidemics/WHO_CDS_CSR_LYO_2004_11/en/

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