

Biosafety Manual



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I. INTRODUCTION

A. Scope

1. The Department of Environmental Health and Safety/Risk Management (EH&S/RM) has developed this manual to minimize staff and student exposure to biohazardous agents and to ensure that university laboratories operate in compliance with all applicable regulations promulgated by governmental regulatory and credentialing agencies. Specific governmental regulations that are applicable to research involving known or potentially biohazardous agents include (but are not limited to) the following:
 - a. [National Institutes of Health \(NIH\)/Centers for Disease Control and Prevention \(CDC\)](#).
 - b. [Occupational Safety and Health Administration \(OSHA\): Bloodborne Pathogens Standard: CFR 29 1910.1030; Laboratory Safety Standard: CFR 29 CFR 1910.1070](#).
 - c. Ohio Environmental Protection Agency, [Regulated Medical Waste Regulations](#).
 - d. [United States Department of Agriculture \(USDA\)](#).
 - e. [United States Department of Health and Human Services \(DHHS\)](#).
 - f. [United States Department of Transportation \(DOT\)](#).
2. Compliance with the conditions set forth in this Biosafety Manual is mandatory for all university owned and leased facilities.
3. The Guidelines developed by the World Health Organization (WHO), NIH, CDC, and OSHA are key components of this Biosafety Manual. All university research laboratories are strongly advised to fully review the information provided in the following websites:
 - a. [World Health Organization](#)
 - b. [NIH/CDC: "Biosafety in Microbiological and Biomedical Laboratories, 4th Edition" \(BMBL\)](#).
 - c. [OSHA Bloodborne Pathogens Standard](#).

B. Responsibilities

1. **Principal Investigators (PIs):** Principal investigators/laboratory directors are responsible for the proper use, storage and disposal of all biohazardous agents, select agents, and recombinant DNA molecules associated with their research. University PIs and research personnel must comply with applicable federal, state and local regulatory standards as well as any administrative requirements established by applicable institutional committees. Failure to comply with this policy may result in

an administrative review and a possible suspension of approval by the Institutional Biosafety Committee (IBC) to work with biohazardous agents and/or non-exempt recombinant DNA molecules.

- a. Principal investigators must provide (free of charge) to staff all required training, personal protective equipment (PPE), engineering control devices, immunizations and emergency response equipment.
 - b. Principal investigators must register all biohazardous agents in use within their laboratory with the IBC.
 - c. Principal investigators must register all select agents with EH&S/RM.
 - d. Principal investigators must submit to the IBC Research Protocols a Memorandum of Understanding and Agreement (MUA) for all proposed new procedures that involve potentially biohazardous agents and rDNA. The related new research procedures may not be commenced prior to receiving approval from the IBC.
 - e. Principal investigators shall submit a completed Institutional Animal Care and Use Committee (IACUC) form for all research protocols involving animal testing. The proposed animal research may not proceed until approval is granted from the IACUC.
 - f. Principal investigators shall ensure that manuals containing thorough/up-to-date standard operating procedures (SOPs), emergency response plans (ERPs), Exposure Control Plans (ECPs), and Job Safety Analyses (JSAs) are maintained in locations familiar to all staff within all research spaces where manipulations with biohazardous agents are performed. SOPs, ERPs, ECPs, and JSAs shall be updated annually or whenever new procedures involving biohazardous agents are performed. Laboratory staff shall receive thorough training regarding the content of the SOP/ERP/ECP/JSA manual annually and whenever new procedures are added to the laboratory regimen.
2. **Institutional Biosafety Committee (IBC):** All institutions awarded NIH funding are required to form IBCs which function per the [Institutional Biosafety Committee Guidelines](#). Critical duties of the IBC include:
- a. Review of all protocols involving biohazardous agents to confirm that university staff are duly protected and that research is conducted in compliance with applicable regulations.
 - b. Review/overview of MUAs for all new protocols involving biohazardous agents.
 - c. Interfacing with IACUC: review of IACUC protocols involving biohazardous agents.
 - d. Review/overview of training programs and requirements for staff working with biohazardous materials.

- e. Conducting of annual safety inspections for laboratories/support facilities utilizing biohazardous agents.
- f. Review/overview of biohazardous waste management practices.

3. **Institutional Animal Care & Use Committee**

- a. Review protocols for all research projects involving animal subjects to ensure ethical treatment of animals and compliance with applicable regulations.
- b. Approval from IACUC is required prior to initiating new research or altering the protocol of existing research projects involving test animals.

4. **Office of Environmental Health & Safety**

- a. Oversees university Biological Safety Program.
- b. Executes university Laboratory Safety Program.
- c. Administers university Respiratory Protection Program.
- d. Conducts annual compliance inspections in all university laboratories where research involving biohazardous agents is conducted.
- e. Provides institutional biosafety officer who serves as the university's main contact for review of protocols, SOPs, and laboratory working procedures and interpretation of compliance requirements of governmental regulatory and credentialing organizations.
- f. Assists the IBC and IACUC in protocol review and other compliance assurance activities.

II. **PRINCIPLES OF BIOSAFETY**

A. Containment: The term “containment” refers to utilizing routine safe methods when handling infectious material in the laboratory. Containment is the first line of defense for reducing exposure potential to university staff, and the possible contamination of the exterior environment. [The Centers for Disease Control and Prevention](#) identify the following two types of containment:

1. **Primary Containment**

a. **Personal Protective Equipment**

- i. Gloves: Must be worn whenever manipulations involving potentially biohazardous agents are performed. Select glove type based on specific biohazardous agents and chemical compound(s) to be handled.
- ii. Safety Glasses/Goggles: Required for all procedures involving potentially biohazardous agents. Select eye protection which provides side shielding and is

ANSI approved (bears Z-87 certification). Manipulations with the potential for splashing and/or spattering of biohazardous agents shall require the use of a face shield in addition to safety glasses.

iii. Laboratory Coats: Laboratory coats must be donned whenever manipulations involving potential biohazards are performed.

iv. Disposable Gowns/Scrubs must be utilized whenever potential for splashing of biohazardous materials exists.

v. Respirators shall be utilized whenever potential for aerosolization or other airborne biohazard exposure threat exists. Utilization of respiratory protection devices is subject to the review and approval of EH&S/RM.

vi. Shorts and other clothing exposing feet or legs, sandals and other open-toed shoes are not suitable laboratory attire.

b. Engineering Controls

i. Biological Safety Cabinets (BSCs): Manipulations having the potential of generating biological aerosols must be performed within certified BSCs. Complete information regarding BSC certification requirements, maintenance procedures, and classifications may be viewed at the following URL:
<http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm> .

ii. Centrifuge safety cups must be utilized when centrifuging materials have the potential of producing biohazardous aerosols.

2. Secondary Containment

a. Facility Construction: Research facilities where manipulations involving potentially biohazardous agents are performed and/or test animals are potentially infected by biohazardous agents must be constructed to satisfy the requirements outlined in the [BMBL](#).

b. Waste Disposal: All biohazardous waste generated within university research facilities must be disposed of through the EH&S/RM biohazardous (infectious) waste program and must be packaged and labeled in accordance with federal and state requirements.

B. Standard Microbiological Practices and Techniques: The most important element of containment is strict adherence to standard microbiological practices and techniques. CDC has developed “biosafety levels” (BSLs)/“animal biosafety levels” (ABSLs) which specify standard operating procedures and facility requirements for work involving biohazardous agents/infected research animals. These biosafety levels range from BSL/ABSL-1, involving manipulations with utilizing agent with minimal risk to people/the environment, through BSL/ABSL-4, which involves research with biohazardous agents that are extremely dangerous to humans and/or the environment (note: research involving BSL/ABSL-4 agents is not permitted at UD). Persons working with infectious agents or potentially infected materials must be aware of potential hazards, recommended biosafety level for the agents being manipulated, must be trained and

proficient in the practices and techniques required to handle such material safely. The PI is responsible for providing or arranging appropriate training of personnel. Personnel must be advised of special hazards and shall be required to read and follow required practices and procedures. A brief outline of the requirements of BSL-1 through BSL- 3 is provided below. For complete listing of the requirements of CDC BSLs/ABSLs refer to the [BMBL](#).

1. Biosafety Level 1 (BSL-1)

- a. Includes agents not known to cause disease in healthy adults.
 - b. Standard Microbiological Practices.
 - c. Safety Equipment (Primary Barriers): None required.
 - d. Facilities (Secondary Barriers): Open bench top sink (allowable).
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2. Biosafety Level 2 (BSL-2)

- a. Agents associated with human disease, hazard (exposure) = auto-inoculation, ingestion or mucous membrane exposure (low aerosol-exposure threat).
 - b. BSL-1 practice plus:
 - i. Limited access.
 - ii. Biohazard warning signs.
 - iii. "sharps" precautions.
 - iv. Biosafety manual defining any needed waste decontamination or medical surveillance policies.
 - c. Safety Equipment:
 - i. Primary barriers = Class I or II BSC or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials.
 - ii. Personal protective equipment (PPE): laboratory coats, gloves, face, and eye protection as needed.
 - d. Facilities: BSL-1 plus: Autoclave available.
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3. Biosafety Level 3 (BSL-3)

- a. Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences.
- b. Practices: BL-2 practice plus:
 - i. Controlled access.
 - ii. Decontamination of all waste/laboratory clothing before laundering.
 - iii. Baseline serum.
- c. Safety Equipment:
 - i. Primary barriers = Class II or III BSCs used for all manipulations of agents.
 - ii. Protective lab clothing, gloves, face, and eye protection.
 - iii. Respiratory protection as needed.
- d. Facilities: BL-2 plus:
 - i. Physical separation from access corridors.
 - ii. Self-closing, double door access.
 - iii. Special security requirements
 - iv. Negative pressure conditions within laboratory, 100% exhausted air from laboratory.
 - v. Nonporous/seamless laboratory surfaces.

C. RISK ASSESSMENT: "Risk" implies the probability that harm, injury, or disease may occur. In the context of microbiological and biomedical laboratories, the assessment of risk focuses primarily on prevention of laboratory-associated infections. When addressing laboratory activities involving infectious or potentially infectious material, risk assessment is a critical exercise that assigns an appropriate biosafety level (facilities, equipment, and practices) in order to reduce worker exposure risk and environmental threat to an absolute minimum. The intent of this section is to provide guidance and to establish a framework for selecting the appropriate biosafety level. The PI is responsible for assessing risks in order to set appropriate biosafety levels. This process should be conducted in close collaboration with the IBC (MUA) to ensure compliance with established guidelines and regulations. Determining factors in risk assessment include:

1. *Pathogenicity* of the infectious agent; pertaining to disease incidence and severity (i.e., mild morbidity versus high mortality, acute versus chronic disease). The more severe the disease, the higher the risk; viruses such as Ebola, Marburg, and Lassa, which cause diseases with high mortality rates with no available vaccines or treatment and are readily transmitted via aerosol, for example, are assigned to the highest risk classification: BSL-4. Research with

human immunodeficiency virus (HIV) and hepatitis B virus (HBV) on the other hand is performed at BSL-2. Although infection with either HIV or HBV can cause potentially lethal disease, both have low aerosol transmission risk; the ability to control transmission via [standard precautions](#) relegates both viruses to BSL-2.

2. *Route of transmission* (e.g., parenteral, airborne, or by ingestion) of newly isolated agents may not be definitively established. Extensive epidemiological research has indicated that agents readily transmitted via aerosol route have caused most laboratory infections making it critical that aerosol transmission potential be considered when working with uncharacterized agents. The greater the potential for aerosol potential: the higher the risk of transmission.

3. *Agent stability* is a consideration that involves aerosol infectivity (e.g., from spore-forming bacteria), and an agent's ability to survive over time in the environment. Factors such as desiccation, exposure to ultraviolet light, and exposure to chemical disinfectants must be considered.

4. *Infectious dose* can vary from one to hundreds of thousands of units. The complex nature of the interaction of microorganisms and the host presents a significant challenge even to the healthiest immunized laboratory worker, and may pose a serious risk to those with lesser resistance. The laboratory worker's immune status is directly related to his/her susceptibility to disease when working with an infectious agent.

5. The *concentration* (number of infectious organisms per unit volume) is important in determining risk of infection. Such a determination will include consideration of the milieu containing the organism (e.g., solid tissue, viscous blood or sputum, or liquid medium) and the laboratory activity planned (e.g., agent amplification, sonication, or centrifugation). The volume of concentrated material being handled is also important. In most instances, the risk factors increase as the working volume of high-titered microorganisms increases, since additional handling of the materials is often required.

6. The *origin* of infectious materials is also critical when preparing a risk assessment. "Origin" may refer to geographic location (e.g., domestic or foreign); host (e.g., infected or uninfected human or animal); or nature of source (potential zoonotic or associated with a disease outbreak). From another perspective, this factor can also consider the potential of agents to endanger domestic livestock and agriculture.

7. The *availability of data* from animal studies, in the absence of human data, may provide useful information in a risk assessment. Information about pathogenicity, infectivity, and route of transmission in animals may provide valuable clues. Caution must always be exercised, however, in translating infectivity data from one species of animal to another.

8. The established *availability of an effective prophylaxis* or therapeutic intervention is another essential factor to be considered. The most common form of prophylaxis is immunization. Risk assessment includes determining the availability of effective immunizations. It should be considered, that however important, immunization serves only as an additional layer of protection beyond standard microbiological practices and techniques.

9. *Medical surveillance* ensures that the safeguards implemented produce the desired health outcomes. Medical surveillance is part of risk management. It may include serum banking, monitoring employee health status, and participating in post-exposure management.

III. BIOHAZARDS

A. BIOHAZARD CLASSIFICATION: Biohazards are infectious agents or biologically derived infectious materials that present a potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment. Infectious agents have the ability to replicate and give rise to potentially large populations when small numbers are released in nature from a controlled situation. Following are categories of biohazards or potentially infectious materials:

1. Human, animal, and plant pathogens: Bacteria, plasmids, prions, rickettsia, fungi, viruses, and parasites.
2. All human blood, blood products, tissues, and certain body fluids.
3. Cultured cells (all human or certain animal) and potentially infectious agents these cells may contain.
4. Allergens.
5. Toxins (bacterial, fungal, plant, etc.).
6. Certain recombinant products.
7. Clinical specimens.
8. Infected animals, animal tissues, animal bedding/waste materials.

B. UNIVERSITY BIOHAZARD POLICIES: All PIs must comply with NIH/CDC standards regarding biological hazards through:

1. Limiting laboratory access to authorized personnel.
2. Limiting unauthorized access to known or potentially biohazardous materials.
3. Limiting handling of biohazardous materials to the minimum possible amount.
4. Insuring proper disinfection and/or disposal of material after usage.
5. Insuring proper usage of appropriate safety equipment, precautions, and procedures when handling biohazardous materials.
6. Maintaining appropriate levels of identification, warning and security in storage of the material.
7. Posting of universal biohazard warning labels on the outside door of each laboratory.
8. Maintaining proper ventilation of the laboratory.
9. Keeping laboratory doors closed during operations involving the material.

10. Following additional standard and special practices as described in the [BMBL](#).

C. MEMORANDUM OF UNDERSTANDING AND AGREEMENT

1. Principal Investigators must complete a MUA prior to commencing new research involving biohazardous agents, rDNA, or gene therapy.
2. Completed MUAs must be submitted to the IBC; commencement of the proposed research project is contingent on receiving written approval from the IBC.

D. MATERIAL SAFETY DATA SHEETS: Material safety data sheets (MSDSs) contain health hazard information such as infectious dose, viability (including decontamination), medical information, laboratory hazard, recommended precautions, handling information and spill procedures. The intent of these documents is to provide a safety resource for laboratory personnel working with these infectious substances. Proper utilization of MSDSs in association with prudent work practices fosters a safer, healthier environment.

E. TRANSFERRING OR RECEIVING OF SELECT AGENTS: In accordance with the DHHS: "[Public Health Security and Bioterrorism Preparedness Act of 2002](#)" and NIH/CDC, additional requirements for the Transfer or Receiving of Select Agents" (42 CFR Part 72) all facilities that transfer, use or store specific agents which are considered capable of rendering substantial harm to humans are subject to strict regulatory requirements. The regulations are intended to act as a deterrent to biological terrorism through controlling access to acutely toxic and infectious "select agents." Failure to comply with the requirements could pose significant legal ramifications to negligent individuals as well as the university.

THE UNIVERSITY OF DAYTON DOES NOT HAVE SELECT AGENTS AND IS NOT CURRENTLY AUTHORIZED TO AT THIS TIME.

1. DEFINITION: "[Select Agents](#)" are defined by the [CDC](#) as: "specific agents which are considered capable of rendering substantial harm to humans".

2. REGULATIONS:

a. Environmental Protection Agency: "[Antiterrorism and Effective Death Penalty Act of 1996](#)": Enacted with intent of acting as a deterrent to biological terrorism through controlling access to acutely toxic and infectious agents.

b. National Institutes of Health/Centers for Disease Control: "[Additional Requirements for the Transfer or Receiving of Select Agents](#)" (42 CFR Part 72)":

- i. Implements, bolsters EPA's "*Antiterrorism and Effective Death Penalty Act of 1996*".
- ii. Identifies viruses, bacteria, rickettsiae, fungi, toxins, and recombinant organisms/molecules which are subject to select agents restrictions (see section III).

- iii. Imposes strict institutional requirements on the transfer/receipt of select agents, including:
 - aa. Submission of detailed information package for review by CDC.
 - bb. Established a registration fee dependent on select agent(s) involved and nature of research. Fees covered three year increments, extension of registration required additional payment of full amount of initial fee (fee requirement was subsequently nullified).
 - cc. Registration approval (issuance of a select agents facility registration number) by CDC.
 - dd. Designation of “Responsible Facility Official,” whose duties include managerial oversight of the transfer process.
 - ee. Record keeping detailing the receipt, transfer, and disposal of select agents.
 - ff. Verification that all other institutions (e.g. shippers, waste disposal facilities) involved in transfer of Select Agents are properly registered with CDC.
 - gg. Maintaining records of depletion of select agents on site.
 - hh. Notification to CDC of any known or suspected incidence of improper handling of select agents and/or attempts to obtain select agents without following proper protocol as mandated by 42 CFR Part 72.
 - ii. Passing all elements of facility inspection conducted by Department of Health and Human Services to be performed within three years of initial registration with select agents program, and randomly thereafter.
- iv. Names Federal Bureau of Investigation as enforcement body:
 - aa. Knowing and willful violation: May constitute criminal (federal) offense.
 - bb. Other violations: Classified as misdemeanor offenses.
- c. Department of Health & Human Services/Department of Agriculture: “[Public Health Security and Bioterrorism Preparedness Act of 2002](#)”:** retains the requirements of 72 CFR 42 but adds the following stipulations:
 - i. Requires all facilities that use, possess, or transfer select agents institutions to register with HHS and submit the following information by September 12, 2002.
 - aa. Verification that adequate security measures are in place to ensure the safekeeping of select agents.

- bb. A listing of all staff who have access to select agents.
- cc. Verification that all staff with access to select agents have received adequate health and safety training.
- ii. Imposes requirement for background checks on all personnel with access to select agents to ensure that “restricted” persons are excluded from use, possession, and transfer process of select agents.
- iii. A “restricted person” according to 72 CFR 42 is defined as:
 - aa. A person reasonably suspected of committing a crime knowing involvement with domestic or international terrorism.
 - bb. Agents of foreign powers.
 - cc. Persons with felonious criminal records.
 - dd. Fugitives from justice.
 - ee. Illegal aliens.
 - ff. Foreign nationals from terrorism-sponsoring nations.
 - gg. Individuals dishonorably discharged from the armed services.

V. EMERGENCY PROCEDURES

A. LABORATORY EMERGENCY POSTINGS

1. Phone numbers of responsible individuals to be contacted in case of emergencies must be posted outside of entrance doors leading into each laboratory.
2. A list of the significant hazards found within the laboratory must be posted for notification of staff and emergency response personnel. The list of hazards that must be identified by signage posted at entrances to laboratories includes (but is not limited to):
 - a. Use/storage of biohazardous agents.
 - b. Use/storage of acute carcinogens and toxic chemicals.
 - c. Use/storage of radiological agents.
 - d. Use/storage of flammable materials.
 - e. Presence of strong magnetic equipment.
 - f. Emission of X-rays.

- g. Required PPE.

B. EMERGENCY EQUIPMENT

1. Verification that proper emergency equipment is provided within laboratory spaces is the responsibility of the PI. Specific emergency response equipment requirements will depend on the nature of research conducted within each laboratory space.

a. Emergency response equipment that is mandatory for all research areas includes:

i. Fire protection equipment:

aa. Fire extinguishers (tested certified quarterly).

bb. Fire alarm pull stations.

cc. Contact EH&S/RM if fire protection equipment is out-of-date or lacking.

ii. *Personal protective equipment.

iii. Emergency eyewash stations (inspected annually by EH&S/RM).

iv. Emergency deluge showers (inspected annually by EH&S/RM).

v. Biological spill kits

vi. Chemical spill kits.

c. Principal investigators are responsible for assessing and acquiring all necessary emergency response equipment prior to initiating new research projects.

d. Principal investigators must ensure that all laboratory personnel are familiar with locations and proper use of emergency equipment within their laboratory.

*For certain hazards, respiratory protection may be required for routine and emergency operations. If respirators are provided, the laboratory must have a written Respiratory Protection Program and all users must be fit-tested and trained in regard to proper use. Information about respirators and respiratory protection programs may be obtained through EH&S/RM.

C. EVACUATION ROUTES: Principal investigators must ensure that staff receive adequate training regarding emergency evacuation procedures that includes the following elements:

1. Familiarization with primary and secondary (alternate) evacuation routes.
2. Awareness of alarm method(s) used to signal a building evacuation.
3. Designation of post evacuation meeting areas for laboratory staff.

4. For assistance in determining proper evacuation procedures contact EH&S/RM.

D. BIOHAZARDOUS MATERIAL SPILL RESPONSE PROCEDURES

1. Principal investigators are responsible for developing emergency response procedures and ensuring that laboratory staff is thoroughly trained in the event of incidents involving biological and/or chemical spills. The essential elements of a biohazardous spill response plan suitable for addressing the two most common types of incidents encountered within university laboratories are listed below:

a. SPILL IN A BIOLOGICAL SAFETY CABINET: A spill that is confined to the interior of a properly operating biological safety cabinet (BSC) may present little or no hazard to personnel in the area. In the event of a biohazardous spill within a BSC, the following procedures shall be followed:

- i. Close sash immediately, but maintain operation of cabinet ventilation system in order to minimize escape of contaminants from cabinet.
- ii. Don appropriate PPE for cleaning operation, this must include, at a minimum; gloves, eye protection and laboratory coat. Response to spills involving high risk biohazardous agents may require additional PPE.
- iii. Lift sash just enough to spray a heavy mist of disinfectant into cabinet interior, close sash, allow 15 minutes for disinfectant to work and potential aerosols to be vented from cabinet space.
- iv. Following waiting period, begin cleanup of cabinet interior: thoroughly spray down spill, walls, all work surfaces, and equipment with a suitable disinfectant. Use appropriate commercially available disinfectants/germicides or 1 part household bleach to 9 parts of water
- v. Thoroughly wipe down wall, work surfaces and equipment. Note: whenever sharps materials are involved, wipe down and collection of waste materials must be conducted via mechanical means (i.e., via forceps or broom and dust pan).
- vi. Repeat steps iv and v.
- vii. Flush drain pans and catch basins below the work surface with disinfectant.
- viii. Lift the front exhaust grill and tray and disinfect/wipe all surfaces.
- ix. Wipe the catch basin and drain/collect excess disinfectant into leak proof, puncture resistant, closable and properly labeled container.
- x. Dispose of all liquid and solid waste generated during spill clean up as biohazardous waste.

b. SPILLS IN OPEN LABORATORY AREAS: Biohazardous spills occurring in open lab areas pose a greater potential for exposure than spills occurring within biological safety cabinets and as such a greater degree of care and preparedness is required for safely responding to

open area incidents. Essential elements of open area biohazard spill response are detailed below:

- i. When potentially biohazardous materials are spilled in open area of the laboratory evacuate the laboratory immediately to limit exposure to aerosols.
 - ii. Upon exiting the lab, warn other personnel in the area of the incident
 - iii. If clothing and/or skin is known or suspected to have been contaminated during incident, proceed immediately to full immersion emergency shower or changing area providing shower suitable for personal decontamination.
 - iv. Remove contaminated clothing with gloved hands, folding contaminated area inward. Discard clothing in a red biohazard bag or place clothing directly in an autoclave.
 - v. Thoroughly wash all potentially contaminated areas, arms, face, and hands with soap and warm water.
 - vi. Avoid reentry into the laboratory for at least 30 minutes to allow for the settling of aerosols potentially generated by the spill.
 - vii. Don appropriate PPE for cleaning operation. This must include, at a minimum: gloves, eye protection and laboratory coat. Spills involving high risk biohazardous agents with high potential for aerosol transmission may require additional PPE including respiratory protection.
 - viii. Cover spill gently with paper towel(s), apply disinfectant onto adjacent surfaces working toward spill. Complete action by applying copious amount of disinfectant to actual spill area.
 - ix. Allow disinfectant to stand for at least 15 minutes, proceed with thorough wipe down of spill and adjacent surface areas. Note: whenever sharps materials are involved wipe down and collection of waste materials shall be conducted via mechanical means.
 - x. Repeat steps viii and ix.
 - xi. Flush floor/sink drains with disinfectant (if affected by spill).
 - xii. Dispose of all liquid and solid waste generated during spill cleanup as biohazardous waste.
2. Advance preparation for management of a spill is an essential element of laboratory biosafety. A "spill kit" which includes necessary PPE, disinfectant, and other materials required for responding to biohazardous spills must be available in all areas where manipulations involving potentially biohazardous agents are conducted. The standard elements of a typical spill kit are detailed in this manual.
3. Whenever spills involve personal injury or biological contamination, call 911 or 9-2121 from any campus phone and request medical assistance. Be sure to state the

type of contaminant involved in the incident. The caller should remain available to brief emergency responders on the type of contamination and proper procedures for handling the material.

E. Medical Factors to Consider in Biosafety

1. A number of medical factors (not necessarily complete) that may need to be considered in the establishment of laboratory-specific safety requirements and/or procedures when infectious agents and organisms are being used. This should be used together with exposure assessment and medical surveillance.

a. Medical Factors in Evaluating Access Restriction

i. Immunizations/Vaccinations: The Authorized Laboratory Supervisor/Unit Safety Coordinator shall evaluate the need for immunizations/vaccinations as a prerequisite for working in the laboratory based upon the virulence of the infectious agents being used, the availability of such immunizations/vaccinations and the risks posed by the types of procedures carried out in the laboratory and provide for such immunizations if needed. Depending upon these factors, an evaluation will need to be made to determine under what circumstances, if any, non-laboratory personnel/students/visitors (not immunized) who are Authorized Occupants should be kept out of the laboratory.

[For example] - unescorted entrance might be allowed only when no open containers with infectious agents are present in the lab or the restriction might only apply when vulnerable operations are being performed. How visitors will be controlled also would need to be addressed.

ii. Individuals with special susceptibilities: The Authorized Laboratory Supervisor/Unit Safety Coordinator shall evaluate the need to identify classes of individuals who would be at special risk based upon the agents/organisms used in the laboratory and the types of activities carried out.

[For example] - Do immuno-compromised or immuno-suppressed individuals have to be warned of special hazards? If such individuals wish to be Authorized Users, is the use of special protective equipment an option and does the option provide sufficient protection? Are non-laboratory personnel/students/visitors of this type warned concerning the hazards? If the evaluation is positive, the necessary procedures shall be established.

iii. The Authorized Laboratory Supervisor/Unit Safety Coordinator shall identify individuals who are allergic to products that are airborne in the laboratory and provide special breathing protection to such individuals if evaluation of the working conditions indicates the need for such protection. Dander, animal bedding, animals, animal residues, etc., are examples of known allergens. Do non-laboratory personnel/students/visitors have to be warned? What will the emergency response be when severe allergic reactions occur?

b. Medical Care

i. Emergency Response to Exposure to Hazardous Biological Agents/Organisms

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall add laboratory-specific procedures to the general emergency procedures address any actions that need to be taken very quickly in order to reduce the magnitude of the medical consequences of the emergency if an evaluation indicates the need. If appropriate, the procedures should specify when and what information should be shared with medical authorities and/or Miami Valley Hospital. In some cases, advance information might be in order. In other cases, information provided at the time of the emergency may be sufficient.

ii. Effects of Chronic Exposure

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall evaluate the risk of long-term biological effects subject to on-going exposure to the agents/organisms being used. If there are unique symptoms that need to be monitored or if there are medical tests that can monitor the status of exposure, appropriate provisions for such monitoring must be included in the Standard Operating Procedures if the level of risk requires it.

[For example] - It may be necessary to obtain baseline serum samples for laboratory and other at-risk personnel/students/visitors. This would require procedures for collection and proper storage of the samples. It may be that periodic samples will need to be provided. (The latter is just one example of many possibilities depending upon the agents being used.)

iii. Effects of acute exposure

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall evaluate the potential risks associated with the use of the agents/organisms in the laboratory and determine whether procedures need to be in place for responding to individuals who develop symptoms associated with exposure to the agents or harm from the organisms.

iv. Public Health Issues

The Authorized Laboratory Supervisor/Unit Safety Coordinator shall evaluate the potential for a public health risk associated with the use of the agents/organisms and the need for procedures that would minimize the risk of public health problems.

VII. STERILIZATION/DECONTAMINATION

A. STERILIZATION: Sterilization is the total destruction of all living microorganisms from a surface or given volume. For protection of personal health and the integrity of research it is critical when working with potentially biohazardous agents, that proper autoclaving procedures be followed. When sterilizing glassware and other reusable instruments, autoclave operators must ensure that cycle times and temperatures are adequate and that autoclave units are functioning properly.

B. DECONTAMINATION: Decontamination is a process whereby viable microorganisms are removed from solutions, surfaces or materials by filtration, heating, radiation or chemical removal. A dilution of household bleach is a frequently employed, quite effective decontaminant. EH&S/RM recommends the use of bleach-water (10% bleach solution) or an approved germicide for the decontamination of spills and work surfaces. Decontaminants are an essential component of an emergency spill response kit. Spill kits are required in all labs conducting research involving potentially biohazardous agents. A listing of the required elements within a spill kit includes:

1. A sufficient reserve to produce at least four liters of 10% bleach solution or other suitable decontaminant.
2. Absorbent materials, such as absorbent pads, vermiculite, or disposable towels, for containing and treating spills.
3. Spray/mist bottles for disinfectant application.
4. "Red bags" for receiving biohazardous waste generated during spill response or for overpacking leaking containers.
5. Leak-proof, puncture-resistant, closable and properly labeled containers for receiving contaminated broken glass and other sharps materials.
6. Protective clothing, and equipment including:
 - a. Liquid impermeable disposable coveralls, if not equipped with hooding provide caps.
 - b. Eye protection gear, including splash resistant safety glasses and face shields.
 - c. Gloves suitable for protection from biological/chemical hazards.
 - d. Rubber boots, and/or foot covers.
 - e. *Protective breathing devices such as N-95 respirators.

*For certain hazards, respiratory protection may be required for routine and emergency operations. If respirators are provided, the laboratory must have a written Respiratory Protection Program and all users must be fit-tested and trained regarding proper use. Information about respirators and respiratory protection programs contact EH&S/RM.

7. Forceps, broom, heavy-duty brush, and dustpan (for spills involving sharps materials).

8. Extra clothing to replace items contaminated during spill/cleanup (scrubs, e.g.).

VIII. BIOHAZARD/BIOHAZARDOUS WASTE MANAGEMENT

A. Regulated Medical Waste: Ohio Environmental Protection Agency and the University policy designate:

1. Cultures and stock of microorganisms and biologicals. Discarded cultures, stocks, specimens, vaccines and associated items likely to have been contaminated with organisms likely to be pathogenic to healthy humans.
2. Human blood/blood products and other potentially infectious material (OPIM), animal blood/blood products. Includes wastes consisting of human and animal blood/blood products (includes serum, plasma etc.), and items contaminated by *significant* amounts human and animal blood/blood products. “Significant” quantities of blood are present when materials render visible release of liquid or dried blood upon being subjected to wringing and/or typical handling procedures. Under this definition materials stained with small quantities of embedded blood/blood products do not require disposal as RMW.
3. Tissues and other anatomical waste. Includes all human anatomical wastes and all human tissues, organs, body parts or body fluids.
4. Sharps materials. Includes all discarded needles and scalpels (regardless of contamination potential), any other sharps materials likely to be contaminated with pathogenic organisms, and all sharps used in patient care and veterinary practice.
5. Intentionally infected animal carcasses, body parts, urine, feces, bedding and related waste. Applies when source animals are known or suspected to be infected with organisms potentially pathogenic to healthy humans.
6. Residues, soils, liquids and other debris - resulting from cleanup of a spill of any regulated medical waste.
7. Solid waste contaminated by, or mixed with regulated medical waste.
8. Other Regulated Biological Materials: In accordance with NIH standards: all rDNA/gene therapy waste (including used instruments that may have potentially come into contact with rDNA molecules or gene therapy waste) must also be considered biohazardous waste.

B. Proper Management & Disposal Procedures: All of the above listed materials shall be considered biohazardous (regulated medical) waste and shall be managed/disposed of as detailed below:

- 1. Biohazardous Waste – Red Bag Protocol:** Biohazardous waste materials packaged in red bags are transported from UD by a licensed hauler to a state permitted treatment facility where they are incinerated under strictly controlled conditions. When utilizing red bags for biohazardous waste disposal the following OEPA and university requirements must be satisfied:

- a. All bags used for disposal of infectious waste must meet the following standards:
 - i. All bags must be red in color.
 - ii. All bags must be highly leak and tear resistant (capable of passing the ASTM 125 pound Standard Test Method for Drop Test of Loaded Containers by Free Fall D5276-92).
 - iii. All bags must bear the label: "Regulated Medical Waste" in large print.
 - iv. All bags must bear the international biohazard symbol.
- b. Regulated medical waste must be containerized within at least two separately sealed red bags prior to being packaged for transport offsite.
- c. All waste-filled red bags must be placed within a rigid container prior to transport off site.
- d. The outer layer of any container (red bag, box, sharps vessel, drum etc.) used for transport of infectious waste materials must bear the following information and labeling:
 - i. The name, address, and telephone number of the generator and date which infectious material was discarded.
 - ii. The warning: "Regulated Medical Waste" in large print.
 - iii. The international biohazard symbol.
- e. Red bags must never be overfilled. Prior to placing in box, seal red bag by gathering ends and wrapping tightly with several loops of heavy tape. The resulting seal must be leakproof.
- f. Free liquids must be placed in sturdy leakproof containers that are highly resistant to breakage prior to being placed within red bag/box units.
- g. Spill response kits must be maintained in all areas where infectious waste is managed.
- h. All areas utilized for staging or storage of red bags must have impervious surfaces; red bags shall never be placed on carpeted or wooden floors.
- i. Stage and store red bag waste in areas that are not readily accessible to the general public; whenever possible limit access to collection and storage areas to specifically designated personnel.
- j. Discarded infectious waste may be stored at room temperature for no more than seven days past generation date (date that bag is sealed). Storage beyond seven

days shall require refrigeration at 2⁰ to 7⁰ Celsius (35⁰ to 45⁰ Fahrenheit).

- k. Infectious waste must not be stored on site for more than 30 days past generation date.
- l. Reusable containers must be thoroughly disinfected (in accordance with manufacturers directions) prior to reuse (refer to Section VIII.D. for further instructions).
- m. Personnel handling red bags must wear leak-resistant gloves at all times. Hands must be thoroughly scrubbed with soap and water following glove removal.

2. Autoclave Sterilization – Orange Bag Protocol: Biohazardous waste material may be sterilized on site via steam autoclaving and disposed of in the municipal waste stream provided all applicable regulations mandated by the OEPA are followed throughout the process. The OEPA requirements are listed below:

- a. Autoclave units must be operated at the following temperature, pressure and time regimens:
 - i. Temperature of not less than 250⁰ Fahrenheit for 90 minutes at 15 lbs./square inch.
 - ii. Temperature of not less than 272⁰ Fahrenheit for 45 minutes at 27 lbs./square inch.
 - iii. Temperature of not less than 320⁰ Fahrenheit for 16 minutes at 80 lbs./square inch.
- b. Autoclave units must undergo quality control testing at a frequency of no less than once per month. Each quality control event shall consist of:
 - i. Testing under full load conditions.
 - ii. Utilization of spores of *B. stearothermophilus* to verify kill capacity (kits providing ready-to-use ampules are available through lab supply catalogues).
 - iii. Recordkeeping of quality control event.
- c. Logbooks must be maintained which record the following data for each autoclave event:
 - i. Date and time of autoclave use.
 - ii. Autoclave cycle (90 minutes at 250⁰ Fahrenheit e.g.).
 - iii. Autoclave operator, identification of responsible laboratory.

- iv. Brief description of waste type and quantity.
- v. Quality control, maintenance and calibration information.
- vi. Logbook records shall be retained for 3 years following last entry date.
- d. Biohazardous waste materials treated via autoclaving must be containerized as follows:
 - i. Bags shall be orange in color, impervious, tear resistant and capable of retaining integrity through heat and pressure of sterilization cycle;
 - ii. Orange bags shall bear the following labels:
 - aa. "BIOHAZARD, REGULATED MEDICAL WASTE".
 - bb. The Biological Hazard Symbol.
 - cc. Individual orange bags shall be sealed to the extent of being leakproof, if tears or holes in bag are evident, the bag must be placed within a second orange bag.
 - dd. Each bag will be tagged with color-indicating (temperature) tape.
- e. Immediately upon the completion of the sterilization cycle, to each orange bag attach a label that includes:
 - i. The date of generation (autoclave cycle).
 - ii. Name/signature and number of the person responsible.
 - iii. A statement that verifies that the material contained within the orange bag has been properly sterilized and is no longer considered regulated medical waste per DEQ regulations.

3. Infectious Sharps Materials: All needles, scalpels, blades, scissors and other items that pose laceration hazards and have potentially come in contact with infectious (biohazardous) agents shall be considered “Infectious Sharps Materials” and must be managed and disposed of in accordance with all applicable federal and state regulations, and university guidelines. Management and disposal requirements for infectious sharps include the following elements:

- a. Infectious sharps materials must be placed in an approved container. Approved infectious sharps containers must have the following properties:
 - i. Containers must be rigid and puncture resistant.
 - ii. Containers must be leak resistant on side and bottom.
 - iii. Containers must be capable of being readily (without coming into contact

with sharps materials) closed and securely sealed properly prior to disposal.

iv. Containers must be clearly marked with the following labeling;
"BIOHAZARD: INFECTIOUS SHARPS".

b. Fingers/hands must never be placed inside of sharps container. In the unlikely event that an item would have to be retrieved or dislodged from a sharps container, forceps or another mechanical device must be utilized.

c. Sharps containers must not be overfilled: sharps materials must fit completely into container - portions of sharps materials shall not be allowed to protrude from the top of the vessel. When containers approach being full, seal them securely and replace with new (empty) sharps containers.

d. Upon filling, infectious sharps containers must be securely sealed and placed inside red bag/incineration box units for disposal.

e. Suitable sharps containers can either be purchased from laboratory supply catalogues or can also be manufactured from thick walled plastic or metal containers. Whenever improvised containers are utilized the labeling and handling requirements listed above must be satisfied.

f. Needles and other sharps materials must not be recapped unless deemed essential to research project by PI. Where alternative means are not available needle recapping may be performed under the following conditions:

i. Recapping of needles may be conducted only by the use of mechanical devices or one-handed scoop technique under the approval of the IBC. Principal investigators wishing to include needle recapping in research protocols are required to complete/submit a waiver form. Upon IBC approval, a copy of the waiver form should be maintained in the laboratory exposure control plan and/or biosafety manual.

ii. Needles, scalpels and other mounted sharps materials may not be removed from mountings or remounted.

g. Breaking and shearing of needles is strictly prohibited.

h. All employees involved in incidents with known or potentially infectious sharps materials shall report immediately to the UD Health Center for medical evaluation.

i. All sharps-related injuries shall be recorded in a sharps injury log which must be obtained from the UD Health Center.

4. Noninfectious Sharps and Glass Materials: The determination that these sharps materials have not come into contact with potentially infectious (biohazardous) agents shall be made by the principal investigator. The following two types of materials and related handling/disposal requirements are included within this category:

a. *Noninfectious sharps materials:* needles, blades, scissors, etc., determined by the principal investigator to have not come into contact with infectious (biohazardous)

agents. Disposal requirements for noninfectious sharps are as follows:

- i. Containers shall be puncture resistant, securely closable, and bear label "Noninfectious Sharps Materials".
- ii. Noninfectious sharps containers shall never be overfilled (materials shall not protrude from container).
- iii. Upon filling, noninfectious sharps containers shall be securely sealed and disposed of within red bag/incineration box units through EH&S/RM.

b. *Non-infectious broken glass*: includes all broken glassware that has not come into contact with potentially infectious agents. These materials may include such items as: glassware broken during or after cleaning, glassware broken while containing noninfectious materials. Glass pasteur pipettes, test tubes, flasks and petri dishes which have not come into contact with potentially infectious agents may also be classified as non-infectious broken glass, if handled accordingly as detailed below:

- i. Place all noninfectious broken glass items into puncture resistant containers (a sturdy cardboard box is preferred).
- ii. Do not fill above the top of the box, when approaching full, seal box and wrap box with several strips of packing or duct tape.
- iii. Clearly label box "NONINFECTIOUS BROKEN GLASS" (indelible black marker preferred).
- iv. Dispose of noninfectious broken glass box through housekeeping (or place in municipal trash dumpster).

C. UTILIZATION OF REUSABLE CONTAINERS FOR STAGING

BIOHAZARDOUS MATERIALS: Regulated medical waste materials including red bagged material and orange bagged materials prior to autoclave sterilization may be conveyed and/or staged in reusable containers or carts under the following conditions:

1. The waste in containers must be packaged fully in compliance with UD requirements. Discrete packages of waste and the reusable container must each be labeled in accordance with OEPA requirements.
2. Immediately following each instance a reusable container is emptied and prior to being reused it must be thoroughly cleaned, rinsed, and effectively disinfected with a hospital grade disinfectant effective against mycobacteria. The area where carts or containers are cleaned, rinsed or disinfected shall be considered a regulated medical waste staging area and must be regularly sanitized and placed under restricted access during times when containers are being disinfected.
3. Unloading of large volume reusable carts and containers must be accomplished through mechanical means that do not involve handling of bags or packages by humans. Mechanical means may consist of tipping floors, chutes, snares and other simple mechanisms.

4. Unloading of small volume containers such as pails or trashcans must be performed with proper personal protective equipment (gloves, lab coat, safety glasses) utilizing techniques which minimize handling of red /orange bags and avoid contact with bag contents.

IX. SHIPPING OF BIOHAZARDOUS MATERIALS

A. Regulatory Requirements: Materials deemed to have a reasonable potential for being contaminated with infectious agents are classified as “Dangerous Goods”. Shipment of dangerous goods is regulated primarily by the United States Department of Transportation (DOT), although several other federal agencies (USDA, CDC, OSHA et.al.), international organizations (United Nations, [World Health Organization](#), et.al.) and foreign governments also have requirements which apply under certain circumstances. The section below outlines basic requirements regarding shipping and packaging of biohazardous materials, dry ice, and diagnostic specimens. Review of this material in no way satisfies the training requirements mandated by DOT for personnel involved in the packaging, transport and receiving of dangerous goods items:

1. Contact EH&S/RM: For questions regarding shipping of dangerous goods involving the packaging, shipping, labeling or other dangerous goods issues contact 9-4503.

X. TRAINING REQUIREMENTS: The OSHA Bloodborne Pathogens Standard and Laboratory Safety Standard specify that employers (PIs, laboratory managers, other supervisory staff) are responsible for ensuring that employees are trained regarding the hazards associated with their job descriptions. University laboratories conducting research involving known or potentially biohazardous agents must meet the following training requirements:

A. General Laboratory Safety Training:

B. Hazard Communication Training:

C. Special Training Requirements: Laboratory staff working under special conditions may require additional training and/or certifications. Examples of duties requiring special training would include:

1. Preparing/receiving dangerous goods shipments.
2. Work in BSL-3 or greater biological containments.
4. Work involving select agents.

XI. RECORDKEEPING REQUIREMENTS

A. Standard Operating Procedures Manual: Standard Operating Procedures (SOPs) must be developed for all laboratory procedures that involve known or potentially biohazardous agents. Laboratory staff must be trained in regard to each SOP on an annual basis, or whenever new procedures are added to the work regimen. Required elements of an SOP include:

1. Descriptive title defining purpose of operation.
2. Preparation and revision dates.
3. Identification of department/laboratory for which SOP is applicable.
4. Brief statement of purpose.
5. Indication of potential undesirable outcomes,
6. Identification of regulatory standards that apply to procedures.
7. Listing, by category of all materials, tools, and equipment required to complete SOP – it is critical that all safety equipment be identified (required PPE, BSCs, etc.).
8. Listing of environmental conditions, time constraints or other factors which may have a negative impact on the execution of the SOP.
9. An overview of the sequence of the SOP describing major functions and anticipated/potential health & safety and environmental impact.
10. Definitions of terms.
11. Prominent display of warnings and cautions prior to description of each task with potential danger involved.
12. Listing of all tasks included within SOP in sequential order.

B. Biological Material Safety Data Sheets: In addition to the inventories of MSDSs compiled for hazardous chemicals, all laboratories performing research with known or potential biohazardous agents must maintain a comprehensive collection of MSDSs for each biohazardous agent.

C. Job Safety Analysis (JSA): OSHA requires that supervisors prepare assessments (JSAs) of safety issues relating to workplace and work activities identifying range of hazards and determining whether existing precautions are adequate. If existing safety precautions are not adequate appropriate corrections must be identified and implemented. Supervisors are further required to explain and discuss the completed Job Safety Analysis with employees and to maintain the JSA within the laboratory.

D. Exposure Control Plan (ECP): In accordance with the requirements of the OSHA Bloodborne Pathogen Standard, laboratories performing research where there is a potential occupational exposure to bloodborne pathogens are required to develop and maintain an ECP. The Department of Environmental Health & Safety/Risk Management has developed an exposure control plan which provides a policy for protection of university personnel who, as part of their job function, face reasonably anticipated exposure to bloodborne pathogens.

E. Sharps Injury Log: In accordance with the requirements of the OSHA Bloodborne Pathogens Standard, laboratories performing research involving known or suspected bloodborne pathogens must document all incidents involving potential employee exposure via sharps injury.

F. Medical Surveillance Program: Principal investigators must retain on file records of all medical examinations, vaccination/vaccination declination, medical treatment required for all employees involved tasks with risk for exposure to biohazardous agents. Medical surveillance records must be maintained on file for the duration of employment plus 30 years.

G. Engineering Control Devices & Safety Equipment, Testing/Certification: Laboratories must arrange for testing services required for maintaining certification of all engineering control devices and safety equipment necessary for achieving compliance with regulatory requirements. An abbreviated list of equipment requiring regular testing and/or certification would include:

1. Biological safety cabinets utilized for procedures involving BSL-2 or greater biohazardous agents: annual testing/certification required.
2. Biological glove box units utilized for procedures involving BSL-2 or greater biohazardous agents: annual testing/certification required.
3. Directional flow/negative pressure ventilation of laboratories operating under BSL-3 conditions: annual verification of suitable conditions required.
4. Chemical fume hoods - annual testing provided by EH&S/RM.
5. Autoclave units utilized for onsite treatment of biohazardous waste – monthly testing & regular documentation required (see section VIII.2).

H. Respiratory Protection Program: Research involving certain toxic chemicals and/or biohazardous agents may require that respiratory protection be provided for employees involved in routine tasks or potential emergency response operations. If respirators are provided, the laboratory must implement a written Respiratory Protection Program and all users must be fit-tested and trained regarding proper use and related health & safety concerns.

I. Additional Records/Documents: Although the primary focus of this section is the identification of biosafety related record keeping requirements, principal investigators and laboratory directors must be aware that they are also responsible for complying with the recordkeeping requirements of a broad range of other environmental and safety programs including: chemical safety, radiation safety, and fire/occupational safety.

Appendix A.

Acronyms/Definitions

Acronyms:

ABSL: Animal Biosafety Level

ANSI: American National Standards Institute

BBP: Bloodborne Pathogen

BMBL: Biosafety in Microbiological and Biomedical Laboratories Manual

BSC: Biological Safety Cabinet

BSL: Biosafety Level

CDC: Centers for Disease Control and Prevention

CHP: Chemical Hygiene Plan
DHHS: Department of Health and Human Services
DNA: Deoxyribonucleic Acid
DOT: United States Department of Transportation
ECP: Exposure Control Plan
ERP: Emergency Response Plan
HBV: Hepatitis B Virus
HCV: Hepatitis C Virus
HIV: Human Immunodeficiency Virus
IACUC: Institutional Animal Care and Use Committee
IBC: Institutional Biosafety Committee
JSA: Job Safety Analysis
MSDS: Material Safety Data Sheet
MUA: Memorandum of Understanding and Agreement
NIH: National Institutes of Health
OBA: Office of Biotechnology Activities (NIH)
OSHA: Occupational Safety and Health Administration
PI: Principal Investigator, Laboratory Director
PPE: Personal Protective Equipment
RAC: Recombinant DNA Advisory Committee (NIH)
rDNA: Recombinant DNA
RNA: Ribonucleic Acid
SOP: Standard or Standing Operating Procedure
USDA: United States Department of Agriculture
WHO: World Health Organization

Definitions:

ANTISEPSIS: Any substance capable of causing a disease; usually refers to a disease-causing microorganism.

BIOHAZARD: A risk of exposure to harmful bacteria, viruses, or other dangerous biological agents, particularly those found in genetic recombination studies or in clinical microbiology labs.

DECONTAMINATION: A process whereby viable microorganisms are removed from solutions, surfaces or materials by filtration, heating, radiation or chemicals.

DISINFECTION: Reduction of the number of pathogenic organisms by the direct application of physical or chemical agents.

ETIOLOGIC AGENT: A viable microorganism or its toxin which causes, or may cause a human disease.

STERILIZATION: Total destruction of all living organisms.

APPENDIX B: SELECT AGENTS LIST

Appendix A to Part 72, CFR 42 (Select Agents)

A. Department of Health and Human Services

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses
4. Equine Morbillivirus
5. Lassa fever virus
6. Marburg virus
7. Rift Valley fever virus
8. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
9. Tick-borne encephalitis complex viruses
10. Variola major virus (Smallpox virus)
11. Venezuelan Equine Encephalitis virus
12. Viruses causing hantavirus pulmonary syndrome
13. Yellow fever virus

Exemptions: Vaccine strains of viral agents (Junin Virus strain candid # 1, Rift Valley fever virus strain MP-12, Venezuelan Equine encephalitis virus strain TC-83, Yellow fever virus strain 17-D) are exempt.

Bacteria

1. *Bacillus anthracis*
2. *Brucella abortus*, *B. melitensis*, *B. suis*
3. *Burkholderia (Pseudomonas) mallei*
4. *Burkholderia (Pseudomonas) pseudomallei*
5. *Clostridium botulinum*
6. *Francisella tularensis*
7. *Yersinia pestis*

Exemptions: vaccine strains as described in Title 9 CFR, Part 78.1 are exempt.

Rickettsiae

1. *Coxiella burnetii*
2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

Fungi

1. *Coccidioides immitis*

Toxins

1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. *Clostridium perfringens* epsilon toxin
5. Conotoxins

6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part II 3 are exempt.

Recombinant organisms/molecules

1. Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.
2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.

Other restrictions

The deliberate transfer of a drug resistance trait to microorganisms listed in this Appendix that are not known to acquire the trait naturally is prohibited by NIH "[Guidelines for Research Involving Recombinant DNA Molecules](#)," if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

Additional Exemptions

1. Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. Section 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. Section 2601 et seq.) are exempt.
2. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents in this Appendix. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the Federal Register for review and comment prior to inclusion in this Appendix.