New Jersey Institute of Technology
NJIT

Biological Safety Guide

Prepared by: NJIT Environmental Health and Safety

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A Guide for those NJIT laboratories engaged in the use, storage, handling, manipulation, or decontamination of biological materials.

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I. Introduction

The Biological Safety Guide has been developed by the New Jersey Institute of Technology (NJIT) Environmental Health and Safety (EHS) Department. This guide is intended as a laboratory supplement, or guide, to the previously approved University Safety Environmental Management System (USEM) - posted on the NJIT Pipeline (intranet). The purpose of the guide is to assist NJIT investigators in developing sound biological safety practices in their laboratories and to help the university comply with applicable guidelines and regulations.

NJIT investigators seeking to conduct research utilizing potentially infectious microorganisms, recombinant DNA, and other biological materials of human origin should submit an NJIT Registration Document for Biohazards to the NJIT Institutional Biosafety Committee (IBC) for evaluation and approval. Forms and instructions may be found on the NJIT Research Compliance Website:

http://www5.njit.edu/research/compliance/biosafety-committee.php

The Registration Document for Biohazards may also be found on the EHS website:

http://www5.njit.edu/environmentalsafety/ehs-forms/

This guide has been implemented in the following NJIT laboratory facility:

Principal Investigator (P.I.):

_____

Laboratory Manager (may be P.I. or designee):

_____

Building/Department:

_____

Rooms Covered by this Guide:

_____

II. Regulatory Review

Primary Biological Safety Regulations and Guidelines:
The principal guidelines governing biological safety in the academic research laboratory include:

- The CDC/NIH Guidelines, entitled: Biosafety in the Microbiological and Biomedical Laboratory (BMBL), US Department of Health and Human Services, 6th Edition
  - Biosafety in Microbiological and Biomedical Laboratories—6th Edition (cdc.gov)
- The NIH Recombinant DNA Guidelines, entitled: NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), April 2019
  - NIH Guidelines – Office of Science Policy
- The OSHA Bloodborne Pathogen Standard entitled: Occupational Exposure to Bloodborne Pathogens, US Department of Labor, 29 CFR 1910.1030
  - 1910.1030 - Bloodborne pathogens. | Occupational Safety and Health Administration (osha.gov)

Additional Biological Safety Regulations and Guidelines:
Additionally, there are a variety of regulations that indirectly affect activities in an academic research laboratory. Principal among them are:

- Biological Agents Provisions of the Antiterrorism and Effective Death Penalty Act of 1996 (and revisions)
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (The USA Patriot Act)
- Federal Select Agent Program, US Department of Health and Human Services and US Department of Agriculture, Final Rule on Select Agents and Toxins: 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73
- Additional Requirements for Facilities Transferring or Receiving Select Infectious Agents; **PHS** 42 CFR part 72
- Hazardous Materials: Revision to Standards for Infectious Substances and Genetically Modified Micro-Organisms; **DOT** 49 CFR parts 171, 172, 173, 177, and 178

Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) Guidelines on: Biosafety in Microbiological and Biomedical Laboratories (BMBL).
In 1984, the CDC/NIH published the first edition of the BMBL. This document describes combinations of standard and special microbiological practices, safety equipment, and facilities that constitute Biosafety Levels 1-4, which are recommended for working with a variety of infectious agents in various laboratory settings. This document also outlines requirements for animal and plant biosafety levels. The BMBL has been revised several times and is commonly seen as the standard for biosafety. NJIT, like many other universities, is using the BMBL as the baseline when determining appropriate biosafety containment levels for protocols submitted by university investigators.

National Institutes of Health (NIH): Guidelines for Research Involving Recombinant and Synthetic DNA Molecules.
These guidelines address the safe conduct of research that involves construction and handling of recombinant and synthetic DNA molecules and organisms containing them. In 1974, a recombinant DNA Advisory Committee (RAC) was established to determine appropriate biological and physical containment practices and procedures for experiments that potentially posed risks to human health and the environment. As a result of the committee's activity, the initial version of the NIH Guidelines was published in 1976. It has been amended and revised many times since then. Included in the Guidelines is a requirement for the institution to establish an Institutional Biosafety Committee (IBC) with authority to approve or disapprove proposed research using the NIH Guidelines as a minimum standard. Additionally, Appendix B of the Guidelines;

Classification of Etiologic Agents on the Basis of Hazard is a somewhat comprehensive list of organisms assigned to appropriate biosafety levels that is updated by the NIH periodically.

OSHA Bloodborne Pathogens Standard.
The United States Department of Labor requires all employers having employees who may be reasonably anticipated to come into contact with blood or other potentially infectious materials (OPIM) to establish and follow a written Exposure Control Plan (ECP). These requirements are stipulated in 29 CFR 1910.1030 (the OSHA Bloodborne Pathogens Standard). This standard was adopted by NJ Public Employees Occupational Safety and Health (PEOSH) and applies to public employees in the state of NJ. In addition to the BMBL and r-DNA Guidelines, previously described, the OSHA Bloodborne Pathogen Standard may apply to research laboratories where blood, other human body fluids, primary human tissue explants and their clonal derivatives, and human cell lines (including those commercially obtained) are in use.

III. NJIT Biological Safety Policy on Research Involving Recombinant DNA, Potentially Infectious Microorganisms, Human-Derived Materials, and Other Potentially Infectious Materials

In an effort to comply with applicable biological safety regulations and guidelines, NJIT Office of Research Compliance and the Environmental Health and Safety Department have instituted the following biosafety program elements:

Registration Document for Biohazards

Completed NJIT Registration Documents are submitted to the NJIT Institutional Biosafety Committee for evaluation and approval. Forms and instructions may be found on the NJIT Research Compliance Website:

http://www5.njit.edu/research/compliance/biosafety-committee.php

The Registration Document for Biohazards may also be found on the EHS website:

http://www5.njit.edu/environmentalsafety/ehs-forms/

The NJIT Office of Research Compliance has developed formal Registration Documents for Biohazards and Recombinant/Synthetic DNA. The completion and submission of these document is required of all investigators conducting research involving recombinant/synthetic DNA, potentially infectious microorganisms, human-derived materials, or other potentially infectious materials. These documents are the mechanism by which biological protocols are presented to the NJIT IBC for review and approval. The documents may be found on the Research Compliance and EHS websites referenced above.

Institutional Biological Safety Committee (IBC)

NJIT has appointed appropriate members to the Institutional Biosafety Committee (IBC), including a community representative, and an adequate number of scientists to ensure that all biological research disciplines at NJIT are represented.

Currently the IBC approves protocols for:

- Biosafety Level 1 protocols are approved for a period of three (3) years
- Biosafety Level 2 protocols are approved for a period of three (3) years
- Approved protocols may be amended at any time

The IBC shall meet periodically, typically once a month during the academic semester. A quorum is achieved when half of the voting IBC membership are present. IBC minutes shall be maintained. Written approval/disapproval letters shall be provided for each protocol submitted documenting assigned biosafety level, providing any specific guidance documents or conditions of approval.

At this time the IBC does not anticipate any research protocol to require approval beyond Biosafety Level 2 containment. If an investigator seeks approval for a protocol requiring containment beyond BL-2, specific written approval outlining enhanced biosafety criteria must be granted by the IBC. These requests will be handled by the IBC on a case-by-case basis.

Completion and Approval of a Laboratory Biological Safety Guide

NJIT Environmental Health and Safety Department has developed a hands-on Biological Safety Guide that includes:

- policies by which biological protocols are reviewed and approved;
- registration documents, forms, and educational materials; and
- descriptions of how biological materials may be safely handled, stored, and decontaminated in the laboratory.

This guide will serve as a supplement to the existing NJIT Biosafety SOP included in the overall University Environmental Management Plan.

Biological Safety Training

NJIT Environmental Health and Safety Department will ensure that all laboratory staff, students, as well as investigators, who may potentially come into contact with biological materials in the laboratory attend a yearly biological safety training session.

IV. Statement of Responsibility

The implementation of a functional biological safety program is a shared responsibility between the various stakeholders involved in biological research at NJIT. These responsibilities are shared by university administration, the faculty, laboratory workers including students and staff, and the Environmental Health and Safety Department. The primary responsibilities of each group are outlined below.

- **NJIT Institutional Biosafety Committee**
  - Meet periodically to review protocols submitted by NJIT faculty
  - Assign appropriate biosafety levels to the submitted protocols
  - Provide Principal Investigators with written approval, listing conditions when appropriate, for submitted protocols
  - Maintain written minutes and records of committee activities
- **Principal Investigators:**
  - Submit biological protocols requiring review and approval to the NJIT Institutional Biosafety Committee (IBC)
  - Conduct a Risk Assessment prior to submitting protocols to the IBC
  - Maintain an up-to-date copy of the NJIT Biological Safety Guide in the laboratory
  - Ensure that laboratory workers under their supervision comply with requirements of the NJIT Biological Safety Guide including:
    - attending required training
    - following written protocols concerning the safe handling, use, storage, transport, decontamination, and disposal of biological material
  - Provide "hands on" training to laboratory personnel concerning biological protocols performed in the laboratory
  - Implement the use of appropriate safety procedures including necessary containment equipment and personal protective equipment
- **Laboratory Workers:**
  - Follow all written protocols established for the handling, use, storage, transport, decontamination, and disposal of biological material in the laboratory
  - Attend required NJIT, departmental and laboratory training sessions
  - Report all incidents to the laboratory supervisor
  - Wear prescribed personal protective equipment
- **The Environmental Health and Safety Department:**
  - Provide Biological Safety and Bloodborne pathogens training as required
  - Conduct laboratory inspections, provide written documentation, and offer assistance with corrective measures
  - Assist Principal Investigators with risk assessment and protocol submission as required
  - Maintain contract for the certification of biological safety cabinets

V. Risk Assessment

Risk assessment is a process used to examine various factors associated with a laboratory procedure involving biological materials in order to identify:

- the hazardous characteristics of the material
- the activities that can result in a person's exposure to an infectious agent,
- the likelihood that exposure will cause a laboratory acquired infection (LAI), and
- the probable consequences of an infection.

Risk Management is the corresponding process of selecting appropriate containment measures to ensure that biohazards are properly controlled. Risk deals with the probability of events. However, due to very little quantitative data with biohazards, qualitative assessment is utilized.

The information identified by risk assessment will provide a guide for the selection of biosafety levels, microbiological practices, safety equipment and facility safeguards that can prevent laboratory acquired infections and reduce environmental contamination risk. Factors to consider in a risk assessment include both agent hazards and laboratory procedure factors.

The CDC/NIH Guidelines recommend the laboratory directors, principal investigators, biosafety committees, and others; perform a risk assessment process when determining the appropriate safeguards to employ to ensure that potentially biohazardous protocols are conducted safely.

The principal investigator (PI) or designated representative is responsible for performing the first risk assessment for biohazards handled in the laboratory. This is important, as those handling biohazards must be aware of the risks involved in the work and also understand why the control measures have been implemented. The assessment process should cover from the initial procurement of a biohazard until it has been securely stored or inactivated upon completion of work. The process also identifies where and how the biohazard will be handled throughout its duration in the lab and by whom. Each step in the work process must be analyzed for potential risk to personnel.

The employer (institution) is responsible for ensuring that the PI completes the written assessment and has developed the appropriate control strategy. Usually, the **Institutional Biosafety Committee (IBC)** and/or the Biological Safety Officer (BSO) handle this verification process. The PI, IBC, and BSO must have appropriate training and knowledge to perform the assessment.

One mechanism to ensure that a formal risk assessment and adequate control measures have been developed for all work with biohazards is to institute a biohazard registration and authorization program that requires formal approval of all research or work with biohazards prior to initiation. The biohazard registration form can be formatted to ensure that all applicable risk assessment questions have been answered. The PI must also submit a written biosafety plan that outlines how workers will be protected in the laboratory. The biohazard registration and written plan can be reviewed by the BSO and IBC.

Risk assessment, which helps to identify the probability and consequences of infection, is used by biosafety professionals and those directly handling infectious agents to ensure that all people potentially exposed to biohazards have an awareness of the potential risk. Only after a risk assessment has been conducted can an appropriate set of containment procedures be selected to protect those involved in research with biohazards. Risk assessment usually considers the factors associated with the agent or pathogen, an evaluation of the procedures or tasks involved in the proposed research or work, and a review of the personnel who will be performing the work. The categories that must be covered by the PI are summarized broadly below.

The Six Ps of Risk Assessment and Risk Management

Risk Assessment

- **Pathogen**: The risks associated with the biohazard
- **Procedures**: Additional risks posed by the proposed manipulations
- **Personnel**: Review of the people who will handle biohazards

Risk Management

- **Practices**: Good microbiological work practices
- **Protective Equipment**: Protective clothing and engineering controls or containment equipment
- **Place**: A review of the work location where biohazards will be handled

Risk Assessment Checklist Overview

Identifying some of the factors associated with a pathogen or biohazard, when performing a risk assessment, is only a starting point. The risk assessment checklist can be used to compile additional pertinent information regarding a pathogen. The goal is to acquire as much information as possible to help answer the following questions:

- How can workers be exposed to the biohazard?
- Is there a high probability of infection if exposed?
- Are there any other potentially harmful effects associated with the biohazard (reproductive pathogen, tumorigenic material, potential effects to the cell cycle)?
- Are others outside the laboratory (close contacts) at risk in the event of a laboratory acquired infection (LAI)?
- How long will the biohazard survive if it is released outside of primary containment or outside of the laboratory?
- How difficult will it be to inactivate the biohazard upon completion of work or in the event of a spill or release?

Detailed Risk Assessment Checklist

This is split between factors associated with the pathogen, agent or biohazard and the procedures that may exacerbate the risk. The checklist can be used to identify the following additional characteristics of the biohazard. Initial risk assessment should address:

- Agent and strain (Genus, species, strain designation, and family of microorganisms).
- Special permits/authorizations required for the agent.
- Disease caused by the agent.
- Incubation period (from exposure to onset of symptoms).
- Signs/symptoms of disease.
- Route(s) of exposure (inhalation, percutaneous, facial mucous membranes, ingestion).
- Infectious dose (quantity of organism required for an infection).
- Pathogenicity (ability to cause disease).
- Virulence (severity of disease caused, ability to evade host immune system).
- Environmental stability (survival outside the host in environment, for example, on work surfaces or fabric).
- Effective disinfectants for inactivation of the pathogen on surfaces, equipment, and in spill situations. It is important to understand the disinfectant (chemical), concentration, and contact time required for decontamination.

- Has the pathogen/agent/biohazard been involved in prior LAIs? If yes, is the route of exposure of LAI known? If it is not known what is the most likely route of exposure?

- If experiments involve research animals:
    - Is the disease caused in animals?
    - Is transmission from animals to other animals possible?
    - Is transmission from animals to humans possible?
    - Can the animal shed the agent in urine, feces, saliva, or other secretions? If shed, what is the anticipated duration of shedding?

Agent Characteristics:

- Agent Name (Biohazard):
- Strain:
- Size of Microorganism/Molecule:
- Source:
- Risk Group:
- Prior Laboratory-Associated Infections (LAIs):
- Route(s) of Exposure:
- Zoonosis:
- Pathogenicity:
- Morbidity:
- Gene Product Effects:
- Toxicity:
- Allergenicity:
- Infectious Dose:
- Incubation Period:
- Environmental Stability:
- Disease(s) Caused:
- Signs/Symptoms of Disease:
- Communicability:
- Host Range:
- Reservoir:
- Endemicity:
- Vector:
- Virulence:
- Mortality:
- Oncogenic Potential:
- Physiological Effects:
- Prophylaxis:
- Immunization:
- Booster:
- Treatment:
- Effective Disinfectants:

Agent Hazards:

- Capability to infect and cause disease in a susceptible host
- Virulence as measured by the severity of disease
- Availability of preventive measures and effective treatments for the disease
- Probable routes of transmission of laboratory infection. The predominant routes of transmission in the laboratory include:
    - mucous membrane exposure,
    - parenteral inoculation,
    - ingestion and
    - inhalation of infectious aerosols
- Infectious dose
- Stability in the environment
- Host range
- Endemic nature
- Reports of laboratory acquired infections
- Origin of the agent

Classification of Infectious Agents on the Basis of Hazard (Risk Groups)

Risk groups (RG) are a method used by the World Health Organization (WHO) and by the National Institutes of Health (NIH) to classify human etiological agents based on hazard to both the individual and the community. There are four risk groups. These correlate to but are not equivalent to biosafety levels. Determining the risk group of a biological agent can be part of the biosafety risk assessment and helps in assigning the correct biosafety level for containment. In general, RG-2 agents are handled at BSL- 2, and RG-3 agents at BSL-3. However, the use of certain RG-2 agents in large quantities might require BSL-3 conditions, while some RG-3 agents may be safely manipulated at a BSL-2, or enhanced BSL-2, under certain conditions.

The following table describes Risk Groups 1 through 4 and is taken from the CDC/NIH Guidelines, Biosafety in the Microbiological and Biomedical Laboratories (BMBL), US Department of Health and Human Services, 6th Edition.

TABLE 1
CLASSIFICATION OF INFECTIOUS MICROORGANISMS BY RISK GROUP

RISK GROUP CLASSIFICATION	NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (April 2019)	WORLD HEALTH ORGANIZATION LABORATORY BIOSAFETY MANUAL 4th EDITION (2020)
Risk Group 1	Agents that are not associated with disease in healthy adult humans.	(No or low individual and community risk) A microorganism that is unlikely to cause human or animal disease.
Risk Group 2	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available.	(Moderate individual risk; low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
Risk Group 3 *****	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (high individual risk but low community risk).	(High individual risk; low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
Risk Group 4 *****	Agents that 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).	(High individual and community risk) A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

*** Please note that the NJIT Institutional Biosafety Committee (IBC) currently approves biosafety protocols up to Risk Group 2 (RG-2) / Biosafety Level 2 / (BSL-2).**

Examples of RG-1 agents include microorganisms like *Escherichia coli*-K12 or *Saccharomyces cerevisiae*. A list of Risk Group 2, 3 and 4 agents can be found in the appendix to this guide. It is important to note however, that no list is all inclusive. Also, those agents not listed in RG-2, RG-3 or RG-4 are not automatically classified in RG-1. Those unlisted agents need to be subjected to a risk assessment based on the known and potential properties of the agents.

Hazards of Genetically-Modified Agents

When conducting a risk assessment of genetically modified agents, consideration of the same factors used in risk assessment of the wild-type organism should be done. However, it is important to address the possibility that the genetic modification could alter (i.e., increase or decrease) the pathogenicity of the agent or affect its susceptibility to antibiotics or other treatments. Sometimes, important information may not be available for a newly engineered agent and the risk assessment may be difficult or incomplete. In these cases, due diligence should be practiced and the biosafety level assignment should be made conservatively. Once more information is available another risk assessment should be completed.

Hazards of Cell Cultures
Human and animal cells and tissues have the potential to harbor latent infectious agents and personnel that handle these materials are at risk for possible exposure. The Centers for Disease Control and Prevention (CDC) and OSHA require that all cell lines of human origin be handled at BSL-2 and are considered Bloodborne pathogens. All personnel working with or handling these materials need to be included in NJIT Bloodborne Pathogen Program and Biological Safety Program.

Primate cell lines derived from lymphoid or tumor tissue, all cell lines exposed to or transformed by a primate oncogenic virus, all clinical material (e.g., samples of human tissues and fluids obtained after surgical resection or autopsy), all primate tissue, all cell lines new to the laboratory (until shown to be free of all adventitious agents) and all virus and mycoplasma-containing primate cell lines are classified as RG-2 and should be handled at a Biosafety Level 2.

Laboratory Procedure Hazards
- Parenteral inoculations
    - Injection of potentially hazardous materials can occur by a needle, other contaminated sharp or by bites from infected animals or arthropod vectors.
- Spills and splashes into skin and mucous membranes
    - Mucous membranes include the eyes, nose and mouth.
- Ingestion through mouth pipetting
- Animal bites and scratches
- Inhalation exposures to infectious aerosols

Aerosols, or respirable sized particles, are extremely hazardous because they are generated in many lab procedures and are usually undetected. The creation of infectious aerosols places the person carrying out the procedure and others in the laboratory at risk. Any procedure that breaks the surface tension of a liquid will produce aerosols. Pipetting, blending, non-self-contained centrifuges, sonicators and vortex mixers all produce aerosols. Procedures and equipment that create aerosols also create larger droplets that rapidly settle out of the air. These droplets can settle on surfaces and may therefore contaminate gloved hands, work spaces and potentially mucous membranes via hand to face contact.

Personnel
The final aspect of risk assessment is an evaluation and medical clearance of the workers with potential exposure. Trained, experienced, and healthy workers should conduct work with biohazards. Individuals with no experience with biohazards, no safety training, or those who are unhealthy or uncomfortable with the work are not suitable for this work.

Medical Information Questions to Address During a Risk Assessment
- Availability of pre- and post-exposure prophylaxis?
    - List immunizations or other pre-exposure prophylaxis
    - List post-exposure treatment options
    - What are the contraindications for pre- or post-exposure prophylaxis (who cannot receive these drugs and why)?
    - Are there any individuals that have had contact with the immunized researcher who are at great risk?
- What populations are at a higher risk of adverse events if exposed to the agent under study?
- Who should be excluded from work with this agent?

Personnel-Related Questions (for each person listed on the project)

- Has each researcher completed all applicable safety training classes? These may include biosafety, lab chemical safety, bloodborne pathogens, radiation safety (if applicable), shipping/transport (if applicable), and effective use of the biological safety cabinet.
- Does each researcher have prior education and work experience commensurate with the proposed experiments?
    - Education: Institution attended, Major(s), Minor(s), and Degree(s) held.
    - Work Experience with biohazards: List of previously handled Pathogens/Agents/Materials, including where, for how long, and the risk group/biosafety level for each of the materials handled.
    - Are all researchers familiar with or experienced with the proposed procedures? If no, describe the hands-on training and experience that will be provided, including: Who will give this training? How long will this last? How will proficiency with the proposed procedures and biosafety procedures be verified?
- Has the PI met with each researcher privately to verify that all workers are comfortable participating on the proposed protocol?
- Has the employee completed all appropriate health screening required by the institution?
- Will an information card be developed and given to every employee working with the biohazard (agent worked with, symptoms of exposure, phone number of PI, or resource information on the agent)?

Once the Risk Assessment has been completed, employers must develop a Risk Management plan to protect workers. This encompasses a review of the place where the experiments will be performed, the primary containment devices, or engineering controls that will be used to place a barrier around the work, the protective clothing that will be worn to protect workers, and the work practices that will be used to prevent exposure.

Conducting a Biological Safety Risk Assessment

Investigators planning to work with potentially infectious biological materials should perform a risk assessment to ensure the appropriate biosafety containment level, work practices, and administrative controls are selected to ensure that laboratory personnel are adequately protected. The 6th edition of the CDC/NIH Guidelines recommends the following five-stage risk assessment process:

1. Agent Hazards

First, identify agent hazards and perform an initial assessment of risk. Consider the principal hazardous characteristics of the agent, which include its capability to infect and cause disease in a susceptible human host, severity of disease, and the availability of preventive measures and effective treatments.

2. Laboratory Procedure Hazards

Second, identify laboratory procedure hazards. The principal laboratory procedure hazards are agent concentration, suspension volume, equipment and procedures that generate small particle aerosols and larger airborne particles (droplets), and use of sharps. Procedures involving animals can present a number of hazards such as bites and scratches, exposure to zoonotic agents, and the handling of experimentally generated infectious aerosols.

3. Select Appropriate Biosafety Containment Level

Third, make a determination of the appropriate biosafety level and select additional precautions indicated by the risk assessment. The selection of the appropriate biosafety level and the selection of any additional laboratory precautions require a comprehensive understanding of the practices, safety equipment, and facility safeguards described in Sections III, IV, and V of this guide.

4. Evaluate Laboratory Staff Proficiencies

Fourth, evaluate the proficiencies of staff regarding safe practices and the integrity of safety equipment. The protection of laboratory workers, other persons associated with the laboratory, and the public will depend ultimately on the laboratory workers themselves. In conducting a risk assessment, the laboratory director or principal investigator should ensure that laboratory workers have acquired the technical proficiency in the use of microbiological practices and safety equipment required for the safe handling of the agent, and have developed good habits that sustain excellence in the performance of those practices. An evaluation of a person's training, experience in handling infectious agents, proficiency in the use of sterile techniques and the biosafety cabinet, ability to respond to emergencies, and willingness to accept responsibility for protecting one's self and others is important insurance that a laboratory worker is capable of working safely.

5. Consult with Biosafety Officer and Biosafety Committee

Fifth, review the risk assessment with a biosafety professional, subject matter expert, and the IBC. A review of the risk assessment and selected safeguards is always beneficial and sometimes required by regulatory or funding agencies, as is the case with the NIH Guidelines.

Additional Resources

- American Biological Safety Association (ABSA). "**Risk Group Database**."
- National Institutes of Health (NIH). April 2019. "**NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)**."
- U.S. Department of Health and Human Services (HHS). June 2020. "**Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition**."
- World Health Organization (WHO), 2020 **"WHO Laboratory Biosafety Manual, 4th Edition (LBM4)"**

VI. Principles of Biological Safety

The CDC/NIH Guidelines entitled Biosafety in Microbiological and Biomedical Laboratories (BMBL) are currently in their sixth edition and are updated periodically. The descriptions of biosafety levels (BL) 1 - 4 in the 6th Edition parallel those established in the NIH Guidelines for Research involving Recombinant DNA as well as those originally used in the Classification of Etiologic Agents on the Basis of Hazard. The BMBL describes various combinations of work practices, safety equipment, and facilities recommended for work with various microorganisms in the laboratory setting. These advisory recommendations are intended to assist laboratory managers in establishing sound biological safety programs.

Exposure Determination
Laboratory personnel are considered to have occupational exposure to infectious microorganisms, or other potentially infectious materials, if they are directly engaged in research or other activities which utilize materials regulated by the CDC/NIH Guidelines at BL-2 containment or higher.

Transmission of Infectious Agents
As described by the American Public Association in "Control of Communicable Diseases in Man", transmission of an infectious agent may occur by four main routes, as follows:

Contact Transmission may be divided into three subgroups.

- **Direct Contact**: Direct physical transfer between a susceptible host and an infected individual, e.g., sexually transmitted diseases.
- **Indirect Contact**: Personal contact of a susceptible person with a contaminated inanimate object (fomite) such as used surgical instruments, contaminated transfer pipette, needles, medical equipment, soiled clothes and bedding.
- **Droplet Contact**: Direct projection of droplet spray on the conjunctiva or mucous membranes of the eyes, nose, or mouth of a susceptible person. Droplet contact involves droplets greater than 5 microns in size and distances of 1 meter of less.

Vehicleborne Transmission: Transfer of an infectious agent to a susceptible host via contaminated items such as water, food, milk, or biological products such as blood, plasma, serum, tissues, and organs.

Airborne Transmission: The dissemination of microbial aerosols to a susceptible host via the respiratory tract.

- **Droplet Nuclei**: The dried residue of respiratory droplets resulting from the evaporation of fluid from droplets emitted by an infectious host, e.g., tuberculosis. Droplet nuclei are generally 1 to 5 microns in size.
- **Dust**: Small particles of various sizes which may arise from clothes bedding, contaminated floors, and soil, e.g., fungal spores separated from dry soil by air currents or by mechanical agitation.

Vectorborne Transmission: Transfer of an infectious agent from an infected host to a susceptible individual via an arthropod or insect.

Laboratory Acquired Infections
The term laboratory-associated infections (LAIs), is used today to discuss all infections that share the laboratory as the starting point for the release of the pathogen. The word "associated" is used to encompass both secondary and tertiary infections that result from the spread of the infection from the primary case to close contacts or others and for infections that are spread to those in the community from the laboratory. The majority of laboratory acquired infections are attained from incidents involving indirect and droplet contact. Needle sticks or other puncture wounds involving contaminated laboratory equipment may be considered

examples of indirect contact. Aerosol droplets projected onto horizontal work surfaces in the laboratory may be transferred to the conjunctiva or mucous membranes of laboratory workers. This type of droplet contact may occur when a laboratory worker touches a contaminated surface in the laboratory and then touches his or her face with their contaminated hand. Eliminating these types of exposure incidents will be discussed in the Work Practice Control section. The parties responsible for reviewing the risk of biohazard research include institutional biosafety committee members, biosafety officers, principal investigators, lab managers and individual researchers.

Containment

In the field of biosafety, the term containment is used to describe proper management of infectious materials. Successful containment of biological material will result in reduced or eliminated exposure to the laboratory worker, ancillary personnel, and the environment. The two principal types of containment include primary and secondary containment.

Primary containment refers to the protection of laboratory workers and the laboratory from contamination. An example of primary containment is confining a manipulation with the potential to generate infectious aerosols within a biological safety cabinet.

Secondary containment refers to the protection of the environment external to the laboratory from contamination. Examples of secondary containment include the physical structure of the laboratory (walls, floors, ceiling) and the non-recirculating ventilation system servicing the laboratory.

In addition to primary and secondary containment, laboratory workers must employ adequate engineering and work practice controls to further reduce or eliminate potential exposure to infectious materials. Engineering and work practice controls are discussed in subsequent sections of this guide. Laboratory supervisors are required to initiate sufficient administrative policies to ensure the safety of laboratory workers. Such administrative policies may cover working in the laboratory during off hours, emergency response, waste disposal, accident reporting, training requirements and supervision of contract employees.

Biosafety Levels

Laboratory biosafety levels 1 through 4 have been established in the current edition of the joint CDC/NIH Guidelines entitled Biosafety in Microbiological and Biomedical Laboratories (BMBL), U.S. Department of Health and Human Services, Public Health Services, Centers for Disease Control and Prevention and the National Institutes of Health. The levels are designated in ascending order, by the degree of protection provided to the worker, the environment, and the community. Each level builds upon the preceding level with BL-1 being the least stringent and BL-4 being the most stringent. This guide will concentrate on discuss BL-1 and BL-2 and briefly discuss BL-3 and BL-4.

The terms risk group and class are often used synonymously with the term biosafety level. The terms risk group and class refer to the risk of infection associated with a particular agent, while the term biosafety level refers to the level of containment required to work safely with a particular agent. The term biosafety level replaced the term physical containment level (P-1 to P-4) originally used by the federal government in discussions of biosafety. The term physical containment level may still be encountered in the recombinant DNA guidelines.

Biosafety Level 1 (BL-1)

BL-1 is appropriate for work with organisms/agents presenting minimal potential hazard to laboratory personnel and the environment. In the laboratory, work is usually conducted on the open bench top without the use of special containment equipment; however, standard microbiological techniques are used. All potentially contaminated waste materials are decontaminated using an approved decontamination technique

such as autoclaving. Scientists with microbiological expertise provide laboratory workers with adequate training and supervision.

Biosafety Level 2 (BL-2)
BL-2 is appropriate for work with organisms presenting moderate potential hazard to laboratory personnel and the environment. BL-2 is more stringent than BL-1. In addition to BL-1 requirements, BL-2 requires that all manipulations with the potential to create aerosols be confined within a properly certified and maintained biosafety cabinet. Additional BL-2 requirements include specific training and supervision by competent scientists, restricted laboratory access, appropriate personal protective equipment (PPE), the adoption of a written biological safety manual, and careful handling of potentially contaminated sharp items.

Biosafety Level 3 (BL-3)
BL-3 is appropriate for work with organisms that may cause serious or potentially lethal disease resulting from exposure via the inhalation route. All manipulations are contained within a properly certified and maintained biosafety cabinet. Laboratory workers must wear enhanced personal protective clothing and equipment when working in the BL-3 laboratory. The BL-3 laboratory is equipped with specialized engineering and design characteristics including directional airflow, restricted access, anteroom, sealed surface penetrations, and a double-door or two-sided (clean and dirty) autoclave.

Biosafety Level 4 (BL-4)
BL-4 is appropriate for work with dangerous and exotic agents that pose high individual risk of life-threatening disease resulting from exposure via the aerosol route. There are usually no effective therapy and/or vaccines for BL-4 agents. The primary hazards to individuals manipulating BL-4 agents are from respiratory exposure, mucous membrane or broken skin exposure, and autoinoculation. BL-4 agents are contained by working in a Class III biological safety cabinet or in a full body positive pressure suit. The BL-4 facility is usually a separate building or zone with elaborate ventilation and waste management characteristics.

Biosafety Laboratory Facilities at NJIT
Currently, NJIT has no biohazard protocols that require more than BL-2 containment. Further, NJIT's laboratories are not equipped to accommodate biohazard protocols that require more than BL-2 containment.

Designation of Biosafety Levels
The CDC/NIH Guidelines, referenced above, and the NIH Guidelines, entitled Guidelines for Research Involving Recombinant and Synthetic DNA Molecules (Appendix B, Classification of Human Etiologic Agents on the Basis of Hazard, included as an appendix to this guide), recommend appropriate biosafety levels, practices, and facilities (laboratory and vertebrate animal) to reduce or minimize laboratory acquired infections. The two guidelines described above are not inclusive documents; rather, they describe those organisms most frequently encountered in clinical and research microbiology, biomedical, and biotechnology laboratories. These guides offer the minimal acceptable containment criteria based on the most recent epidemiological data available to the CDC/NIH. Individual laboratory directors may impose more stringent requirements.

The table below is intended to illustrate general relationships between the classification of microorganisms into risk groups and the required biosafety levels, laboratory type, laboratory practices, and required safety equipment.

Relationship of Risk Groups to Biosafety Levels, Practices, and Equipment				
Risk Group	**Biosafety Level**	**Laboratory Type**	**Laboratory Practices**	**Safety Equipment**
RG-1	BL-1	Basic Teaching	GMT	Open Bench
RG-2	BL-2	Clinical, Research, Diagnostic	GMT plus Protective Clothing and Biohazard Symbol	Open Bench plus BSC to Contain Potential Aerosols
RG-3	BL-3	Special Research or Diagnostic	Level 2 plus special clothing, PPE, Controlled Access, and Directional Airflow	BSC and/or Other Primary Containment for All Activities
RG-4	BL-4	Maximum Containment Facility	Level 3 plus Airlock Entry, Shower Exit, Special Waste Treatment	Class III BSC or Positive Pressure Suits, Double-Ended Autoclave, Filtered Air, Water Treatment

GMT - Good Microbiological Techniques
BSC - Biological Safety Cabinet

Viral Vectors

Viral vectors have become indispensable tools of the molecular biology and it is important for users to understand the origins of these tools and potential implications of their use. Suggested biosafety containment levels are provided for various viral vector systems. Use of a higher-level containment may be required in some cases, depending on the specific properties of the vector and/or insert. Special care should be given to the design and handling of viral vectors containing genes that make growth-regulating products, products released into the circulation, and products that may have a general effect on the host immune system. The table below, adapted from Rutgers University, Stanford University, Michigan State University, and University of Iowa sources, provides information concerning many common viral vectors and general guidance on appropriate biosafety levels. Please note that investigators submitting a Registration Document for Biohazards that includes work with viral vectors will need to provide risk assessment rationale for their protocol's anticipated biosafety level.

Biosafety Levels and Characteristics of Current Viral Vector Systems

Vector	Notes
Adenovirus	Adenoviruses are infectious human viruses which often cause mild respiratory illness, pink eye or gastroenteritis. Rare cases of severe disease can occur, and its use as a genetic vector therefore requires the use of adequate containment equipment and practices.
Adeno-Associated Virus (AAV)	AAV are infectious human viruses with no known disease association. The NIH Guidelines state that "adeno-associated virus (AAV) types 1 through 4, and recombinant AAV constructs, in which the transgene does not encode either a potentially tumorigenic gene product or a toxin molecule and are produced in the absence of a helper virus" can **in most cases** be handled at BL-1.
Epstein - Barr Virus (EBV)	EBV is a member of the herpesvirus family and one of the most common human viruses. The virus is found worldwide and most people become infected with EBV sometime during their lives. In the United States, as many as 95% of adults between 35 and 40 years of age have been infected. Among persons not infected with EBV in their childhood years, EBV infection during adolescence may cause infectious mononucleosis 35% to 50% of the time. A late event in a very few carriers of this virus is the emergence of Burkitt's lymphoma and nasopharyngeal carcinoma. EBV is a transforming virus and is often used to produce immortalized cell lines. BSL-2 is appropriate for most experiments.
Herpesviruses	Herpesviruses include infectious human viruses such as herpes simplex virus type-1 (HSV-1), which is the most commonly used vector system. HSV-1 is common in the general population, but can cause encephalitis in rare cases; its utility as a vector system stems from its broad host cell range, ability to transduce neurons, and its large insert capacity. Biosafety Level 2 is appropriate for many constructs.
Retrovirus	Retrovirus are infectious viruses which can integrate into transduced cells with high frequency, and which may have oncogenic potential in their natural hosts. Retrovirus vector systems are typically based on murine viruses - most commonly, these systems include ecotropic viruses (which can infect only murine cells), amphotropic viruses (which can infect human cells) or pseudotyped viruses, when vector particles express glycoproteins (GPs) derived from other enveloped viruses (which can also infect human cells). The most common GP currently used is VSV-g; however, there are newer pseudotypes being derived from viruses such as measles (Rubeola), Ebola and Marburg. Pseudotyping vectors often results in a higher Biosafety level. Containment for vectors with the ability to infect human cells (amphotropic) will usually be recommended at BSL-2/2+, whereas for ecotropic vectors with no ability to infect human cells, BSL-1 containment may be appropriate.
Lentiviruses	Lentiviruses are a subset of retroviruses, with the ability to integrate into host chromosomes, and to infect non-dividing cells. These viruses can cause severe immunologic and neurologic disease in their natural hosts. Lentivirus vector systems can include viruses of non-human/non-primate origin (feline immunodeficiency virus, equine infectious anemia virus) as well as simian viruses (simian immunodeficiency virus) and human viruses (HIV). The more recent generation vectors have been designed to significantly diminish the possibility for recombination to occur resulting in a wild type-potentially infectious virus. Typical lentivirus vectors are packaged using pseudotyped enveloped proteins. The most common envelope protein used for this purpose is from vesicular stomatitis virus (VSV). It is usually recommended that work with nonhuman lentiviruses that are incapable of establishing productive infections in humans be conducted at BSL-2. Work with simian or human lentiviruses (SIV, HIV) is typically conducted at a higher containment level.

Vector	Notes
Moloney Murine Leukemia Virus (MMLV)	The host range of recombinant MMLV vectors is dependent on the specificity of the viral envelope. The ecotropic env gene produces particles that infect only rodent cells. Amphotropic env gene allows infection of murine and nonmurine cells, including human cells. VSV-G envelope allows infection in a wide range of mammalian and non-mammalian cells. Biosafety Level 2 is appropriate for many constructs, while higher levels may be required depending upon the construct.
Poxvirus	Poxvirus vectors include avian viruses (avipox vectors) such as NYVAC and ALVAC, which cannot establish productive infections in humans, as well as mammalian poxviruses, which can productively infect humans -such as vaccinia virus and modified vaccinia viruses (MVA). Poxviruses are highly stable, and vaccinia virus can cause severe infections in immunocompromised persons, persons with certain underlying skin conditions, or pregnant women. Such individuals should not work with vaccinia virus. The use of BSL-2 is appropriate for many poxviruses and constructs.
Baculovirus	Baculovirus are non-mammalian virus vectors that infect insects; these are very stable and may remain dormant in the environment for years before infecting insects. Work is mostly done at the BSL-1 level.
Rabies virus	Rabies virus is a member of the Rhabdoviridae family and is a common zoonotic infection from bats and other wild mammals. Infection results in encephalitis or paralysis, and is often fatal. Due to its neuronal tropism, pseudotyped rabies virus vectors can be used to study neuronal trafficking or express endogenous genes efficiently in neurons. Biosafety Level 2 (BSL-2) is appropriate for many constructs.
Sendai virus (SeV)	Sendai virus (SeV) causes respiratory disease in rodents and sometimes swine. There is limited evidence of zoonotic transmission to humans. However, the virus is capable of infecting human cell lines and is similar to human parainfluenza virus type 1. For these reasons, SeV work is usually classified as BSL-2

Note: Currently, NJIT's laboratory facilities are equipped to accommodate protocols at BL-1 and BL-2 containment only.

Human Blood, Blood Products, and Primary Tissue Explants

The OSHA Bloodborne Pathogen Standard, 29 CFR 1910.1030, specifies BL-2 containment for all laboratory manipulations of human blood and blood products. Additionally, the concept of **Universal Precautions** is introduced which instructs all those who may come in contact with human blood, blood products, and other potentially infectious materials to assume that these materials are contaminated with the Hepatitis-B Virus (HBV) and the Human Immunodeficiency Virus (HIV), or other potential bloodborne pathogens and to take the appropriate precautions.

Long Term Cell and Tissue Culture

Appendix H of the most recent edition of the BMBL Guidelines, published in 2020, recommend BL-2 practices, containment, waste decontamination and PPE when handling human and non-human primate cells and tissues. These recommendations are based on the potential for these materials to harbor latent viral infectious agents including: HBV, HIV, HCV, HTLV, EBV, HPV, and CMV. Further risk may be associated with cell lines immortalized with viral agents including: SV-40, EBV, adenovirus, and HPV. Based on these potential risks, the NJIT IBC recommends BL-2 containment for protocols involving human and non-human cell and tissue culture.

Summary of Biosafety Levels for Common Biological Materials that May be Encountered at NJIT

The table below depicts biosafety containment levels typically assigned to some common biological materials that may be encountered at NJIT. Currently at NJIT, it is not anticipated that investigators will be working with materials that require more than BL-2 containment. Further, current NJIT's laboratory facilities are not equipped to accommodate research protocols requiring greater than BL-2 containment. Any

NJIT investigator seeking approval for a protocol requiring containment beyond BL-2, specific written approval outlining enhanced biosafety criteria must be granted by the IBC. These requests will be handled by the IBC on a case-by-case basis.

Material	Risk Group	Biosafety Level	Notes
Potentially Infectious Microorganisms	1, 2	1, 2	CDC/NIH Guidelines (BMBL)
Recombinant DNA	1, 2	1, 2	NIH rDNA Guidelines
Low and Moderate Risk Oncogenic Viruses	1, 2	1, 2	NIH rDNA/NCI Guidelines
Animal Viral Etiologic Agents in Common Use	1, 2	1, 2	NIH rDNA/NCI Guidelines
Human Blood, Blood Products, Serum, Plasma	2	2	OSHA BBP Std.
Other Human Body Fluids Described in BBP Std.	2	2	OSHA BBP Std.
Human and Non-Human Primate Cell Lines	2	2	OSHA BBP Std.
Viral Vectors	1, 2	1, 2	NIH rDNA Guidelines

SOP for Viral Vectors

- Entry into the lab is limited/restricted, and doors are not propped open.
- A "Caution" sign is posted on the outside lab door and displays the current emergency contact information and hazard pictograms for the lab.
- Biohazard symbol and biosafety level is on door of labs working with human cells or other human-derived materials, and/or BSL2 or higher pathogens.
- No food or drink consumed or stored in the lab.
- No pipetting by mouth.
- Do not eat, drink, smoke, handle contact lenses, apply cosmetics (including chap stick), etc. in the lab.
- Plants or animals not involved in experiments are not allowed in the lab.
- An insect and rodent control program is in effect.
- Lab workers are current with safety trainings.
- Lab personnel are aware of procedures of decontamination before disposal.
- Collection flasks and vacuum lines have an in-line HEPA filter or equivalent between them.
- Procedures that may generate aerosols are performed under a BSC.
- Sealed rotors or safety cups are available and opened inside a BSC.
  For centrifuging human derived and/or infectious materials.
- There is no recapping or bending of sharps, or removal of needles from syringes.
- If you are transporting cultures/samples between buildings on campus:
  Infectious or biohazardous materials must be transported in a sealed primary container inside a sealed durable and leak proof secondary container that has been labeled with a biohazard sticker.
- While working with the virus: always use aseptic technique and avoid the spread of contamination and immediately replace gloves, if contamination is suspected.

VII. Control of Infectious Materials

Engineering Controls
Engineering controls refer to devices, mechanical or otherwise, that may be used to eliminate, minimize, or reduce occupational exposure to biological material. Engineering controls are usually designed to control contamination at the source thereby preventing the release of the contaminant into the worker's environment (example: biological safety cabinet). Additionally, engineering controls may be designed to minimize the effect of an accidental release of a contaminant into the work environment (example: laboratory ventilation system).

Examples of common biosafety engineering controls include:

Biological Safety Cabinet (BSC)
A ventilated and HEPA filtered cabinet that provides laboratory workers with protection from potentially infectious aerosols and provides a clean surface on which to perform microbiological manipulations (protects laboratory workers, the product, and the environment from contamination). All manipulations of potentially infectious materials that have the potential to produce aerosols should be confined within a biological safety cabinet. Biological safety cabinets should be certified by an approved vendor (according to NSF Standard 49) upon set-up, whenever moved or repaired, and annually thereafter. Biological Safety Cabinets should not be placed in laboratory locations where their air flow patterns will be disrupted, for example: BSCs should not be located directly below HVAC supply and/or exhaust ducts, adjacent to laboratory entrances and exits, chemical fume hoods, open windows, etc.

Sharps Container
Sharps containers are closable, leak-proof, puncture-resistant containers into which sharps are deposited for disposal. Disposable syringes, scalpel blades, and other sharp items should be deposited directly into an appropriately labeled sharps container immediately after use. Disposable needles should never be recapped, bent, broken, sheared, or removed from disposable syringes.

Steam Autoclave
Steam autoclaves are generally considered to be the method of choice for decontaminating infectious laboratory waste. Gravity displacement autoclaves operate at 121 degrees C. (15 lbs./in^2 pressure) while vacuum-type autoclaves operate at 132 degrees C. (27 lbs./in^2 pressure). It is important to consider appropriate load characteristics and autoclave operating parameters in order to determine adequate decontamination time. Further, autoclave bags must not be over-filled in order to allow proper steam/heat penetration into the bag during processing. In some instances, it may be necessary to add a small amount of water to the load being decontaminated to assure steam penetration into the center of the load.

Mechanical Pipetting Device
A wide variety of mechanical pipetting devices are commercially available which allow for the measurement and transfer of potentially infectious liquids while eliminating the need for mouth pipetting. Many of these devices utilize disposable tips and a high efficiency filtration system.

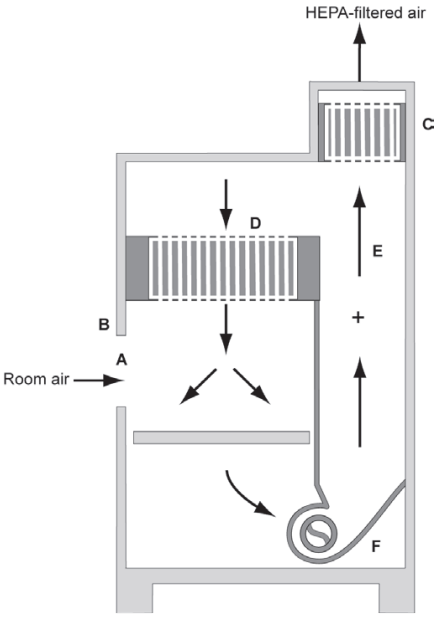
Other examples of engineering controls designed to eliminate or minimize occupational exposure to potentially infectious biological material may include: laboratory bench splash guards, self-sheathing needles, and centrifuge safety caps. An example of an engineering control designed to minimize the effect of an accidental release of contamination in the work environment is a non-recirculating (single pass)

ventilation system. Specialized laboratory ventilation systems may have other specialized infection control characteristics including uni-directional air flow and air pressure differentials.

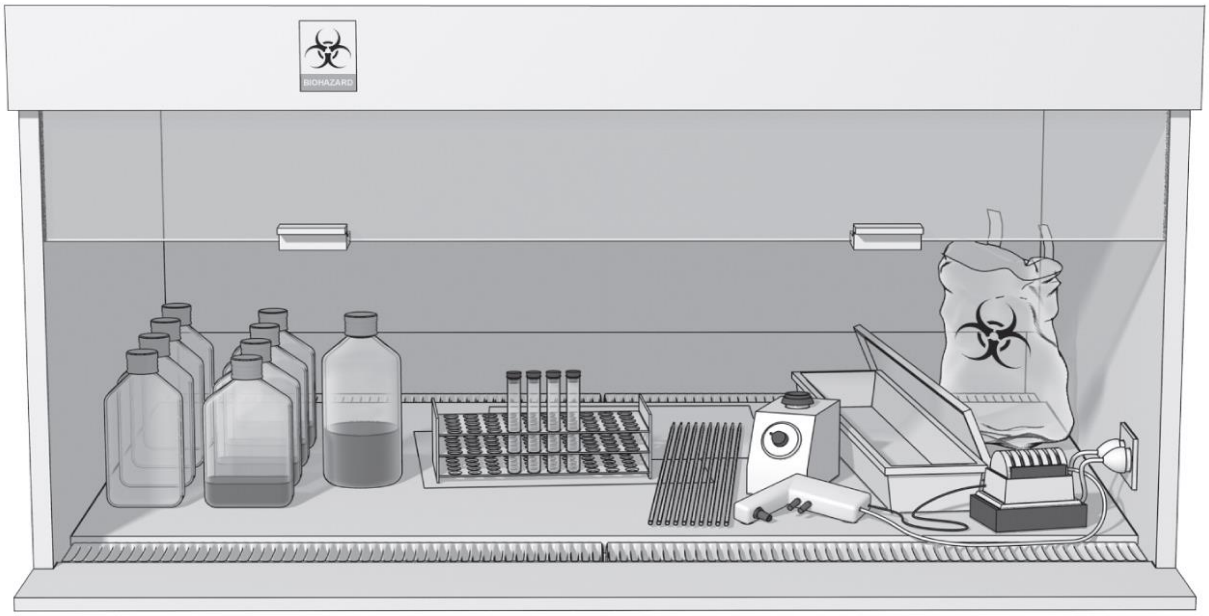
Biological Safety Cabinets

As previously described Biological Safety Cabinets (BSC) are used in microbiology laboratories to contain manipulations of potentially infectious materials with the potential to produce aerosol droplets. The BSC is the primary means of aerosol containment and performs three main functions:

- protection of the laboratory worker by providing a negative pressure enclosure that draws air into the cabinet and away from lab personnel;
- protection of the laboratory procedure by providing a sterile work area; and
- protection of the environment by discharging HEPA filtered air.



The Class II, Type A1 Biological Safety Cabinet (BSC): (A) front opening; (B) sash; (C) exhaust HEPA filter; (D) supply HEPA filter; (E) common plenum; (F) blower. This cabinet is the most common BSC encountered in the academic research laboratory. The Class II, Type A BSC returns HEPA filtered air to the laboratory environment and is not appropriate for the manipulation of volatile chemical hazards.
(Source: CDC/NIH BMBL, 6th Edition)



A typical layout for working "clean to dirty" within a Class II BSC. Clean cultures (left) can be inoculated (center); contaminated pipettes can be discarded in the shallow pan and other contaminated materials can be placed in the biohazard bag (right). This arrangement is reversed for left-handed persons.
(Source: CDC/NIH BMBL, 6th Edition)

Many common laboratory microbiological techniques produce aerosols and droplets of various sizes. Some of these procedures include:

- Decanting and pouring of liquids
- Pipetting
- Pipette mixing of fluid culture
- Removal of screw caps
- Vortex mixing
- Grinding
- Blending
- Shaking
- Opening containers whose internal pressure is different from ambient pressure
- Opening lyophilized cultures
- Centrifugation
- Cell sorting (cell analysis in a lesser extent) with flow cytometers
- Inoculation of animals
- Tissue harvesting
- Dropping tubes or flasks of cultures
- List compiled from: Biosafety in the Laboratory; Prudent Practices for the Handling and Disposal of Infectious Material, National Academy Press, 1989, Laboratory Biosafety Manual, 2nd Edition World Health Organization, 1993, and P. Herman, Belgian Biosafety Server, http://www.biosafety.be, 2012.

Working in a Biological Safety Cabinet

Conduct all BL-2 procedures with the potential to produce aerosol droplets within a properly functioning and certified biological safety cabinet (BSC). When working in the BSC:

- Decontaminate the BSC work surfaces both before and after each use.
- Allow the BSC to run for several minutes prior to use so that appropriate air flow patterns may be established.
- Appropriate personal protective equipment shall be worn while working in the BSC.
- Laboratory workers should move their arms, material, and equipment into and out of the BSC gently and as infrequently as possible in an attempt to minimize air flow disruption.
- The front air intake grill must never be blocked with paper, lab supplies, or equipment.
- Equipment, large items, aerosol generating devices should be placed toward the rear edge of the work surface without blocking the rear air intake grill.
- Work should flow from the clean side of the cabinet to the contaminated side of the cabinet.
- The autoclavable biohazard collection bag and pipette collection tray should not be placed outside the BSC as the frequent in-and-out movement needed to use these containers is disruptive to the integrity of the cabinet's air barrier, and can compromise both personnel and product protection.
- Ultraviolet lights are not required in BSCs, however, if they are used, they should be cleaned weekly to remove any dust and dirt that may block the germicidal effectiveness of the light. Ultraviolet light intensity should be checked when the cabinet is recertified to ensure that light emission is appropriate.

Ultraviolet lights must be turned off while the room is occupied, to protect eyes and skin from inadvertent exposure.

- Open flames should not be used in a BSC.

- Any spills within the BSC should be cleaned up immediately while the BSC continues to run. Decontamination solution should be applied in a way to minimize splash, splatter, and spray within the BSC.

- Pay attention to all alarms while working in the BSC. Sash position and air flow alarms are common. A sash position alarm may indicate that the sash window is in an inappropriate position. An air flow alarm may indicate that there is inadequate airflow into or out of the BSC. Either alarm may indicate that the BSC is not functioning properly. Work within the BSC should discontinue, cultures and materials secured, work surfaces decontaminated, and arrangements should be made for BSC evaluation and repair.

Work Practice Controls

Work practice controls refer to practices and procedures which reduce or eliminate the chance of occupational exposure to potentially infectious materials. Examples of work practice controls include:

- A current Biosafety Plan with lab-specific SOPs and other applicable safety manuals are available in the lab.

- The PI establishes policies and procedures whereby only persons who have been advised of the potential hazards and meet specific entry requirements may enter the laboratory.

- Lab workers are current with Biosafety Trainings.

- An insect and rodent control program is in effect.

- Animals not involved in the work being performed are not permitted in the lab.

- Entry into the lab is limited/restricted, and doors are not propped open.

- Always wear the appropriate personal protective equipment for the task being performed.

- Appropriate gloves are available and worn when necessary.

- Contain all manipulations of potentially infectious materials with the potential to create aerosol droplets within a properly functioning and certified biological safety cabinet.

- Biological Safety Cabinet (BSC) has been inspected/certified within the last 12 months.

- Perform manipulations of potentially infectious materials in a manner designed to minimize splash, spray, or splatter whenever possible.

- No pipetting by mouth.

- When centrifuging potentially infectious materials, sealed rotor heads and centrifuge safety cups should be loaded and unloaded within the biological safety cabinet.

- Maintain an appropriate biological spill kit in all laboratories where potentially infectious materials are stored or manipulated.

- Use Universal Precautions when handling human-derived materials.

- Appropriate eye protection is available and worn when necessary.

- Wash hands promptly after removal of gloves, prior to exiting a laboratory, and prior to eating and/or drinking.

- Sinks are functional and accessible with soap and paper towels for handwashing.

- Do not eat, drink, smoke, apply lip balm or makeup, and handle contact lenses in areas where occupational exposure to potentially infectious material may occur.

- Handle and dispose of contaminated sharps carefully. Minimize the use of sharps whenever possible.

- There is no recapping or bending of sharps, or removal of needles from syringes.

- Never store food or drink in refrigerators, freezers, cabinets, or on shelves, countertops, and benchtops, where potentially infectious material may be (or have been) present.

- Freezers, refrigerators, and similar storage units are labeled with the biohazard warning sign.

- Observe hazard warning signs and labels applied to all biological safety cabinets, laminar flow hoods, incubators, and other pieces of laboratory equipment where potentially infectious materials may be (or have been) stored (see Hazard Communication, below).

- Ensure that laboratory personnel remove all potentially infectious material, contaminated equipment, and sharp objects from any piece of laboratory equipment that is to be serviced.

- Ensure that all laboratory equipment that was used to store or manipulate potentially infectious material is appropriately surface decontaminated by laboratory personnel prior to moving or servicing.

- Promptly decontaminate all laboratory benches, work surface or equipment following exposure to potentially infectious material.

- Know the most suitable disinfectant for the materials being manipulated in your laboratory.

- Do not lean or sit on laboratory bench tops or other laboratory equipment where blood or other potentially infectious materials may have been stored or manipulated.

- Laboratory paperwork should not be prepared on laboratory bench tops, on top of centrifuges, refrigerators, freezers, or other pieces of laboratory equipment where blood or other potentially infectious materials may have been stored or manipulated.

- Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

Handling of Sharps

Contaminated sharps such as needles, scalpel blades, broken test tubes, and other sharp instruments present a significant risk of transmission of biological agents in the laboratory. Disposable syringes, scalpel blades, glass Pasteur pipettes, and other sharp items should be deposited into an appropriate leak-proof, puncture-resistant, and labeled sharps container immediately after use. Disposable needles should never be recapped, bent, broken, sheared, or removed from disposable syringes.

Sharps containers should be located in all work locations where it is reasonably anticipated that sharps may be used. Sharps containers should only be filled to within one inch of the top of the container. Sharps containers should never be overfilled. Never attempt to force additional material into a full container.

Laboratories engaged in research utilizing human-derived materials are regulated by the OSHA Bloodborne Pathogen Standard (BBP). The BBP standard requires laboratories engaged in research utilizing human-derived materials to develop a safe sharps program, seek to eliminate sharps from their research protocol, and encourage the use of non-sharp alternatives wherever possible.

Personal Protective Equipment

Personal protective equipment (PPE) are items that are worn to protect workers from exposure to potential occupational hazards. PPE is especially important when exposure cannot be prevented by other means, e.g., engineering and work practice controls. These items provide protection by establishing a barrier between the employee and the potentially infectious material. PPE must be accessible and available in sizes that fit all employees. PPE will be repaired or replaced as needed. Examples of PPE worn to protect workers from occupational exposure to potentially infectious material include:

Gloves

Non-sterile single use nitrile examination gloves are appropriate for most, if not all, activities and procedures related to pathogenic microorganisms performed in NJIT laboratories. This section of the safety manual does not discuss gloves worn for purposes other than protection from infectious agents, e.g., formaldehyde. Gloves must be worn when there is the potential for exposure to blood or other potentially infectious material.

Disposable gloves must be changed periodically throughout the work day and after any overt incident where the glove may have been contaminated. Gloves should be changed at the completion of each experimental protocol or at various stopping points in longer more complex protocols. Hands must be washed each time disposable gloves are removed. Employees with non-intact skin should cover affected area with a suitable bandage prior to donning gloves. Hypoallergenic gloves, glove liners, powderless gloves or other alternatives shall be made available to those NJIT employees who are allergic to the typical gloves provided.

To Remove Potentially Contaminated Disposable Gloves:

- Pinch with two fingers the outside of one glove (near the inner wrist) with the other gloved hand.
- Turn the glove inside out as it is pulled off.
- Hold removed glove loosely in the still gloved hand.
- Reach inside second glove with two fingers of the bare hand and pinch it.
- Turn the glove inside out as it is removed, enclosing the first glove.

- Properly discard the entire package.

- Wash hands.

NJIT employees may also use heavier non-disposable utility gloves for activities where less tactile sensitivity and/or more protection is required such as waste decontamination or laboratory clean-up activities. Unlike disposable gloves, which must be discarded after a single use, non-disposable utility gloves may be washed or otherwise decontaminated and used again. It is important that non-disposable utility gloves are inspected often to ensure that they maintain their integrity.

Protective Eyewear
Protective eyewear must be worn during procedures which generate aerosols or splatter or splash potentially infectious materials. **When working with potentially infectious material, safety glasses must be worn at all times**. Protective eyewear includes items such as safety glasses with solid side shields, goggles, and full-length face shields.

Reusable protective eyewear issued to NJIT employees meet the criteria established by the American National Standard Institute Standard Z87.1-1989 entitled Practice for Occupational and Educational Eye and Face Protection.

Dust Masks, Surgical Masks, and Face Shields
It is not anticipated that typical laboratory manipulations require the use of respiratory protection when working at BL-1 or BL-2 containment. When engaged in certain activities, laboratory workers may consider the use of a dust mask or surgical mask. These activities may include animal surgery, the cleanup of a spilled biological culture or the packaging of biological waste prior to decontamination.

When deemed necessary by the Environmental Health and Safety Department, dust masks, surgical masks, and face shields may be worn during procedures which generate aerosols or splatter or splash potentially infectious materials. The use of higher levels of respiratory protection, beyond surgical masks and dust masks, require employees to participate in NJIT's Respiratory Protection Program that includes training, medical evaluation, and respirator fit testing.

Lab Coats, Gowns and Aprons
Protective gowns, aprons, lab coats, clinic jackets or similar outer garments must be worn during procedures which generate aerosols or splatter or splash potentially infectious materials. Any gown or other protective outer garment that is visibly soiled with blood or other potentially infectious material should be immediately removed and disposed of properly. Gowns, lab coats and other protective outer garments should not be worn out of the clinic, lab, or other work location. Reusable cloth gowns or other protective outer garment shall be cleaned and laundered on a regular basis at no cost to the employee.

Cleaning, Disinfection, and Sterilization
Cleaning refers to the physical removal of organic material or soil from objects. Cleaning is generally considered to be the first step when disinfecting or sterilizing reusable instruments or equipment. Organic materials may contain high concentrations of microorganisms. Additionally, organic materials may protect the microorganisms from the decontamination or sterilization process. The preferred method of cleaning is soap and water. A brush may be used to help remove foreign matter adhering to the surface being cleaned. An example of items that require periodic cleaning include reusable PPE such as safety glasses, goggles, and face shields.

Disinfection refers to the destruction of most pathogenic organisms but not bacterial spores. Prior to disinfection, equipment and work surfaces should be thoroughly cleaned. Commercial germicides approved for use and EPA registered as "hospital disinfectants", which are also tuberculocidal, are recommended by the CDC for disinfecting environmental surfaces. A 10% solution of household bleach: approximately 1 1/2 cups of household bleach in 1 gallon of tap water may also be used for disinfection. Household bleach contains 5.25% sodium hypochlorite by weight. Once the bleach solution is mixed, the container should be affixed with a label stating the ingredients, the concentration, and the date. Reusable personal protective equipment soiled by blood or other potentially infectious material shall be cleaned and disinfected prior to reuse.

Sterilization refers to the destruction of all microbial life, including a high percentage of bacterial spores. Sterilization is necessary for instruments, equipment, or objects that penetrate skin, come into contact with the bloodstream or other normally sterile areas of the body, and equipment used in certain clinical and research laboratory procedures. Autoclaving is the preferred method of sterilization for small laboratory equipment, laboratory reagents, and potentially infectious waste materials. Autoclave tape, bacterial culture vials, and chemical indicator strips may be used to assure adequate sterilization. Dry heat and immersion in EPA approved chemical sterilants are alternative sterilization methods that may be acceptable. Disposable (single-use) items have eliminated the need to reprocess and sterilize equipment in many instances. Please refer to Appendix III for more information regarding common laboratory disinfectants.

Housekeeping

Environmental surfaces such as walls, floors, and ceilings are not normally associated with the transmission of infections to employees because they do not routinely come into contact with susceptible tissue (e.g., mucous membranes, conjunctiva of the eye). However, since dirt is a reservoir for disease and a potential vehicle for the transmission of infection, cleaning and removal of dust, dirt, and soil should be done routinely by laboratory personnel. The type of area, the type of surface being cleaned, and the level of dirt or contamination present will determine cleaning schedules and methods of decontamination.

Work surfaces contaminated by infectious material shall be cleaned and decontaminated by laboratory personnel as soon as possible after the completion of a procedure. Protective coverings such as plastic wrap, aluminum foil, lab table soakers, or other materials used to cover environmental surfaces and equipment shall be removed and replaced as soon as possible after contamination. Additionally, these materials will be removed and replaced by laboratory personnel on a regular basis (e.g., after each shift, daily, or weekly) depending on the frequency of contamination. Bins, pails, cans, and other similar receptacles, which may become contaminated and are intended for reuse, shall be frequently inspected, cleaned and decontaminated as required.

Broken glassware, which may be contaminated, shall never be picked up by hand. Rather, mechanical means such as forceps will be used. When picking up this type of material care must be taken not to aerosolize the blood or other potentially infectious contaminant. Additionally, adequate personal protective equipment shall be worn to protect the employee from accidental contamination. Spills of blood or other potentially infectious materials will be cleaned and decontaminated immediately.

Spill Clean Up Procedures

In the event of a spill of a potentially infectious biological material, including human blood, human cell cultures, recombinant materials, or other potentially infectious material (OPIM) the following emergency response procedures shall be followed:

- Notify: All spills of potentially infectious biological material shall be reported to the Laboratory Director (typically the Principal Investigator) and to the Environmental Health and Safety Department.

- Retrieve and Don: Retrieve laboratory biological spill kit and don appropriate PPE.

- Spill Inside Biological Safety Cabinet:
  - Keep biosafety cabinet running
  - Cover affected area with absorbent material
  - Gently apply a liberal amount of disinfectant on top of covered spill
  - Allow adequate contact time which is typically 20 to 30 minutes
  - Please refer to Appendix III for more information regarding common laboratory disinfectants
  - Collect absorbent material and place into plastic biohazard bag within the BSC
  - Clean affected area again with disinfectant
  - Placed soiled cleaning materials into biohazard bag
  - Remove potentially contaminated PPE and place in biohazard bag within the BSC
  - Wash hands before removing safety glasses
  - Seal biohazard bag and place in medical waste box for ultimate disposal
  - Wash hands

- Spill Outside Biological Safety Cabinet:
  - Attend to any injured persons and follow appropriate emergency response protocols
  - Evacuate affected area or entire laboratory if necessary
  - Allow 30 minutes for aerosol droplets to settle
  - Follow spill protocol for spills inside biosafety cabinet:
    - Cover affected area with absorbent material
    - Gently apply a liberal amount of disinfectant on top of covered spill
    - Allow at least 20 minutes of contact time
    - Collect absorbent material and place into plastic biohazard bag
    - Clean affected area again with disinfectant
    - Placed soiled cleaning materials into biohazard bag
    - Remove potentially contaminated PPE and place in biohazard bag
    - Wash hands before removing safety glasses
    - Seal biohazard bag and place in medical waste box for ultimate disposal
    - Wash hands
  - Contact the NJIT Environmental Health and Safety Department if spill is beyond the capacity of properly trained and equipped NJIT laboratory employees
  - Document incident

Responsibility for Spill Clean Up

NJIT advocates a tiered approach to the clean-up of biological spills in NJIT laboratories. Laboratory workers must exercise judgment when deciding if they have the appropriate training and equipment to safely clean up the spill.

- Small spills of BL-1 and BL-2 material occurring within the BSC: appropriate for the laboratory worker to clean up with standard PPE, laboratory biological spill kit, and appropriate decontamination solution.

- Moderate spills of BL-1 and BL-2 material occurring within the BSC: appropriate for the laboratory worker to clean up with standard PPE, laboratory biological spill kit, and appropriate decontamination solution.

- Large spills BL-1 and BL-2 occurring within the BSC: not appropriate for the laboratory worker to clean up; contact NJIT Environmental Health and Safety Department for assistance.

- Small spills of BL-1 material occurring outside the BSC: appropriate for the laboratory worker to clean up with standard PPE, laboratory biological spill kit, and appropriate decontamination solution.

- Small, moderate and large spills of BL-2 material occurring outside the BSC: not appropriate for the laboratory worker to clean up; contact NJIT Environmental Health and Safety Department for assistance.

Any laboratory worker who is uncomfortable engaging in spill clean up activities shall have the option to contact more experienced laboratory colleagues or the NJIT Environmental Health and Safety Department to assist with spill clean up activities.

Biological Spill Kits
All NJIT laboratories engaged in research activities involving potentially infectious materials will be equipped with a biological spill kit. Biological spill kits may be custom made or purchased commercially. At a minimum biological spill kits must include:

- Appropriate PPE (gloves, eye protection, surgical mask, laboratory coat or Tyvek suit)
- Approved decontamination solution
- Absorbent material
- Autoclavable waste bag and sharps container

Biological/Regulated Medical Waste Disposal
Laboratories working with recombinant materials, potentially infectious microorganisms, human and non-human primate cell lines, viral vectors, and other potentially infectious materials are required to decontaminate their liquid and solid biological waste materials prior to discarding the sealed bags in Regulated Medical Waste (RMW) box located in individual laboratories. Properly sealed and labeled RMW boxes will be disposed through a licensed medical waste vendor in accordance with federal, state, and local regulations. Please refer to Appendix III (Characteristics of Common Laboratory Disinfectants) and Appendix IV (Biological Waste Management) for more information.

Transport of Biological Material
During the course of research activities, it may become necessary to transport biological material between labs, between floors, or between buildings at NJIT. In terms of transportation regulations, biological materials are typically defined as any materials taken from humans or animals, living or dead, fresh or preserved (cells, tissues, organs, blood and body fluids), viruses, DNA, or parasites used for diagnostic or research purposes. In order to eliminate potential exposure to biological material during transport, lab workers must adhere to the following guidelines:

- Transport of biological materials may occur by hand or with a cart.
- Individual samples must be stored in a sealed and labeled primary container.
- Sealed and labeled primary containers must be placed in leak proof secondary containers during transport.
- When transporting liquids, secondary containers must be large enough to contain more than the total volume of liquid being transported and must be lined with an absorbent material.
- Examples of some common transport methods are described below:

An example of a secondary container, lined with an absorbent material, suitable for transporting liquid biological materials between labs or floors. It is recommended that this secondary container be transported on a cart as an additional safeguard.

An example of a commercially available specimen transport container. This container has a tight fitting, sealable lid, with a rubber gasket. This container may be hand carried or placed on a cart. When used to transport biological materials, this container should be properly labeled.

An example of a commercially available cooler being utilized for specimen transport. In this example, individual sample tubes are placed within a zip lock and labeled plastic bag. The transport cooler is properly labeled and contains absorbent material.

If evidence of a leak or spill is detected when opening a container used to transport biological material, it is important to ensure that all potentially contaminated items are adequately decontaminated with a suitable disinfectant.

Additionally, NJIT personnel transporting biological materials in their personal vehicles must:

- be trained in the proper procedures for packaging and transport of biological materials;
- conform with the shipping and transport requirements described above; and
- sign a Material of Trade Disclosure Form as required by the NJIT EHS Department.

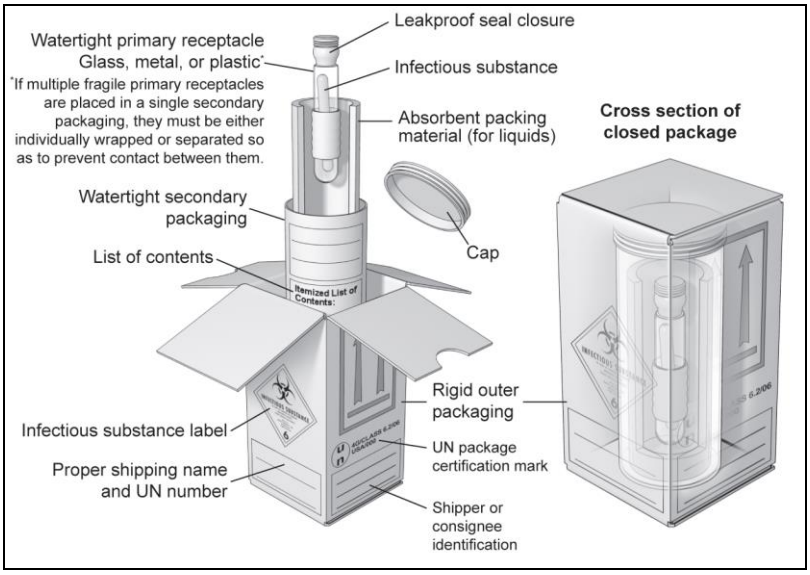
Shipping of Biological Material

The guidelines and examples described above pertain only to the transport of biological materials between labs, floors, or building at NJIT. When it becomes necessary to ship biological materials to locations outside of NJIT, additional guidelines and regulations must be adhered to. The following regulations apply to the packaging and shipment of biological materials:

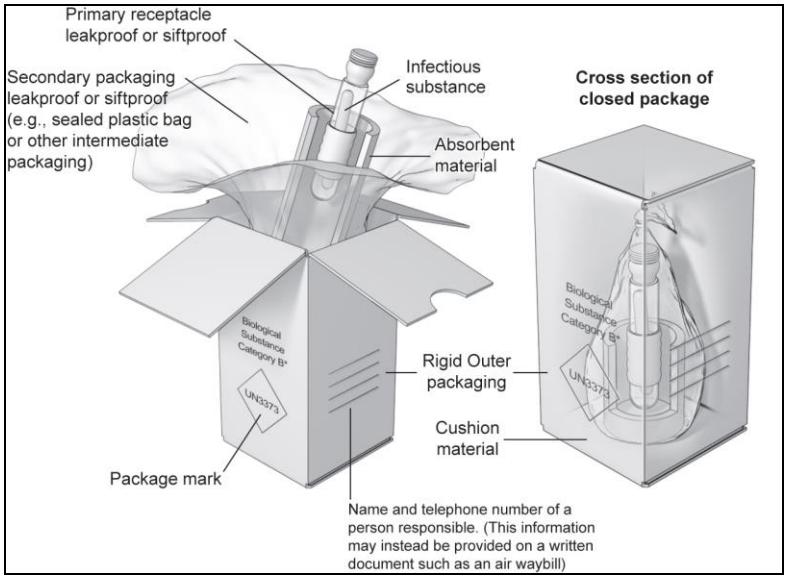
- U.S. Department of Transportation, 49 CFR Parts 171-180 and amendments
- U.S. Public Health Service, 42 CFR Part 72, Interstate Shipment of Etiologic Agents
- U.S. Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Bloodborne Pathogens
- International Air Transport Association (IATA), Dangerous Goods Regulations
- U.S. Postal Service, 39 CFR Part 111, Mailability of Etiologic Agents, Mailability of Sharps and Other Medical Devices, and Publication 52, Acceptance of Hazardous, Restricted or Perishable Matter

All NJIT personnel involved in the shipping of biological specimens will complete semi-annual training as required by the IATA Dangerous Goods Regulations; as the IATA Dangerous Goods Regulations are the primary regulation governing the shipment of biological materials by air.

The diagram below, from the CDC/NIH Guidelines, 6th edition, shows an example of the UN standard triple packaging system for materials known or suspected of being a Category A infectious substance (known human pathogens that are capable of causing serious disease).



The diagram below, from the CDC/NIH Guidelines, 6th edition, shows an example of the UN standard triple packaging system for materials known or suspected of being a Category B infectious substance. This type of packaging is also appropriate for clinical and diagnostic specimens.



Laboratory groups that are uncertain regarding the required protocols to follow when transporting or shipping biological materials or have questions regarding shipping requirements for the specific biological materials shall contact the NJIT Environmental Health and Safety Department for guidance.

Hazard Communication
In order to communicate the existence of a potential biological hazard to others, all containers of regulated medical waste must be labeled with the Universal Biohazard Symbol. These labels shall be fluorescent orange or orange-red with lettering and symbols printed in a contrasting color. These labels are commercially available from a variety of sources. A sample biohazard warning label is depicted below.

Biohazard warning labels shall also be affixed to biological safety cabinets, refrigerators, freezers, incubators, and other equipment used to manipulate, store, transport, and ship blood or other potentially infectious material.

Entrance doors to work areas in clinical, academic and research laboratories where potentially infectious materials are in use shall be posted with the biohazard warning label. In addition to the biohazard symbol, these labels shall include the name of the infectious agent in use, any special requirements for entrance to the area, and the name and telephone number of the laboratory director or other responsible person, see attached label.

Laboratories engaged in recombinant DNA manipulations must also post areas and containers where recombinant materials are manipulated, transported, and stored. The Universal Biohazard Symbol is not required for recombinant DNA laboratories operating at BL-1 containment. An alternative labeling method that includes the words "r-DNA/BL-1" may be used. However, the Universal Biohazard Symbol is required for recombinant DNA laboratories operating at BL- 2 or higher.

Laboratory Access
In order to control unnecessary and unintended foot traffic through the laboratory, laboratory doors will be closed whenever BL-2 work is in progress. Further, BL-2 "Experiment in Progress" signs will be affixed to laboratory doors when potentially infectious materials are being manipulated.

HIV and HBV Research Laboratories and Production Facilities
All research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV or HBV shall meet the criteria set forth in 29 CFR 1910.1030(e) (Section (e) of the Bloodborne Pathogen Standard). Additionally, these laboratories shall conform to BL-2 standards, practices, equipment and facilities established by the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health in Biosafety in Microbiological and Biomedical Laboratories (BMBL), HHS Publication No. (CDC) 93-8395. Further, these laboratories will follow operational guidelines established by the Centers for Disease Control and Prevention's Agent Summary Statement for Human Immunodeficiency Virus and Report on Laboratory-Acquired Infection with Human Immunodeficiency Virus, MMWR, April 1, 1988, Vol 37, No. S-4. In some instances, depending on the concentration of the virus being grown, BL-3 standards, practices, equipment, or facilities may be required.

Training
NJIT employees engaged in the manipulation of recombinant and biological materials shall attend a biological safety training session on an annual basis. At the end of a Biological Safety training session NJIT employees will be able to:

- Obtain a copy of the Biological Safety Guide and be aware of the primary regulations;
- Define potentially infectious material and cite examples;
- Understand modes of transmission of infectious materials especially those which apply to the laboratory setting;
- Understand the basic principles of Biosafety and the containment criteria established for BL-1 and BL-2 laboratories;
- Identify tasks and situations that may involve exposure to potentially infectious material;
- Understand control measures to eliminate, minimize, or reduce exposure to potentially infectious material by using appropriate engineering controls, work practice controls, and PPE;
- Understand the process by which biological waste generated in NJIT laboratories is properly managed, disinfected, and disposed;
- Understand how biological safety cabinets function to protect laboratory personnel, maintain product sterility, and protect the environment;
- Take appropriate measures in response to an exposure incident or a spill of potentially infectious material. Additionally, employees will understand the post-exposure medical evaluation and follow-up required after an exposure incident;
- Recognize the universal biohazard symbol and understand its appropriate use; and
- Understand the process by which biohazard protocols are reviewed and approved at New Jersey Institute of Technology.

Recombinant DNA
BL-1 through BL-4 have been established in the joint CDC/NIH Guidelines primarily to minimize the potential of laboratory acquired infections among microbiological and biomedical laboratory workers and ancillary personnel. Other guidelines and regulations have been established to regulate laboratory activities involving recombinant DNA manipulations. The NIH Guidelines for Research Involving Recombinant DNA Molecules has been updated regularly since 1978 to keep pace with technological changes in molecular genetics as well as the application of this technology.

All experiments, research, and other activities involving recombinant DNA manipulations performed in NJIT facilities should be conducted in accordance with applicable sections of the NIH Guidelines, cited above. The NIH Guidelines contain an appendix entitled, "Classification of Human Etiologic Agents on the Basis of Hazard". This supplementary information is included as an Appendix to this Biosafety Guide. Because the NIH updates the Recombinant DNA Guidelines often, this listing is usually the most current classification of infectious organisms into risk groups and/or biosafety levels published by a regulatory agency. NJIT employees may consult it in the event that a risk assessment involving a particular infectious agent or procedure is required.

The purpose of the NIH Guidelines is to "specify practices for constructing and handling recombinant DNA molecules and organisms and viruses containing recombinant DNA molecules". The NIH Guidelines define recombinant DNA molecules as "molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell or molecules that result from the replication of those described above". Like the joint CDC/NIH Guidelines, the NIH guidelines are intended to minimize the potential of laboratory acquired infections among laboratory workers. Additionally, the NIH Guidelines are intended to protect the environment from potentially adverse or unknown affects associated with genetically manipulated plants, organisms, and products.

The NIH Guidelines classify microorganisms into 4 Risk Groups (RG) according to their relative pathogenicity for healthy adult humans as follows:

Risk Group 1
Well characterized agents that are not associated with disease in healthy adult humans and of minimal potential hazard to laboratory personnel and the environment. [No or very low individual and community risk].

Risk Group 2
Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available and the risk of spread of infection is limited. [Moderate individual risk, low community risk].

Risk Group 3
Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available and the risk of spread of infection is limited. [High individual risk, low community risk].

Risk Group 4
Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available and can be readily transmitted from one individual to another, directly or indirectly. [High individual and community risk].

The following table is intended to illustrate general relationships between the classification of microorganisms into Risk Groups and the required biosafety level. The table is presented to instill in NJIT

employees an appreciation of the equivalent biological hazards associated with recombinant DNA technology.

Relationship of Risk Groups to BL-s, Practices, and Equipment				
Risk Group	**Biosafety Level**	**Laboratory Type**	**Laboratory Practices**	**Safety Equipment**
RG-1	BL-1	Basic Teaching	GMT	Open Bench
RG-2	BL-2	Clinical, Research, Diagnostic	GMT plus Protective Clothing and Biohazard Symbol	Open Bench plus BSC to Contain Potential Aerosols
RG-3	BL-3	Special Research or Diagnostic	Level 2 plus special clothing, PPE, Controlled Access, and Directional Airflow	BSC and/or Other Primary Containment for All Activities
RG-4	BL-4	Maximum Containment Facility	Level 3 plus Airlock Entry, Shower Exit, Special Waste Treatment	Class III BSC or Positive Pressure Suits, Double-Ended Autoclave, Filtered Air, Water Treatment

GMT - Good Microbiological Techniques
BSC - Biological Safety Cabinet

Biological Containment
A previous section of this guide (Principles of Biosafety) has introduced the term containment to describe those techniques used to manage or "contain" infectious materials. Generally, containment techniques are of two types: primary containment and secondary containment. Additionally, containment techniques can be divided into two categories: laboratory practices and safety equipment. Recombinant DNA experiments lend themselves to a third category of containment known as biological containment. Biological containment refers to the specific natural biological barriers which exist that limit either the infectivity of a vector or vehicle (plasmid or virus) for specific hosts or its dissemination and survival in the environment. Host-vector systems should be chosen or constructed to minimize the survival of the vector in its host outside the laboratory and to minimize the transmission of the vector from the propagation host to other non-laboratory hosts.

Disposal of Recombinant-DNA Waste
All wastes generated when conducting recombinant DNA manipulations require adequate decontamination prior to disposal. Recombinant DNA wastes are to be treated as biohazardous. The same techniques and equipment shall be used when decontaminating recombinant DNA waste as when decontaminating biohazardous waste. Please refer to section on biohazardous waste disposal, above, and Appendix IV, attached, for additional information. Although generally non-infectious, BL-1 recombinant DNA waste requires adequate decontamination prior to disposal. Similarly, transgenic plant materials require adequate "decontamination" prior to disposal.

Dual Use Research of Concern (DURC)

Introduction

Dual Use Research of Concern (DURC) may comprise those research activities that can reasonably be anticipated to provide knowledge, information, products, or technology that may be misapplied for malevolent purposes. The consequences of DURC may result in threats to public health and safety, agriculture, national security, or the environment. The aim of government oversight of potential DURC is to preserve the benefits of life science research while minimizing the risk of misuse.

Definitions - United States Government (USG) 2014

- **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 malevolent purposes.
- **Dual use research of concern (DURC)** is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.
- **Institutional Contact for Dual Use Research (ICDUR)** is an individual designated by the organization to serve as an organizational point of contact for questions regarding compliance with and implementation of the requirements for the oversight of DURC, as well as the liaison between the organization and the relevant USG funding agency.
- **Institutional Review Entity (IRE)** is a committee established by the organization to perform the review and risk mitigation tasks required in the policy.
- **National Science Advisory Board for Biosecurity (NSABB)** is a federal advisory committee that addresses issues related to biosecurity and dual use research at the request of the USG.

Responsible Code of Conduct

Responsible code of conduct is essentially a stewardship opportunity for individuals involved in any stage of life sciences research. This code obligates investigators to avoid or minimize the risks and harm that could result from harmful use of life sciences research. Investigators that follow responsible code of conduct have the following responsibilities (NSABB 2010):

- Assess their own research efforts for dual use potential and report it as appropriate
- Stay informed of literature, guidance, and requirements related to dual use research
- Train others to identify DURC, manage it appropriately, and communicate it responsibly
- Serve as role models of responsible behavior, especially when involved in research that meets the criteria for DURC
- Be alert to potential misuse of research

Agents and Toxins

Scientists are encouraged to be cognizant of the DURC potential of their research activities and to accept responsibility for the DURC potential of their work. Life sciences research that uses one or more of the agents or toxins listed in the table below, and can be reasonably anticipated to produce one or more of the effects listed in Categories of experiments section will be evaluated for DURC potential

Agents and Toxins		
Avian influenza virus (highly pathogenic)	**Ebola virus**	**Rinderpest virus**
Bacillus anthracis	**Foot-and-mouth disease virus**	**Toxin-producing strains of Clostridium botulinum**
Botulinum neurotoxin5	**Francisella tularensis**	**Variola major virus**
Burkholderia mallei	**Marburg virus**	**Variola minor virus**
Burkholderia pseudomallei	**Reconstructed 1918 Influenza virus**	**Yersinia pestis**

Dual Use History and Background

In 2003, the National Academies published *Biotechnology Research in an Age of Terrorism*, also referred to as the "Fink Report." The report noted that although extensive controls were in place to mitigate risk from potential dual use research, a more comprehensive enforcement of the controls was needed. The report also outlined categories of experiments of concern that should be identified by investigators before research occurs and results are published. In general, experiments of high concern were those that would greatly alter the transmissibility, detectability, and/or pathogenicity of a biological agent allowing possible harmful use. The Fink Report also identified the need for enhanced responsibilities of **Institutional Biosafety Committees (IBCs)** to assess and provide oversight to these types of experiments.

Categories of Experiments of Concern

a) Enhances the harmful consequences of the agent or toxin
b) Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
c) Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
d) Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
e) Alters the host range or tropism of the agent or toxin
f) Enhances the susceptibility of a host population to the agent or toxin
g) Generates or reconstitutes an eradicated or extinct agent or toxin listed in table, above.

Responsibilities of Principal Investigators (PIs)

PIs hold a fundamental responsibility with regards to DURC oversight. Under the policy, PIs must:

- Notify the IRE and provide an assessment as soon as research involves one or more of the agents or toxins listed above, which aims to produce, or can be reasonably anticipated to produce one or more of the seven results outlined in the types of experiments listed above.
- Work with the IRE to assess the dual use risks and benefits of the DURC and to develop risk mitigation measures. All work must be done in accordance with the developed risk mitigation plan.
- Comply with all organizational and USG policies and requirements for DURC oversight. The PI must ensure that his/her laboratory personnel working with DURC are trained on the policy, and the risk mitigation measures in place to alleviate possible ill-effects of the research.
- The PI must ensure that the assessment of potential DURC must occur prior to work begins. Risk mitigation plan and measures must be in place before work begins when the research is DURC.
- Communicate DURC in a responsible manner. Communication of research and research findings is an essential activity for all researchers, and occurs throughout the research process, not only at the point of publication. Researchers planning to communicate DURC should do so in compliance with the approved risk mitigation plan.

Organization

Any organization that receives USG funds must establish and implement internal policies and practices that provide for the identification and effective DURC oversight when research is identified by a PI that uses one of the agents or toxins listed above. The organization must establish an IRE. An IRE may utilize already existing committee structures such as a committee established for dual use review, an existing committee like the IBC, or an externally administered committee. The IRE must:

- Be composed of at least five (5) members
- Be empowered by the organization to make decisions about DURC
- Be sufficiently knowledgeable about biosafety and biosecurity issues
- Have a range of life sciences expertise
- Have membership (at least one (1) person) that is familiar with the organization's procedures and policies

References

- National Science Advisory Board for Biosecurity (NSABB). 2010. "Enhancing Responsible Science: Considerations for the Development and Dissemination of Codes of Conduct for Dual Use Research."
- United States Government (USG). 2014. "**United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern**."

Embryonic Stem Cell Research Oversight (ESCRO) Committees

Before human embryonic stem (hES) cell research is conducted at NJIT, an Ad Hoc ESCRO Committee will be formed, in addition to other oversight committee(s), in order to ensure that NJIT follows federal bioethics policies and guidelines. Once hES cell lines have been derived, Principal Investigators (PIs) and the institution, through the ESCRO Committee and other relevant committees (such as an Institutional Animal Care and Use Committee (IACUC), an Institutional Biosafety Committee (IBC), or a radiation safety committee) should monitor their use in research. The National Academies assigns several responsibilities to **Embryonic Stem Cell Research Oversight (ESCRO) Committees** in its 2005 *Guidelines for Human Embryonic Stem Cell Research* to manage the ethical and legal concerns in hES cell research, which are as follows:

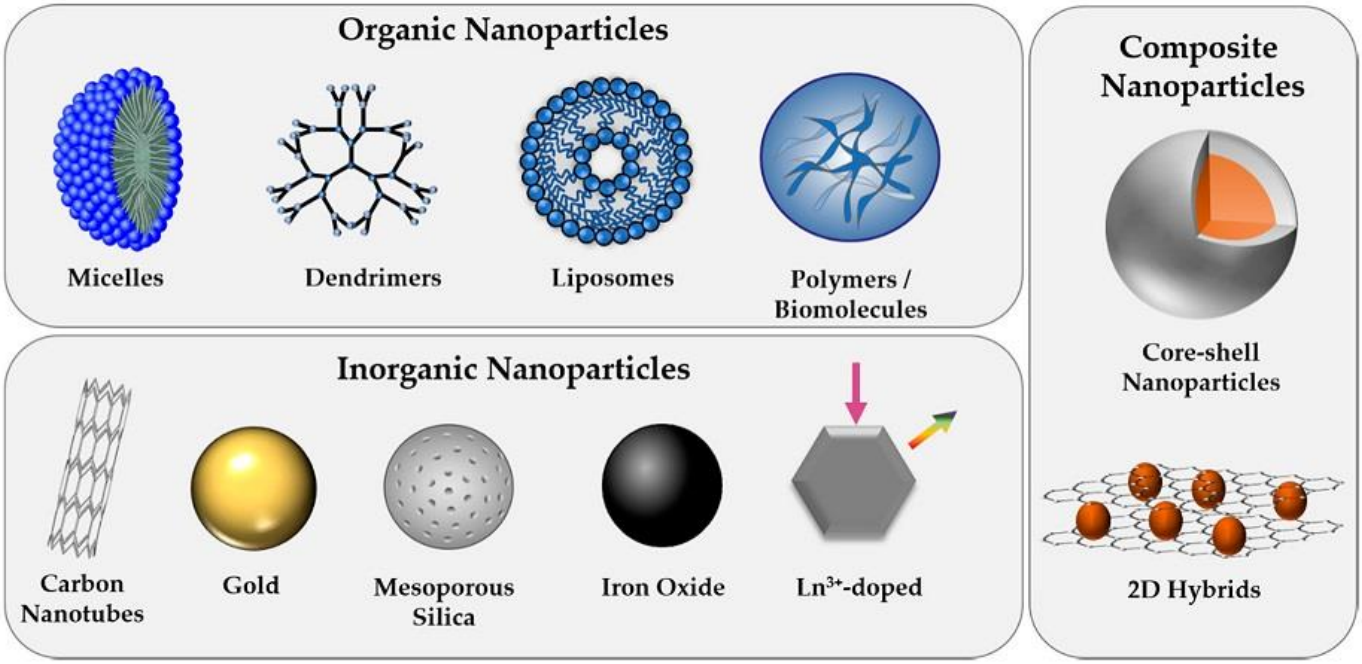
- provide oversight over all issues related to derivation and use of hES cell lines
- review and approve the scientific merit of research protocols
- review compliance of all in-house hES cell research with all relevant regulations and these guidelines
- maintain registries of hES cell research conducted at the institution and hES cell lines derived or imported by institutional PIs
- facilitate education of PIs involved in hES cell research.

References

- Guidelines for Human Embryonic Stem Cell Research
- 2007 Amendments to the National Academies' Guidelines for Human Embryonic Stem Cell Research

Nanotechnology

Nanoparticles are ultrafine particles with at least one dimension between 1 and 100 nanometers (nm) (NIOSH 2009). Therefore, the term “nanoparticle” is broad and can include diverse organic, inorganic, and composite (hybrids or nanocomposites) substances of many shapes and forms (Contera et al. 2020). For instance, organic nanoparticles may be composed of lipids, carbohydrates, or polymers. Inorganic nanoparticles may be composed of metals, ceramics, or oxides. Nanocomposites may be a combination of ceramics, polymers, and metal-based materials. The following graphic illustrates a few examples of organic, inorganic, and hybrid nanoparticles (Spirescu et al. 2021):



Risks to Human Health and the Environment

Nanotechnologies provide various benefits in medicine and other fields. However, they also present adverse effects and risks to human health and the environment. Uncertainties about the impact of nanotechnologies on the environment and human health arise from the novel properties of nanomaterials. Engineered nanoparticles are often built using a bottom-up approach (putting atoms or molecules together), which gives them unique physical-chemical composition and activity that results in different behaviors than their original parent form.

Toxicity and Biological Effects

Unlike naturally occurring or incidental nanoparticles, 40 to 50 percent of atoms in engineered nanoparticles are created on the surface. Therefore, they have greater reactivity and different biological effects such as the induction of reactive oxygen species. In a given volume, both engineered nanoparticles and environmental nanoparticles have high numbers and surface areas as compared to larger sized particles. When inhaled, both are capable of depositing in all parts of respiratory tract, but nanoparticles can enter then into subcellular structures by different mechanisms (Oberdorster 2010).

U.S. Regulations Concerning the Use of Nanoparticles

In the U.S., there is not a single set of regulations for nanotechnology. However, under the National Nanotechnology Initiative (NNI 2017) more than 30 "federal departments, independent agencies, and commissions work together toward the shared vision of a future in which the ability to understand and control matter at the nanoscale leads to ongoing revolutions in technology and industry that benefit society. The NNI enhances interagency coordination of nanotechnology research and development (R&D), supports a shared infrastructure, enables leveraging of resources while avoiding duplication, and establishes shared goals, priorities, and strategies that complement agency-specific missions and activities." The three main agencies that proactively address nanotechnology are the Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the National Institute for Occupational Safety and Health (NIOSH)

SOP for Nanoparticles

- Only trained personnel are allowed to access nanoparticle synthesis and use areas
- A limited number of personnel are allowed in the vicinity
- Assign hazard classes to all engineered nanomaterials according to the globally harmonized system for classifying and labeling chemicals for use in Safety Data Sheets (SDS's) (in keeping with the World Health Organization's [WHO 2017] recommendation)
- Store powder (dust) or an airborne spray form of nanomaterial samples and stocks in proper enclosures as they could be easily aerosolized and released into workplace
- Use disposable pads to handle products containing engineered nanomaterials
- Open containers with engineered nanomaterials under containment and keep them closed at all times except while in use

References

- Contera, Sonia, Jorge Bernardino de la Serna, and Teresa D. Tetley. 2020. "Biotechnology, nanotechnology and medicine." *Emerging Topics in Life Science* 4(6):551-4.
- The National Institute for Occupational Safety and Health (NIOSH). 2009. "**Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials**."
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VIII. Bloodborne Pathogen Standard (for Laboratories)

In 1991 OSHA promulgated Occupational Exposure to Bloodborne Pathogens, US Department of Labor, 29 CFR 1910.1030; commonly referred to as the Bloodborne Pathogen or BBP Standard. This standard is intended to protect employees by eliminating or minimizing occupational exposure to blood and other potentially infectious materials. The standard applies to all employees who may be reasonably anticipated to come into contact with blood or other potentially infectious materials during the performance of their assigned duties. The BBP standard requires that employers implement a written exposure control plan designed to eliminate or minimize potential employee exposure to blood, other body fluids, and other potentially infectious materials. One key component of the exposure control plan is the concept of **Universal Precautions**. This concept instructs employees to assume that all blood and certain other body fluids, no matter the source, are known to be contaminated with bloodborne pathogens and handled appropriately. The exposure control plan is the main component of an overall BBP Program that includes engineering controls, work practice controls, personal protective equipment, information and training, Hepatitis B vaccination, post exposure medical evaluation and follow-up, and hazard communication.

Application of the BBP Standard

The BBP Standard applies to all employees who may have reasonably anticipated contact with blood or other potentially infectious materials as a result of performing their normally assigned duties. Laboratories utilizing human-derived materials are required to adhere to applicable sections of the Bloodborne Pathogen Standard. These requirements are in addition to compliance with the NIH/CDC Guidelines (BMBL) or the NIH Guidelines for recombinant DNA. Included below is the text of the regulatory compliance letters written between the US Department of Labor and the President of the American Biosafety Association. These letters serve as the regulatory basis for including human materials, including cell lines, manipulated in academic research laboratories within the purview of the OSHA Bloodborne Pathogen Standard.

June 21, 1994 OSHA Standards Interpretation and Compliance Letters entitled "Applicability of 1910.1030 to Established Human Cell Lines"

> The Bloodborne Pathogens Standard (BPS) provides protection to employees who have occupational exposure to human blood or other potentially infectious materials (OPIM). Established human cell lines* which are characterized** to be free of contamination from human hepatitis viruses, human immunodeficiency viruses, and other recognized bloodborne pathogens, are not considered to be OPIM and are not covered by BPS. Established human or other animal cell lines which are known to be or likely infected/contaminated with human microbes or agents classed as bloodborne pathogens, especially hepatitis viruses and human immunodeficiency viruses are covered by the BPS. The final judgment for making the determination that human or other animal cell lines in culture are free of bloodborne pathogens must be made by a Bio-safety Professional or other qualified scientist with the background and experience to review such potential contamination and risk, in accordance with the requirements of the BPS. Documentation that such cell lines are not OPIM should be a matter of written record and on file with the employer for OSHA review.
>
> All primary human cell explants from tissues and subsequent in vitro passages of human tissue explant cultures (human cell "strains" ***) must be regarded as containing potential bloodborne pathogens and should be handled in accordance with the BPS. Non-transformed, human cell "strains", characterized by documented, reasonable laboratory testing as described in the attachment, to be free of human immunodeficiency virus, hepatitis viruses, or other bloodborne pathogens may be exempted from the standard's requirements. However, if such tissue explants or subsequent cultures are derived from human subjects known to carry bloodborne pathogens, such as hepatitis viruses or human immunodeficiency viruses or are deliberately infected with bloodborne pathogens, they must

be handled in accordance with the precautions noted in the BPS. Likewise, animal tissues, explants or cell cultures known to be contaminated by deliberate infection with human immunodeficiency virus or Hepatitis B virus are also subject to the BPS.

All laboratory work with primary human tissues or body fluids is covered by the BPS.

Definitions:

Human Cell Line*
A Human Cell Line is defined as **in vitro** or animal passaged (e.g., nude mouse) cultures or human cells that fulfill traditional requirements of a **cell line** designation. That is, the cells are **immortalized** cells, transformed by spontaneous mutation or natural or laboratory infection with an immortalizating agent such as Epstein-Barr virus (EBV). EBV is a bloodborne pathogen. It should be noted that human cervical carcinoma cells or other transformed human cell lines like HeLa cells are sometimes adulterated with laboratory pathogens accidentally introduced by cultivation with other cell cultures, or physically contaminated by other cell cultures handled in the same lab. In order to handle human HeLa cells, without having to comply with the requirements of the bloodborne pathogens standard (BPS), human HeLa cells should be documented to be pure HeLa cells and shown to be free of bloodborne pathogens by testing.

Characterization of Human Cells**
Characterization of human cells, for inclusion or exclusion from compliance with the BPS, would include screening of the cells lines or "strains" for viruses characterized as bloodborne pathogens by the Standard, including human immunodeficiency viruses, hepatitis viruses or EBV, if the cells are capable of propagating such viruses. Most cell lines are screened for human mycoplasmas and are free of bacterial and mycotic contaminants. Testing may include antigenic screening for viral or agent markers, co-cultivation with various indicator cells that allow contaminants to grow, or using molecular technology (polymerase chain reaction or nucleic acid hybridization) to identify latent viruses capable of infecting humans such as Herpes viruses (e.g., EBV), or papilloma members of the **Papovavirus group**, etc. Cell lines that are procured from commercial vendors or other sources with documented testing to be free of human bloodborne pathogens and which have been protected by the employer from environmental contamination may be excluded from the BPS.

Human Cell Strains***
Human cell strains are defined as cells propagated in vitro from primary explants of human tissue or body fluids which have finite lifetime (non-transformed) in tissue culture for 20-70 passages. Human cell "strains" must be handled as potential biohazards unless characterized by testing to be free of bloodborne pathogens (i.e., WI-38 cells are often so documented).

Exposure Determination
The following NJIT job classifications in which employees may have laboratory exposure to bloodborne pathogens include: Principal Investigators, post-doctoral fellows, graduate students, undergraduate students, and other laboratory workers who may be reasonably anticipated to come into contact with human-derived materials should be covered by the NJIT Bloodborne Pathogens Program.

Assignment of Responsibility
Administrative aspects of the NJIT Bloodborne Pathogens Program are under the direction of the NJIT Director of Environmental Health and Safety.

NJIT Laboratory Workers Shall:

- become familiar with the NJIT Exposure Control Plan;
- follow safe work practices as described in the Work Practice section of the Exposure Control Plan;
- be cognizant of the presence of potentially infectious materials in the laboratories in which they work;
- attend required training;
- wear appropriate personal protective equipment (PPE);
- maintain PPE in an acceptable manner;
- report all accidents, injuries, exposure incidents, and hazardous conditions to their supervisor;
- seek prompt treatment for work related injuries and exposures; and
- comply with other pertinent sections of the Exposure Control Plan.

The Bloodborne Pathogen Standard and the NJIT Biological Safety Guide
There are many aspects of the Bloodborne Pathogens Standard that are similar to laboratory biosafety issues which have been previously described in various sections of this guide. Previous sections of this guide have described:

- Transmission of Infectious Agents
- Laboratory Acquired Infections
- Personal Protective Equipment
- Gloves
- Protective Eyewear
- Face Masks
- Labcoats, Gowns and Aprons
- Cleaning, Disinfection, and Sterilization
- Sharps
- Housekeeping
- Handwashing
- Regulated Medical Waste Disposal
- Hazard Communication
- HIV and HBV Research Laboratories and Production Facilities

Since the above-mentioned subjects have been addressed in previous sections of this guide as they apply to potentially infectious microorganisms, recombinant DNA, viral vectors, human cell lines, long term cell culture, etc., there is no need to repeat these subjects in the BBP section of the guide.

However, where the BBP Standard has specific regulatory requirements beyond those biosafety criteria addressed by the CDC/NIH Guidelines (BMBL) and the NIH rDNA Guidelines; these requirements will be addressed in the subsequent sections of the guide.

Transmission of Bloodborne Pathogens
The BBP standard is principally concerned with eliminating or minimizing the occupational transmission of the Hepatitis B Virus (HBV) and the Human Immunodeficiency Virus (HIV). HIV and HBV are transmitted in a similar manner; by sexual contact, by needle sharing, and by perinatal transmission. In the workplace, however, both viruses have been transmitted only by contaminated needle stick, other contaminated puncture wound, and by contact of an open wound, non-intact skin, or mucous membrane with contaminated blood, body fluids, or concentrated virus. Blood is the most important source of HIV and HBV in the occupational setting. It may be reasonably anticipated that NJIT employees may come into contact with potentially

contaminated materials when performing laboratory manipulations involving human body fluids (see list below) or with potentially contaminated human-derived materials, e.g., human cell or tissue culture and human cell lines. Eliminating potential exposure incidents will be discussed in the Work Practice section of the Exposure Control Plan.

Environmental Survivability
One milliliter (ml) of blood from a person infected with HBV may contain more than 100 million infectious virus particles. In a dried state HBV may remain viable on work surfaces (e.g., laboratory bench or within a biosafety cabinet) for one week or longer. In contrast, one ml of blood from an individual infected with HIV may contain several hundred to 10,000 infectious viral particles. Experiments conducted by the Centers for Disease Control and Prevention (CDC) have shown that viral concentrations of HIV have been reduced by up to 99% by drying (air exposure) within several hours. The above data indicates that HBV is significantly hardier than HIV. Although the consequences of an HIV infection are obviously severe, occupational HBV exposure and infection are more common, easier to acquire, and harm more workers than occupational HIV infection.

Exposure Control Plan/Methods of Compliance

Universal Precautions
In 1993 the CDC introduced the concept of "Universal Blood and Body Fluid Precautions" (Universal Precautions) to be applied in the care of all patients and in the handling of blood and body fluid specimens. This approach is based on the concept that all patients, blood, and body fluid specimens are to be handled as if they are known to be infected with HIV, HBV, or other bloodborne pathogens. Universal Precautions require that adequate safeguards, e.g., barrier precautions, be taken to eliminate or minimize occupational exposure to blood and body fluids. The OSHA BBP standard requires the use of Universal Precautions in occupational settings where contact with blood or other body fluids may be reasonably anticipated.

Body Fluids to Which Universal Precautions Apply
Blood is the most important source of HIV, HBV, and other bloodborne pathogens in the occupational setting. Other body fluids, in addition to blood, and laboratory materials to which Universal Precautions apply include:

- semen,
- vaginal secretions,
- cerebrospinal fluid
- synovial fluid,
- pleural fluid,
- pericardial fluid,
- peritoneal fluid,
- amniotic fluid,
- saliva in dental procedures,
- any body fluid that is visibly contaminated with blood,
- all body fluids in situations where it is difficult to differentiate between body fluids,
- unfixed human primary tissue explants,
- HIV, HBV, HCV cell, tissue, and organ cultures,
- potentially contaminated culture media or other laboratory solution,
- blood, organs, or tissues from experimental animals infected with HIV, HBV, or HCV,
- human cell lines
- other potentially infectious material

Other Potentially Infectious Material (OPIM)
Other Potentially Infectious Material (OPIM) is a term commonly used to describe various materials that are not specifically included on the list of body fluids covered by the BBP, but may still be considered potentially infectious. Examples may include a bloody bandage encountered in a doctor's office or a contaminated paper towel used to clean up a spill of contaminated cell culture media, etc.

Body Fluids to Which Universal Precautions Do Not Apply
Unless visibly contaminated with blood, the following body fluids are not considered as potentially infectious materials under the BBP standard:

- saliva,
- urine,
- feces,
- vomit.

Field Settings
The handwashing requirements, described above, generally apply to clinical or laboratory settings which may be termed "housed settings". Handwashing requirements specified for housed settings are also desirable for field settings. If for any reason an NJIT employee requires handwashing facilities when none are available (for example when collecting field samples) the employee will utilize antiseptic towelettes or germicidal hand cream followed by the application of a moisturizing lotion. Clean cloths or paper towels may also be used. The employee will then wash their hands with soap and water at their first opportunity.

Hepatitis B Vaccination
Although the potential for occupational exposure to HBV is much higher than HIV, HBV infection is preventable by vaccination. A safe and effective vaccine to prevent HBV has been available since 1982. The original vaccine was plasma derived; made from the pooled sera of positive carriers. Currently, the vaccine most often used for protection against HBV is a genetically engineered yeast-based vaccine called Recombivax. Vaccines produced through recombinant DNA technology are termed subunit vaccines. There is no risk of infection with subunit vaccines. Typically, the hepatitis B vaccine protects 90% of those who receive it for approximately 7 years.

The Hepatitis B vaccine is available to all NJIT employees who may be reasonably anticipated to have contact with blood or other potentially infectious materials in the laboratory setting. The Director of the Environmental Health and Safety Department will ensure that all eligible NJIT employees are offered the hepatitis B vaccine at no cost to the employee.

The vaccine is to be given after eligible NJIT employees receive initial BBP training (described below) and sign the "Hepatitis B Vaccine Consent Form" but no later than one month from the consent date. The vaccine will be offered to new eligible NJIT employees within 10 days of the new assignment of duties with occupational exposure.

An eligible NJIT employee may decline the vaccine by signing the "Hepatitis B Vaccine Declination Form" An eligible NJIT employee who initially declined the vaccination may change their mind at any time and request the vaccination by signing the "Hepatitis B Vaccine Consent Form".

Work Practice Controls
Work practice controls refer to practices and procedures which reduce or eliminate the chance of occupational exposure to bloodborne pathogens. Examples of work practice controls include:

- Always wear the appropriate personal protective equipment for the task being performed.

- Always perform laboratory manipulations of potentially infectious materials with the potential to create aerosol droplets in a properly functioning and certified biological safety cabinet.

- When potentially infectious materials must be manipulated outside of a biological safety cabinet, always use Universal Precautions.

- Follow Biosafety Level 2 (BL-2) safeguards when handling blood, human body fluids, and human-derived materials (including human cell lines) in the laboratory.

- Wash hands promptly after removal of gloves, after performing laboratory procedures, prior to exiting a laboratory, and prior to eating and/or drinking.

- Do not eat, drink, smoke, apply lip balm or makeup, and handle contact lenses in areas where occupational exposure to blood or other potentially infectious material may occur.

- Never store food or drink in refrigerators, freezers, cabinets, or on shelves, countertops, and benchtops, where blood and other potentially infectious materials may be (or have been) present.

- Observe hazard warning signs and labels applied to all biological safety cabinets, laminar flow hoods, incubators, and other pieces of laboratory equipment where blood and other potentially infectious materials may be (or have been).

- Ensure that all laboratory equipment that was used to store or manipulate blood or other potentially infectious material is appropriately surface decontaminated prior to servicing.

- Promptly decontaminate any work surface or equipment following exposure to blood or other potentially infectious material.

Handling of Sharps

Contaminated sharps such as needles, scalpel blades, broken test tubes, Pasteur pipettes, and other sharp instruments present the greatest risk of transmission of bloodborne pathogens in the laboratory. Disposable syringes, scalpel blades, and other sharp items should be deposited into an appropriate leak-proof, puncture-resistant, and labeled sharps container immediately after use. Disposable needles should never be recapped, bent, broken, sheared, or removed from disposable syringes.

Sharp items should be deposited directly into the sharps container immediately following use. Full sharps containers should be disposed as Regulated Medical Waste.

Sharps containers should be located in all work locations where it is reasonably anticipated that sharps may be used. Sharps containers should only be filled to within one inch of the top of the container. Sharps containers should never be overfilled. Never attempt to force additional material into a full container.

Wherever possible the use of sharps should be eliminated or minimized from protocols involving blood, human body fluids, and human-derived materials (including human cell lines) in the laboratory. When sharp use is essential great care must be used to handle sharps carefully to reduce the chance of occupational exposure.

Needle Stick and Mucous Membrane Exposure Policy
A needle stick may be defined as a skin puncture with a needle or other sharp object that has been used to inject a patient, draw blood from a patient, or penetrate a patient's skin or mucous membrane. Alternatively, a needle stick may be defined as a skin puncture with a needle or other sharp object that has been used to manipulate blood or other potentially infectious material in the laboratory or other setting. Needle sticks with an unused sterile needle or needles used to draw up medications are not considered needle sticks in the context of the Bloodborne Pathogen Standard; however, needle sticks of this type should be reported to the employee's supervisor. A mucous membrane exposure may be defined as a splash, spray, or aerosolization of blood or other potentially infectious material that comes into direct contact with an employee's eyes, nose, or mouth or penetrates an employee's open wound or sore.

In the event that an NJIT employee sustains:

- a needle stick, cut, or puncture wound involving a piece of potentially contaminated laboratory equipment;
- a splash of blood or other potentially infectious material to the face;
- contact with blood or other potentially infectious material to an open wound, sore, or non-intact skin the following procedures shall be followed:

Employee

- Incidents or injuries that require medical attention must be addressed immediately. Typically, all laboratory incidents are reported to the NJIT Public Safety Department by calling 3111 or 911 from an NJIT phone or 973-596-3111 from a non-NJIT phone. In extreme situations NJIT employees may be required to dial 911 or report to a local hospital emergency room for medical attention.

- Immediately clean the exposed area. The skin should be thoroughly washed with soap and running water. Vigorous scrubbing should be avoided as this may damage the skin and increase the chance of disease transmission. Exposed mucous membranes should be thoroughly rinsed with copious amounts of running water.

- Immediately after cleaning the exposed area, the affected employee will contact their laboratory manager (usually the Principal Investigator) and report the incident. All information concerning the exposure incident should be reported.

- At their earliest opportunity, the affected employee will complete an NJIT Incident Report Form. Information will be reported in a complete and honest manner. All information concerning the exposure incident, the location where the exposure occurred, the nature of the exposure, should be included in the incident report. This information will assist NJIT administrators to determine the root cause(s) of the incident and determine if additional safeguards or procedures need to be established.

- Following an exposure incident where an NJIT employee is required to receive medical attention at a local hospital emergency room or other medical provider, NJIT management may require the employee to report to a specified health care provider for medical evaluation and follow-up.

Laboratory Supervisor

- Assure that injured employee receives appropriate emergency medical attention.
- Assure proper protocol is followed while maintaining appropriate medical confidentiality.
- Alert NJIT management of the incident as well as the need for individual counseling, if applicable.
- Assure that injured employee promptly presents to the specified NJIT health care provider for medical evaluation and follow up.
- Provide a description of the exposed employee's duties as they relate to the exposure incident to the specified NJIT health care provider. The BBP Standard also requires that a copy of the BBP Standard is provided to the health care provider performing the evaluation. The NJIT Director of Environmental Health and Safety, or other administrative official, may have already provided the BBP Standard to the specified health care provider.
- Document the route(s) of exposure and circumstances under which the exposure occurred and provide that information to the specified NJIT health care provider.
- Complete the NJIT Incident Report Form and submit to NJIT management within 24 hours of the incident.
- Since much of the same information is required by the specified health care provider and NJIT management, it is prudent that a copy of the completed Injury and Incident Report Form accompany the affected employee when they present to the specified health care provider for medical evaluation and follow-up.

Specified Health Care Provider

- Assure confidentiality of all medical information.
- Inspect contact site of exposed employee and ensures that proper immediate care was provided.
- If applicable, counsel source patient/individual and obtains informed consent for HIV antibody testing and authorization for the use of confidential HIV related information.
- Provide post-test counseling for exposed employee, if applicable.
- Provide the exposed employee with a confidential medical evaluation and follow-up that includes:
    - Documentation of source individual's HIV and HBV status as determined by serological testing, if applicable.
    - Review of all medical records, including vaccination status, relevant to the appropriate treatment of the exposed employee.
    - Collection and testing of the exposed employee's blood for serological status.

    - Provide post-exposure prophylaxis, when necessary, as recommended by the U.S. Public Health Service.

    - Advise employee with respect to medical risks, treatment options, vaccination status, and results of medical evaluation and serological testing.

- Provide NJIT management with a written opinion. NJIT management is responsible to provide the affected employee with a copy of the written opinion within 15 days of the completion of the evaluation.

- The written opinion shall be limited to whether the HBV vaccine is indicated for the affected employee and if the employee has received the HBV vaccination.

- Information in the written opinion concerning post-exposure evaluation and follow-up shall be limited to a statement that the employee has been informed of the results of the evaluation. Also, that the employee has been informed of any medical conditions resulting from exposure to blood or other potentially infectious material that require further evaluation or treatment. All other finding or diagnoses shall remain confidential and not be included in the written report.

- Provide the unit supervisor with documentation that the exposed employee has been evaluated and that the appropriate treatment and follow up has been offered.

Training

NJIT employees who are reasonably anticipated to come into contact with blood or other potentially infectious material will participate in a training program provided at no cost to the employee and conducted during normal working hours. The purpose of the training is to alert employees of the potential hazards posed by bloodborne pathogens and to assist employees in eliminating or minimizing occupational exposure to bloodborne pathogens in their work environment. Training will be offered to eligible NJIT employees initially and upon assignment to new duties in which exposure to blood or other potentially infectious material may be reasonably anticipated. Refresher training will be offered to all eligible employees on an annual basis. At the end of a Bloodborne Pathogen training session an employee will be able to:

- Obtain a copy of the NJIT Biosafety Guide including the Exposure Control Plan and the BBP Standard's regulatory text.

- Define bloodborne pathogen, and cite examples.

- Understand modes of transmission of bloodborne pathogens as well as basic symptoms of bloodborne diseases.

- Identify tasks and situations that may involve exposure to blood or other potentially infectious material.

- Take measures to eliminate, minimize, or reduce exposure to blood or other potentially infectious material by using appropriate administrative and work practice controls and personal protective equipment.

- Recognize the benefits of the Hepatitis B vaccination for employees who have potential exposure to blood and other potentially infectious materials. Additionally, employees will know how to obtain the HBV vaccination, understand information regarding its safety, efficacy, method of administration, and that it is offered at no cost.

- Take appropriate measures in response to an exposure incident or other contact involving blood or other potentially infectious materials. Additionally, employees will understand the post-exposure medical evaluation and follow-up required after an exposure incident.

- Recognize the biohazard symbol as well as other signs and labels pertinent to this standard and understand their appropriate use.

Recordkeeping
The Bloodborne Pathogen Standard requires that employers maintain medical records and training records for all eligible employees.

Medical Records
NJIT will establish and maintain a medical record for each eligible employee. The Administrative Safety Officer will maintain medical records for the duration of the employee's employment plus 30 years in a confidential manner. Medical records will not be disclosed or reported without the employee's written permission to any person within or outside of NJIT. However, medical records may be made available, upon request, to the Assistant Secretary of Labor, U.S. Department of Labor. Medical records will include at least the following:

- Employee's name, social security number, and job title.

- The employee's HBV vaccination status including the dates of all vaccinations and all medical records relative to the employee's ability to receive the vaccine.

- Results of medical examinations, medical testing, and post-exposure evaluation and follow-up.

- The employer's copy of the healthcare professional's written opinion limited to the information described above.

- A copy of the information provided to the healthcare professional.

Training Records
NJIT will maintain training records relative to the training requirements of the Bloodborne Pathogen Standard. Training records will be maintained for three years from the date the training occurred. Training records may be made available, upon request, to the Assistant Secretary of Labor, U.S. Department of Labor, or an authorized representative. Training records will include:

- The employee's name and job title.

- Dates and summaries of the training sessions.

- Names and qualifications of persons conducting training.

Transfer of Records
In the event that NJIT ceases to do business, and there is no successor employer to receive and retain the above described medical and training records, in the prescribed time period, NJIT may be required to transmit the records to an appropriate government agency. In this event NJIT will notify the NIOSH Director, or designated representative, at least three months prior to cessation of company activities and transmit the training records if required by the Director to do so.

New Jersey Institute of Technology
Laboratory Specific Exposure Control Plan (ECP) Summary

The New Jersey Institute of Technology's Exposure Control Plan (ECP) has been developed in compliance with 29 CFR 1910.1030; the OSHA Bloodborne Pathogens Standard. The ECP is intended to establish policies, practices, and procedures that minimize or eliminate occupational exposure to potentially infectious materials among NJIT employees. Acknowledging that the OSHA Bloodborne Pathogens standard (and the written ECP required by the standard) are generic in nature, NJIT has developed the following Laboratory Specific ECP to document specific policies and procedures of each laboratory group.

Please enter the required information in the spaces below. The Laboratory Specific ECP should be updated on an annual basis or whenever required (e.g., new hire, new laboratory protocol).

Laboratory Group/Department:

Supervisor/Director/Principal Investigator:

Location: Date:

Eligible Employee Listing: In the space below please list the names, titles, and assigned duties of all eligible employees in this laboratory/work location. Eligible employees include those who may be reasonably anticipated to come into contact with human-derived materials including human blood or other potentially infectious materials (OPIM) as a result of performing their job duties.

Employee Name	Title	Assigned Duties

Engineering Controls: In the space below please list all engineering controls in use in this laboratory/work location that serve to eliminate or minimize occupational exposure to human-derived materials including human blood or OPIM. Engineering controls are mechanical devices serve to create a barrier between a worker and a potential hazard.

Engineering Control	Nature of Potential Hazard

Work Practice Controls: In the space below please list the work practice controls in use in this laboratory/work location that serve to eliminate or minimize occupational exposure to human blood or OPIM. Work practice controls are policies and procedures put into place to help eliminate or minimize occupational exposure to human blood or OPIM. Please use general categories (e.g., proper control of sharps, universal precautions, adhering to aerosol minimization techniques) rather than listing each individual work rule except those work rules that may be unique to this particular setting.

Work Practice Control	Nature of Potential Hazard

Personal Protective Equipment: In the space below, please list all personal protective equipment (PPE) issued to employees in this laboratory/work location that serve to protect workers from occupational exposure to human blood and OPIM. Please be specific when describing the type of PPE (e.g., disposable non-sterile nitrile exam gloves, cloth lab coat, disposable Tyvek lab coat, safety glasses with side shields).

Personal Protective Equipment	Nature of Potential Hazard

Cleaning, Disinfection, and Sterilization: In the space below, please list and describe the frequency and method of cleaning, disinfection, and sterilization in this laboratory/work location.

Work Surfaces:

Item (e.g., bench, hood)	Disinfectant	Frequency	Method

Personal Protective Equipment:

Item (e.g., safety glasses, reusable gloves)	Disinfectant	Frequency	Method

Waste Materials:

Item (e.g., sharp containers, medical waste)	Disinfectant	Frequency	Method

Reusable Instruments, Equipment, Other:

Item	Disinfectant	Frequency	Method

Emergency Response: In the space below please list and note the location of all emergency response equipment on hand in this laboratory/work location (and in adjacent locations that may be used) to safely and effectively clean and decontaminate a spill of human-derived materials including human blood or OPIM.

Emergency Equipment	Location	Intended Use

Emergency Contact Information: In the space below please list the applicable emergency contacts for this laboratory/work location.

Emergency Contact	Daytime Phone Number(s)	Off-Hour Phone Number(s)
Lab/Department Director		
NJIT Safety Officer		
Public Safety		
Fire		
Ambulance		
Other		

Appendices

Appendix I	Registration Documents for Biohazards
Appendix II	Classification of Human Etiological Agents on the Basis of Hazard
Appendix III	Characteristics of Common Laboratory Disinfectants (Excerpted from the World Health Organization's Laboratory Biosafety Manual, Third Edition, Geneva, 2004)
Appendix IV	Biological Waste Management
Appendix V	29 CFR 1910.1030; OSHA Bloodborne Pathogen Standard

Appendix I

Registration Document for Biohazards

Amendment Form for Previously Approved Biohazard Protocol

Protocol #:

Registration Document For Biohazards

All applicants are required to complete the following sections:

- Principal Investigator Information
- Location of Study
- Section A: General Administrative Information
- Section B: Material Use Checklist and Risk Assessment
- Section H: Transport
- Section I: Dual Use Research of Concern
- Section J: Protocol Specific Laboratory Safety

In addition to the sections above, please complete the appropriate protocol-specific sections:

- Section C: Exempt Recombinant DNA Experiments
- Section D: Non-Exempt Recombinant DNA Experiments
- Section E: Research with Potentially Infectious Biological Agents
- Section F: Human and Non-human Primate Blood, Body Fluids, Cell Lines, and Tissue Explants
- Section G: Toxins of Biological Origin

P.I Information

Name:	Title:
Department:	Email:
Phone Number:	

Location of Study

Building:	Room #'s:
Are the facilities shared: ☐ Yes ☐ No	If yes, with what group:
Date of study:	

Section A: General/Administrative Information

Protocol Title:	
PI's Anticipated Biosafety Level:	

Brief Description of Protocol (please describe experimental protocol including how the biological material will be utilized in the laboratory, attach additional sheet if necessary):

Section B. Material Use Checklist and Risk Assessment

Please check the materials that are used in your lab then complete the specified section for each material.

1) Recombinant DNA: Genetic manipulation of microorganisms including inserting or deleting genes, use of viral vectors, development of human gene therapy, experiments involving siRNA, development of synthetic DNA constructs, etc.	
☐	Recombinant DNA, gene transfer and/or host vector systems
☐	Use of transgenic animals (including knockouts, knock ins, crossbreeding of two different transgenic strains)
☐	Use of transgenic plants
☐	Complete Section C for Exempt rDNA Experiments
☐	Complete Section D for Non-Exempt rDNA Experiments
2) Microorganisms/Potentially Infectious Agents:	
☐	Bacteria
☐	Virus
☐	Yeast and other Fungi
☐	Prions and/or Parasitic Agents
☐	Complete Section E for Potentially Infectious Biological Agents
☐	Complete Section E for Host Organisms Listed in Section B and C (Above)
3) Human/Non-Human Primate Derived Materials, Blood, Body Fluids, and Cell Lines:	
☐	Human cell lines including established human cell lines from commercial sources
☐	Primary human tissue explants
☐	Non-Human primate cell lines
☐	Primary non-human primate tissue explants
☐	Human and/or non-human primate blood, body fluids
☐	Complete Section F for human and non-human primate cell lines, tissue explants, and body fluids
4) Other:	
☐	Biological Toxins - NOT Select Agents (please complete section G)
☐	CDC/APHIS Select Agents
☐	Human Subjects - Embryonic Stem Cells
☐	Human Subject Research - Other
☐	Vertebrate Animal
☐	Non-Viral Delivery Systems (nanoparticles, liposomes, etc.)

Section B. Material Use Checklist and Risk Assessment (Continued)

Please check the materials that are used in your lab then complete the specified section for each material

5) Risk Assessment: Please describe the risk assessment process and how the appropriate biosafety precautions were determined for this protocol.

Describe the potential risk posed by the organism, vector, product, genetic insert, toxin, cell line, product, or material:

Describe the potential risk posed by the laboratory manipulations and procedures that are to be performed (will aerosols or droplets be generated, will sharps be utilized, are large volumes of culture involved, etc.):

Describe the laboratory equipment and facilities utilized to mitigate the risk described above:

Describe the training, proficiency, and experience of the laboratory director, staff, and students in performing experimental procedures with a similar risk potential:

Describe the supervision and oversight provided by the laboratory director to assure adherence to safety guidelines:

Describe the safety literature consulted, search terms used, and risk assessment process:

☐	rDNA Guidelines	☐	CDC-NIH Guidelines
☐	OSHA BBP Standard	☐	NJIT Safety Literature
☐	PubMed Search, Search Terms:	☐	CDC-NIH Guidelines
☐	rDNA Guidelines	☐	NJIT Safety Literature
☐	Other (*describe*):		

Section B. Material Use Checklist and Risk Assessment (Continued)

Please check the materials that are used in your lab then complete the specified section for each material

6) Protocol Specific Laboratory Safety: Please complete Section J for all protocols submitted to the Biosafety Committee for consideration.

Principal Investigator Acknowledgement:

By signing below, the Principal Investigator acknowledges that the laboratory workers (including students, faculty, staff or visitors) under his or her direction have received appropriate training required to manipulate, store, and disinfect the microorganisms, human-derived materials, recombinant or other materials proposed for use in the following protocol. Further, laboratory workers have been instructed on emergency procedures involving potentially infectious materials as outlined in the NJIT Biological Safety Guide.

Principal Investigator:_____ Date: _____

Biosafety Committee Action:

This protocol was reviewed by the NJIT Institutional Biosafety Committee on:_____
The following IBC action was taken:

☐	Protocol Approved
☐	Protocol Withdrawn
☐	Protocol Conditionally Approved
☐	Protocol Tabled Until Next Meeting
☐	Protocol Not Approved

Protocol Approved By:	
Assigned Biosafety Level:	
Signature:	

Section C: Exempt Recombinant DNA Experiments

(please check those sections of the NIH Guidelines under which your experiments are exempt)

☐	**Section III-F-1**. Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of Section III-C, it is not exempt under this Section.
☐	**Section III-F-2**. Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.
☐	**Section III-F-3**. Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.
☐	**Section III-F-4**. Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another
☐	**Section III-F-5**. Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
☐	**Section III-F-6**. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV-C-1-b-(1)-(c), Major Actions). See Appendices A-I through A-VI, Exemptions under Section III-F-6--Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the NIH Guidelines.
☐	**Section III-F-7**. Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.
☐	**Section III-F-8**. Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment.
☐	**Appendix C-VII**. The Purchase or Transfer of Transgenic Rodents
☐	**Appendix C-VIII**. Generation of BL1 Transgenic Rodents via Breeding The breeding of two different transgenic rodents or the breeding of a transgenic rodent and a non-transgenic rodent with the intent of creating a new strain of transgenic rodent that can be housed at BL1 containment will be exempt from the NIH Guidelines if: (1) both parental rodents can be housed under BL1 containment; and) neither parental transgenic rodent contains the following genetic modifications: (i) incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or (ii) incorporation of a transgene that is under the control of a gamma retroviral long terminal repeat (LTR); and) The transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses.

Section C: Exempt Recombinant DNA Experiments (continued)

(please check those sections of the NIH Guidelines under which your experiments are exempt

Most experiments involving E. coli K-12 host vector systems and *Saccharomyces cerevisiae* and *Saccharomyces uvarum* host vector systems are exempt from the NIH Guidelines. If the answer to all 3 of the following questions are no, then the experiments are exempt according to Appendix C-II (for *E. coli* K-12) or Appendix C-III (for *Saccharomyces cerevisiae and Saccharomyces uvarum*).

Yes	No	*Please check yes or no for the following questions*
☐	☐	Do any experiments involve Risk Groups 3, 4 or restricted organisms or nucleic acids from Risk Groups 3, 4 or restricted organisms?
☐	☐	Do any experiments involve introduction of genes coding for molecules toxic for vertebrates?
☐	☐	Will there be any large-scale experiments (more than 10 liters of culture)?

Please include only information regarding **Exempt** rDNA experiments in the tables below.

#	**Host (s)** Indicate the host(s) into which the recombinant material (rDNA, RNA, virus) will be introduced. Examples include: *E. coli, S. cerevisiae*, human/animal cells, whole animals, plants.	**Species** Subspecies, variety, serotype, strain.	**Vectors** Which host-vector system will be used for this research? Examples include: bacterial plasmids, yeast plasmids, cultured cell plasmid vectors, baculovirus, AAV, other viral vectors	**DNA Sequence** List names of genes or DNA segments that will be evaluated	**Proteins** List proteins produced if applicable
#1					
#2					
#3					
#4					
#5					
#6					

Yes	No	*Please check yes or no for the following questions*
☐	☐	Will an attempt be made to purify any of the foreign gene products encoded by the gene?
☐	☐	Will a virus-derived vector system that is engineered to be replication-incompetent be used?

Revision Date: 01/19/2022

Section D: Non-Exempt Recombinant DNA Experiments

This section describes experiments covered by the NIH Guidelines. Check the appropriate registration category(s) for your experiment.

Experiments that require IBC approval BEFORE initiation:	
☐	**Section III-D-1-a**. Introduction of recombinant or synthetic nucleic acid molecules into risk group 2 agents
☐	**Section III-D-2-a**. Introduction of DNA from risk group 2 (or 3) agents into non-pathogenic bacteria or lower eukaryotes
☐	**Section III-D-3-a**. Use of infectious risk group 2 virus (or defective virus plus helper virus) in tissue culture systems
☐	**Section III-D-3-e**. Use of infectious risk group 1 virus (or defective virus plus helper virus) in tissue culture systems
☐	**Section III-D-4-a**. Transfer of recombinant or synthetic nucleic acid molecules EXCEPT for >2/3 of eukaryotic viral genomes into any non-human vertebrate or invertebrate organism
☐	**Section III-D-4-b**. Transfer of recombinant or synthetic nucleic acid molecules from risk group 2 (or higher risk group) human or animal pathogens into whole animals
Experiments that require IBC notification CONCURRENT WITH initiation:	
☐	**Section III-E-1**. Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any eukaryotic virus
☐	**Section III-E-2**. All components derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes
☐	**Section III-E-3**. Experiments involving transgenic rodents
Some experiments require additional review/approval by NIH OBA before initiation:	
☐	**Section III-A-1-a**. Transfer of a drug resistant gene into microorganisms that do not acquire the gene naturally that could compromise use of the drug to control disease in humans, veterinary medicine or agriculture
☐	**Section III-B-1**. Cloning of genes for toxins with LD50 of > 10 ng/kg body weight

If your non-exempt research does not fall into any of the categories listed above, review Section III of the NIH Guidelines and use the space below to provide a brief description of the research and the appropriate NIH Guidelines referenced.

Section of the NIH Guidelines:	
Description:	

Section D: Non-Exempt Recombinant DNA Experiments (Continued)

Generation and Use of rDNA

Complete this section if you are generating and/or using non-exempt rDNA in your laboratory.

Answer questions 1-8 for EACH host-vector system.

Transgene

1. Describe the gene sequence(s) inserted into the recombinant vector:

a. Source of gene(s) (genus/species):

b. Do any of the gene sequences increase oncogenic potential, originate from an HHS or USDA select agent or toxin, transfer a drug resistance trait that has the potential to compromise the use of the drug to control disease or have the potential to increase the pathogenicity or virulence of a vector system?

☐ No

☐ Yes, explain below:

c. Describe the function and activity of the transgene(s):

If you are planning on using an extensive number of transgenes, list classes.

If you are using a genome-wide approach, indicate the components of the constructs in the library or libraries.

2. If any of the above genes are from a viral source, do they compromise more than 2/3 of the viral genome?

☐ No

☐ Yes, specify:

3. Will a deliberate attempt be made to obtain expression of the foreign gene encoded in the recombinant DNA or RNA?

☐ No

☐ Yes

4. Identify vector system – Please check appropriate boxes below and describe host-vector systems:

☐ Bacterial Plasmid

☐ Adeno-Associated Virus

☐ Adenovirus

☐ Simple Retrovirus

☐ Lentivirus

☐ Viruses other than lentivirus, simple retrovirus, adenovirus or adeno-associated virus
Describe:

☐ Non-Viral Delivery Systems (nanoparticles, liposomes, other):

Section D: Non-Exempt Recombinant DNA Experiments (Continued)

5. List host cell line or packaging cells for recombinant vector propagation:

6. Viral vector system(s)	
a. What % of the viral genome remains?	
b. Is a helper virus required for replication?	
☐	No
☐	Yes

7. Target Recipient(s) - Indicate the recipient(s) of the DNA (check all that apply):	
☐	Bacterial Cells
☐	Animal Cells in Culture
☐	Animals
☐	Modified Tissue Culture Cell Lines into Animals
☐	Plant Cells
☐	Plants
☐	DNA Vaccine, specify target recipient(s)

8. Investigators assessment of risk – This work will be conducted at (check appropriate biosafety level):	
☐	Biosafety Level 1
☐	Biosafety Level 2

Please fill out a separate section D for each additional non-exempt host-vector system used in the lab

Section E: Research with Potentially Infectious Biological Agents

Complete this section if you are working with an agent that could cause an infection in humans, including opportunistic infections. Provide the information requested below for each agent.

Please check yes or no for each question		Yes	No	Please Provide Details Below
1.	Name of agent (include genus, species, sub-species, strain, etc.):	☐	☐	
2.	Will antibiotic resistance be expressed?	☐	☐	
3.	Will toxin be produced?	☐	☐	
4.	Largest volume of agent to be cultured?	☐	☐	
5.	Will agent be concentrated?	☐	☐	
6.	If agent is to be concentrated, how will it be concentrated?	☐	☐	
7.	How frequently will agent be manipulated?	☐	☐	
8.	How will agent be inactivated?	☐	☐	
	a. heat	☐	☐	
	b. chemical	☐	☐	
	c. other (list):	☐	☐	
9.	Will agent be introduced into animals?	☐	☐	
10.	Have all personnel that will be handling this agent received appropriate biosafety training?	☐	☐	

Please fill out a separate section E for each additional potentially infectious agent used in the lab.

Section F: Human and Non-human Primate Blood, Body Fluids, Cell Lines, and Tissue Explants

Identify the type and source of the materials to be used:

1. Samples to be manipulated (for human or non-human primate cells lines, indicate if cells are established or primary):
2. Source of samples:
3. If commercially obtained, please list vendor and specific cell lines:
4. Have all personnel who work with human material completed the appropriate Biological Safety/Bloodborne Pathogens training program (please answer below and complete section J)?
5. Is laboratory equipped with biological safety cabinet or other containment equipment to safely manipulate these materials (please answer below and complete section J)?

Section G: Toxins of Biological Origin

Complete this section if you are working with a toxin of biological origin. Provide the information requested below for each toxin.

1. Name of toxin(s):
2. Largest quantity in use and stored:
3. Describe how the toxin is stored:
4. Describe the toxin deactivation and disposal procedures:
5. At what Biosafety Level is this material to be handled:

Please fill out a separate section G for each additional toxin used in the lab.

Section H: Transportation/Shipping (includes 'hand-carrying' specimens)

If you are involved in shipping hazardous materials and/or dangerous goods please contact the EHS department at 973-596-3059 or at healthandsafety@njit.edu

Will materials be transported outside of the laboratory in which they are being used? (*please check one*)	☐	Yes	☐	No

Please describe the nature of the materials to be transported

Describe:

Please describe the proposed method of transport

Describe:

Section I: Dual Use Research of Concern

Complete this section to determine if your research is considered dual use research of concern—research that may be used for beneficent goals as well as malevolent purposes

1. Please check any categories below that apply to your research	
☐	Increase in virulence of the pathogen
☐	Production of a novel toxin
☐	Enhance transmissibility of the pathogen
☐	Alteration of the pathogen's host range
☐	Interfere, by-pass or diminish the effectiveness of diagnostic tools and therapeutic or prophylactic antimicrobial or antiviral treatments
☐	Enhance capacity for spreading or for easy release of making them weapons-grade
☐	Not Applicable

2. Please describe how your research fits any of the above category

3. Please identify and address additional risks to employees, the environment and/or public health that this research could present

Section J: Protocol Specific Laboratory Safety

1. Personnel and Training

Please list all laboratory personnel involved in this protocol and indicate the dates of the required training. If training has not yet been scheduled, please indicate pending or TBD.

Name	Title	Date of Biosafety Training	Date of BBP Training	Other Protocol Specific Training

2. Laboratory Inspection

Please list date of last laboratory Inspection conducted by the EHS Department. If your lab has not been inspected, please contact EHS at 973-596-3059 or at healthandsafety@njit.edu

Building	Department	Room Numbers	Date of Inspection	Approved Biosafety Level

Section J: Protocol Specific Laboratory Safety (Continued)

3. Containment and Safety Equipment

Please list type and location of containment equipment (e.g., biological safety cabinet) and date of last certification. Please note if Biological Safety Cabinet is shared with other groups.

Containment Equipment	Location	Type/Class	Certification Date
Biological Safety Cabinet			
Biological Safety Cabinet			
Other Laminar Flow Device			
Centrifuge with Safety Caps and Sealed Rotors			
Splash Guard			
Other:			

4. Equipment and Surface Decontamination

Please list the decontamination solution used, concentration, and frequency for various laboratory equipment and work surfaces.

Equipment and/or Work Surfaces	Decontamination Solution	Concentration	Frequency
Biological Safety Cabinet			
Laboratory Bench			
Mechanical Pipetter			
Reusable Safety Equipment			
Other:			

Section J: Protocol Specific Laboratory Safety (Continued)

5. Spill Control
Please describe available laboratory spill control equipment and procedures used for biological spills

6. Waste Decontamination
Please describe how potentially contaminated laboratory waste, both liquid and solid, is decontaminated and subsequently disposed. Please note location of autoclave if one is available for waste decontamination.

7. Control of Sharps:
Please describe how sharps are handled in the lab. Is an attempt made to limit the use of sharps when working with potentially infectious materials?

NJIT New Jersey Institute of Technology

Previously Approved Protocol #:

Amendment to Registration Document For Biohazards

Section A: P.I. Information

Name:	Title:
Department:	Email:
Phone Number:	

Location of Study

Building:	Room #'s:
Are the facilities shared: ☐ Yes ☐ No	If yes, with what group:
Date of study:	

Section B: General/Administrative Information

Protocol Title:	
PI's Anticipated Biosafety Level:	

Brief Description of Protocol (please describe experimental protocol including how the biological material will be utilized in the laboratory, attach additional sheet if necessary):

Section C: Biohazard Registration Amendment

Please check all that apply and describe the nature of the requested amendment in the spaces below and complete the Principal Investigator Acknowledgement section

Please check all that apply

☐	**Addition of Exempt Recombinant DNA Experiments**	☐	**Addition of Non-Exempt Recombinant DNA Experiments**
☐	**Addition of Research with Potentially Infections Biological Agents**	☐	**Addition of Human and Non-human Primate Blood, Body Fluids, Cell Lines, and Tissue Explants**
☐	**Addition of Toxins of Biological Origin**	☐	**Addition of new laboratory workers**
☐	**Addition of Viral Vector**	☐	**Other Addition**

For all recombinant DNA protocols be sure to list specific host cells (genus and species), vectors, DNA sequences (gene of interest), and commercial and non-commercial sources for all recombinant materials.

Describe:

Host(s) Indicate the host(s) intowhich the recombinant material (rDNA, RNA, virus) will be introduced. Examples include: E. coli, S. cerevisiae, human/animal cells, whole animals, plants	**Species** Subspecies, variety, serotype, strain	**Vectors** Which host-vector system will be used for this research? Examples include: bacterial plasmids, yeast plasmids, cultured cell plasmid vectors, baculovirus, AAV, other viral vectors	**DNA Sequence** List names of genes or DNA segments that will be evaluated	**Proteins** List proteins produced if applicable

For all biological agents, human and non-human blood, body fluids, cell lines, and tissue explants besure to describe material in detail including specific cell lines (if applicable), product numbers, commercial and non-commercial sources, and how material will be used.
Describe:

For all protocols, describe if the amendment changes any protocol-specific laboratory safety issues described in the original protocol. A statement regarding containment, training, lab members, lab safety practices, decontamination and disposal should be included.
Describe:

Section D: Principal Investigator Acknowledgement:

By signing below, the Principal Investigator acknowledges that the laboratory workers (including students, faculty, staff or visitors) under his or her direction have received appropriate training required to manipulate, store, and disinfect the microorganisms, human-derived materials, recombinant or other materials proposed for use in the following protocol. Further, laboratory workers have been instructed on emergency procedures involving potentially infectious materials as outlined in the NJIT Biological Safety Guide.

Principal Investigator:_____ Date:_____

Biosafety Committee Action:

This protocol was reviewed by the NJIT Institutional Biosafety Committee on:_____
The following IBC action was taken:

☐	Protocol Approved
☐	Protocol Withdrawn
☐	Protocol Conditionally Approved
☐	Protocol Tabled Until Next Meeting
☐	Protocol Not Approved

Protocol Approved By:	
Assigned Biosafety Level:	
Signature:	

Appendix II

Classification of Etiological Agents on the Basis of Hazard

NIH Recombinant DNA Guidelines (April, 2019)

APPENDIX B. CLASSIFICATION OF HUMAN ETIOLOGIC AGENTS ON THE BASIS OF HAZARD

This appendix includes those biological agents known to infect humans as well as selected animal agents that may pose theoretical risks if inoculated into humans. Included are lists of representative genera and species known to be pathogenic; mutated, recombined, and non-pathogenic species and strains are not considered. Non-infectious life cycle stages of parasites are excluded.

This appendix reflects the current state of knowledge and should be considered a resource document. Included are the more commonly encountered agents and is not meant to be all-inclusive. Information on agent risk assessment may be found in the *Agent Summary Statements* of the CDC/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories* (see Sections V-C, V-D, V-E, and V-F, *Footnotes and References of Sections I through IV*. Further guidance on agents not listed in Appendix B may be obtained through: Centers for Disease Control and Prevention, Biosafety Branch, Atlanta, Georgia 30333, Phone: (404) 639-3883, Fax: (404) 639-2294; National Institutes of Health, Division of Safety, Bethesda, Maryland 20892, Phone: (301) 496-1357; Biosafety Manager, National Animal Disease Center, U.S. Department of Agriculture - ARS, Ames, Iowa 50010, Phone: (515) 337-7772.

Appendix B - Table 1. Basis for the Classification of Biohazardous Agents by Risk Group (RG)

Risk Group 1 (RG1)	Agents that are not associated with disease in healthy adult humans
Risk Group 2 (RG2)	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (high individual risk but low community risk)
Risk Group 4 (RG4)	Agents that 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)

Appendix B-I. Risk Group 1 (RG1) Agents

RG1 agents are not associated with disease in healthy adult humans. Examples of RG1 agents include asporogenic *Bacillus subtilis* or *Bacillus licheniformis* (see Appendix C-IV-A, *Bacillus subtilis* or *Bacillus licheniformis* Host-Vector Systems, Exceptions); adeno- associated virus (AAV – all serotypes); and recombinant or synthetic AAV constructs, in which the transgene does not encode either a potentially tumorigenic gene product or a toxin molecule and are produced in the absence of a helper virus. A strain of *Escherichia coli* (see Appendix C-II-A, *Escherichia coli* K-12 Host Vector Systems, Exceptions) is an RG1 agent if it (1) does not possess a complete lipopolysaccharide (*i.e.*, lacks the O antigen); and (2) does not carry any active virulence factor (*e.g.*, toxins) or colonization factors and does not carry any genes encoding these factors.

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

Appendix B-II. Risk Group 2 (RG2) Agents

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

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

--*Acinetobacter baumannii* (formerly *Acinetobacter calcoaceticus*)
--*Actinobacillus*
--*Actinomyces pyogenes* (formerly *Corynebacterium pyogenes*)

--*Aeromonas hydrophila*
--*Amycolata autotrophica*
--*Archanobacterium haemolyticum* (formerly *Corynebacterium haemolyticum*)
--*Arizona hinshawii* - all serotypes
--*Bacillus anthracis*
--*Bartonella henselae, B. quintana, B. vinsonii*
--*Bordetella* including *B. pertussis*
--*Borrelia recurrentis, B. burgdorferi*
--*Burkholderia* (formerly *Pseudomonas* species) except those listed in Appendix B-III-A (RG3))
--*Campylobacter coli, C. fetus, C. jejuni*
--*Chlamydia psittaci*, *C. trachomatis*, *C. pneumoniae*
--*Clostridium botulinum*, *C. chauvoei, C. haemolyticum, C. histolyticum, C. novyi, C. septicum, C. tetani*
--*Coxiella burnetii* – specifically the Phase II, Nine Mile strain, plaque purified, clone 4
--*Corynebacterium diphtheriae, C. pseudotuberculosis, C. renale*
--*Dermatophilus congolensis*
--*Edwardsiella tarda*
--*Erysipelothrix rhusiopathiae*
--*Escherichia coli* - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including *E. coli* O157:H7
--**Francisella tularensis* specifically **F. tularensis* subspecies *novicida* [aka *F. novicida*], strain Utah 112; **F. tularensis* subspecies *holarctica* LVS; **F. tularensis* biovar *tularensis* strain ATCC 6223 (aka strain B38) *For research involving high concentrations, BL3 practices should be considered (see Appendix G-II-C-2. Special Practices (BL3)).
--*Haemophilus ducreyi, H. influenzae*
--*Helicobacter pylori*
--*Klebsiella* - all species except *K. oxytoca* (RG1)
--*Legionella* including *L. pneumophila*
--*Leptospira interrogans* - all serotypes
--*Listeria*
--*Moraxella*
--*Mycobacterium* (except those listed in Appendix B-III-A (RG3)) including *M. avium* complex, *M. asiaticum, M. bovis* BCG vaccine strain, *M. chelonae, M. fortuitum, M. kansasii, M. leprae, M. malmoense, M. marinum, M. paratuberculosis, M. scrofulaceum, M. simiae, M. szulgai, M. ulcerans, M. xenopi*
--*Mycoplasma*, except *M. mycoides* and *M. agalactiae* which are restricted animal pathogens
--*Neisseria gonorrhoeae*, *N. meningitidis*
--*Nocardia asteroides, N. brasiliensis, N. otitidiscaviarum, N. transvalensis*
--*Pseudomonas aeruginosa*
--*Rhodococcus equi*
--*Salmonella* including *S. arizonae, S. choleraesuis, S. enteritidis, S. gallinarum-pullorum, S. meleagridis, S. paratyphi,* A, B, C, *S. typhi*, *S. typhimurium*
--*Shigella* including *S. boydii, S. dysenteriae,* type 1, *S. flexneri, S. sonnei*
--*Sphaerophorus necrophorus*
--*Staphylococcus aureus*
--*Streptobacillus moniliformis*

--*Streptococcus* including *S. pneumoniae, S. pyogenes*
--*Treponema pallidum, T. carateum*
--*Vibrio cholerae, V. parahaemolyticus, V. vulnificus*
--*Yersinia enterocolitica*
--*Yersinia pestis* specifically $pgm^{(-)}$ strains (lacking the 102 kb pigmentation locus) and $lcr^{(-)}$ strains (lacking the LCR plasmid)

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

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

--*Paracoccidioides braziliensis*
--*Penicillium marneffei*
--*Sporothrix schenckii*
--*Trichophyton*

Appendix B-II-C. Risk Group 2 (RG2) - Parasitic Agents

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

Appendix B-II-D. Risk Group 2 (RG2) - Viruses

Adenoviruses, human - all types

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

Arenaviruses
--Junin virus candid #1 vaccine strain
--Lymphocytic choriomeningitis virus (non-neurotropic strains)
--Tacaribe virus complex
--Other viruses as listed in the reference source (see Section V-C, *Footnotes and References of Sections I through IV*)

Bunyaviruses
--Bunyamwera virus
--Rift Valley fever virus vaccine strain MP-12
--Other viruses as listed in the reference source (see Section V-C, *Footnotes and References of Sections I through IV*)

Caliciviruses

Coronaviruses

Flaviviruses - Group B Arboviruses
--Dengue virus serotypes 1, 2, 3, and 4
--Japanese encephalitis virus strain SA 14-14-2
--Yellow fever virus vaccine strain 17D
--Other viruses as listed in the reference source (see Section V-C, *Footnotes and References of Sections I through IV*)

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

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

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

Papilloma viruses
--All human papilloma viruses

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

Parvoviruses
--Human parvovirus (B19)

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

Poxviruses - all types except Monkeypox virus (see Appendix B-III-D, *Risk Group 3 (RG3) - Viruses and Prions*) and restricted poxviruses including Alastrim, Smallpox, and Whitepox (see Section V-L, *Footnotes and References of Sections I through IV*)

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

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

Rubivirus (Togaviruses)
--Rubella virus

Appendix B-III. Risk Group 3 (RG3) Agents

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

Appendix B-III-A. Risk Group 3 (RG3) - Bacterial Agents Including Rickettsia

--*Bartonella*

--*Brucella* including *B. abortus, B. canis*, *B. suis*
--*Burkholderia (Pseudomonas) mallei, B. pseudomallei*
--*Coxiella burnetii (*except the Phase II, Nine Mile strain listed in Appendix B-II-A, *Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia)*
--*Francisella tularensis (*except those strains listed in Appendix B-II-A, *Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia)*
--*Mycobacterium bovis* (except BCG strain, see Appendix B-II-A, *Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia*), *M. tuberculosis*
--*Orientia tsutsugamushi* (was *R. tsutsugamushi*)
--*Pasteurella multocida* type B -"buffalo" and other virulent strains
--*Rickettsia akari*, *R. australis*, *R. canada*, *R. conorii*, *R. prowazekii*, *R. rickettsii*, *R, siberica*, *R. typhi* (*R. mooseri*)
--*Yersinia pestis (*except those strains listed in Appendix B-II-A, *Risk Group 2 (RG2) - Bacterial Agents Including Chlamydia)*

Appendix B-III-B. Risk Group 3 (RG3) - Fungal Agents

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

Appendix B-III-C. Risk Group 3 (RG3) - Parasitic Agents

None

Appendix B-III-D. Risk Group 3 (RG3) - Viruses and Prions

Alphaviruses (Togaviruses) - Group A Arboviruses
--Chikungunya virus (except the vaccine strain 181/25 listed in Appendix B-II-D Risk Group2 (RG2) – Viruses)
--Semliki Forest virus
--St. Louis encephalitis virus
--Venezuelan equine encephalomyelitis virus (except the vaccine strains TC-83 and V3526, see Appendix B-II-D (RG2) – Viruses)
--Other viruses as listed in the reference source (see Section V-C, *Footnotes and References of Sections I through IV*)

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

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

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

Flaviviruses - Group B Arboviruses
--Japanese encephalitis virus (except those strains listed in Appendix B-II-D Risk Group2 (RG2) - Viruses)
--West Nile virus (WNV)
--Yellow fever virus
--Other viruses as listed in the reference source (see Section V-C, *Footnotes and References of Sections I through IV*)

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

Poxviruses
--Monkeypox virus

Prions
--Transmissible spongiform encephalopathies (TSE) agents (Creutzfeldt-Jacob disease and kuru agents)(see Section V-C, *Footnotes and References of Sections I through IV*, for containment instruction)

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

Rhabdoviruses
--Vesicular stomatitis virus (except those strains listed in Appendix B-II-D Risk Group2 (RG2) - Viruses)

Appendix B-IV. Risk Group 4 (RG4) Agents

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

Appendix B-IV-A. Risk Group 4 (RG4) - Bacterial Agents

None

Appendix B-IV-B. Risk Group 4 (RG4) - Fungal Agents

None

Appendix B-IV-C. Risk Group 4 (RG4) - Parasitic Agents

None

Appendix B-IV-D. Risk Group 4 (RG4) - Viral Agents

Arenaviruses
--Guanarito virus
--Lassa virus

--Junin virus (except the candid #1 vaccine strain listed in Appendix B-II-D Risk Group2 (RG2) – Viruses)
--Machupo virus
--Sabia

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

Filoviruses
--Ebola virus
--Marburg virus

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

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

Paramyxoviruses
--Equine Morbillivirus (Hendra virus)

Hemorrhagic fever agents and viruses as yet undefined

Appendix B-V. Animal Viral Etiologic Agents in Common Use

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

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

Baculoviruses

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

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

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

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

--Murine sarcoma virus
--Rat leukemia virus

Appendix B-V-1. Murine Retroviral Vectors

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

Appendix III

Characteristics of Common Laboratory Disinfectants (WHO)

Organization, W. H. (2004). Disinfection and sterilization. In *Laboratory Biosafety Manual* (3rd ed., pp. 82-93). World Health Organization.

14. Disinfection and sterilization

A basic knowledge of disinfection and sterilization is crucial for biosafety in the laboratory. Since heavily soiled items cannot promptly be disinfected or sterilized, it is equally important to understand the fundamentals of cleaning prior to disinfection (precleaning). In this regard, the following general principles apply to all known classes of microbial pathogens.

Specific decontamination requirements will depend on the type of experimental work and the nature of the infectious agent(s) being handled. The generic information given here can be used to develop both standardized and more specific procedures to deal with biohazard(s) involved in a particular laboratory.

Contact times for disinfectants are specific for each material and manufacturer. Therefore, all recommendations for use of disinfectants should follow manufacturers' specifications.

Definitions

Many different terms are used for disinfection and sterilization. The following are among the more common in biosafety:

Antimicrobial – An agent that kills microorganisms or suppresses their growth and multiplication.

Antiseptic – A substance that inhibits the growth and development of microorganisms without necessarily killing them. Antiseptics are usually applied to body surfaces.

Biocide – A general term for any agent that kills organisms.

Chemical germicide – A chemical or a mixture of chemicals used to kill microorganisms.

Decontamination – Any process for removing and/or killing microorganisms. The same term is also used for removing or neutralizing hazardous chemicals and radioactive materials.

Disinfectant – A chemical or mixture of chemicals used to kill microorganisms, but not necessarily spores. Disinfectants are usually applied to inanimate surfaces or objects.

Disinfection – A physical or chemical means of killing microorganisms, but not necessarily spores.

Microbicide – A chemical or mixture of chemicals that kills microorganisms. The term is often used in place of "biocide", "chemical germicide" or "antimicrobial".

Sporocide – A chemical or mixture of chemicals used to kill microorganisms and spores.

Sterilization – A process that kills and/or removes all classes of microorganisms and spores.

Cleaning laboratory materials

Cleaning is the removal of dirt, organic matter and stains. Cleaning includes brushing, vacuuming, dry dusting, washing or damp mopping with water containing a soap or detergent. Dirt, soil and organic matter can shield microorganisms and can interfere with the killing action of decontaminants (antiseptics, chemical germicides and disinfectants).

Precleaning is essential to achieve proper disinfection or sterilization. Many germicidal products claim activity only on precleaned items. Precleaning must be carried out with care to avoid exposure to infectious agents.

Materials chemically compatible with the germicides to be applied later must be used. It is quite common to use the same chemical germicide for precleaning and disinfection.

Chemical germicides

Many types of chemicals can be used as disinfectants and/or antiseptics. As there is an ever-increasing number and variety of commercial products, formulations must be carefully selected for specific needs.

The germicidal activity of many chemicals is faster and better at higher temperatures. At the same time, higher temperatures can accelerate their evaporation and also degrade them. Particular care is needed in the use and storage of such chemicals in tropical regions, where their shelf-life may be reduced because of high ambient temperatures.

Many germicides can be harmful to humans or the environment. They should be selected, stored, handled, used and disposed of with care, following manufacturers' instructions. For personal safety, gloves, aprons and eye protection are recommended when preparing dilutions of chemical germicides.

Chemical germicides are generally not required for regular cleaning of floors, walls, equipment and furniture. However, their use may be appropriate in certain cases of outbreak control.

Proper use of chemical germicides will contribute to workplace safety while reducing the risk from infectious agents. As far as possible, the number of germicidal chemicals to be used should be limited for economic reasons, inventory control and to limit environmental pollution.

Commonly used classes of chemical germicides are described below, with generic information on their applications and safety profiles. Unless otherwise indicated, the germicide concentrations are given in weight/volume (w/v). Table 12 summarizes the recommended dilutions of chlorine-releasing compounds.

Table 12. ***Recommended dilutions of chlorine-releasing compounds***

	"CLEAN" CONDITIONS[a]	"DIRTY" CONDITIONS[b]
Available chlorine required	0.1% (1 g/l)	0.5% (5 g/l)
Sodium hypochlorite solution (5% available chlorine)	20 ml/l	100 ml/l
Calcium hypochlorite (70% available chlorine)	1.4 g/l	7.0 g/l
Sodium dichloroisocyanurate powder (60% available chlorine)	1.7 g/l	8.5 g/l
Sodium dichloroisocyanurate tablets (1.5 g available chlorine per tablet)	1 tablet per litre	4 tablets per litre
Chloramine (25% available chlorine)[c]	20 g/l	20 g/l

[a] After removal of bulk material.
[b] For flooding, e.g. on blood or before removal of bulk material.
[c] See text.

Chlorine (sodium hypochlorite)

Chlorine, a fast-acting oxidant, is a widely available and broad-spectrum chemical germicide. It is normally sold as bleach, an aqueous solution of sodium hypochlorite (NaOCl), which can be diluted with water to provide various concentrations of available chlorine.

Chlorine, especially as bleach, is highly alkaline and can be corrosive to metal. Its activity is considerably reduced by organic matter (protein). Storage of stock or working solutions of bleach in open containers, particularly at high temperatures, releases chlorine gas thus weakening their germicidal potential. The frequency with which working solutions of bleach should be changed depends on their starting strength, the type (e.g. with or without a lid) and size of their containers, the frequency and nature of use, and ambient conditions. As a general guide, solutions receiving materials with high levels of organic matter several times a day should be changed at least daily, while those with less frequent use may last for as long as a week.

A general all-purpose laboratory disinfectant should have a concentration of 1 g/l available chlorine. A stronger solution, containing 5 g/l available chlorine, is recommended for dealing with biohazardous spillage and in the presence of large amounts of organic matter. Sodium hypochlorite solutions, as domestic bleach, contain 50 g/l available chlorine and should therefore be diluted 1:50 or 1:10 to obtain final concentrations of 1 g/l and 5 g/l, respectively. Industrial solutions of bleach have a sodium hypochlorite concentration of nearly 120 g/l and must be diluted accordingly to obtain the levels indicated above.

Granules or tablets of calcium hypochlorite ($Ca(ClO)_2$) generally contain about 70% available chlorine. Solutions prepared with granules or tablets, containing 1.4 g/l and 7.0 g/l, will then contain 1.0 g/l and 5 g/l available chlorine, respectively.

Bleach is not recommended as an antiseptic, but may be used as a general-purpose

disinfectant and for soaking contaminated metal-free materials. In emergencies, bleach can also be used to disinfect water for drinking, with a final concentration of 1–2 mg/l available chlorine.

Chlorine gas is highly toxic. Bleach must therefore be stored and used in well-ventilated areas only. Also, bleach must not be mixed with acids to prevent the rapid release of chlorine gas. Many by-products of chlorine can be harmful to humans and the environment, so that indiscriminate use of chlorine-based disinfectants, in particular bleach, should be avoided.

Sodium dichloroisocyanurate

Sodium dichloroisocyanurate (NaDCC) in powder form contains 60% available chlorine. Solutions prepared with NaDCC powder at 1.7 g/l and 8.5 g/l will contain 1 g/l or 5 g/l available chlorine, respectively. Tablets of NaDCC generally contain the equivalent of 1.5 g available chlorine per tablet. One or four tablets dissolved in 1 l of water will give approximately the required concentrations of 1 g/l or 5 g/l, respectively. NaDCC as powder or tablets is easy and safe to store. Solid NaDCC can be applied on spills of blood or other biohazardous liquids and left for at least 10 min before removal. Further cleaning of the affected area can then take place.

Chloramines

Chloramines are available as powders containing about 25% available chlorine. Chloramines release chlorine at a slower rate than hypochlorites. Higher initial concentrations are therefore required for efficiencies equivalent to those of hypochlorites. On the other hand, chloramine solutions are not inactivated by organic matter to the same extent as hypochlorite solutions, and concentrations of 20 g/l are recommended for both "clean" and "dirty" situations.

Chloramine solutions are virtually odour-free. However, items soaked in them must be thoroughly rinsed to remove any residue of the bulking agents added to chloramine-T (sodium tosylchloramide) powders.

Chlorine dioxide

Chlorine dioxide (ClO_2) is a strong and fast-acting germicide, disinfectant agent and oxidizer, often reported to be active at concentrations levels lower than those needed by chlorine as bleach. Chlorine dioxide is unstable as a gas and will undergo decomposition into chlorine gas (Cl_2), oxygen gas (O_2), giving off heat. However, chlorine dioxide is soluble in water and stable in an aqueous solution. Chlorine dioxide can be obtained in two ways: (1) on-site generation by mixing of two separate components, hydrochloric acid (HCl) and sodium chlorite ($NaClO_2$); and (2) ordering its stabilized form, which is then activated on-site when required.

Of the oxidizing biocides, chlorine dioxide is the most selective oxidant. Ozone and chlorine are much more reactive than chlorine dioxide, and they will be consumed by most organic compounds. Chlorine dioxide, however, reacts only with reduced sulfur

compounds, secondary and tertiary amines, and some other highly reduced and reactive organic compounds. A more stable residue can therefore be achieved with chlorine dioxide at much lower doses than when using either chlorine or ozone. Generated properly, chlorine dioxide can be used more effectively than ozone or chlorine in cases of higher organic loading because of its selectivity.

Formaldehyde

Formaldehyde (HCHO) is a gas that kills all microorganisms and spores at temperatures above 20 °C. However, it is not active against prions.

Formaldehyde is relatively slow-acting and needs a relative humidity level of about 70%. It is marketed as the solid polymer, paraformaldehyde, in flakes or tablets, or as formalin, a solution of the gas in water of about 370 g/l (37%), containing methanol (100 ml/l) as a stabilizer. Both formulations are heated to liberate the gas, which is used for decontamination and disinfection of enclosed volumes such as safety cabinets and rooms (see section on Local environmental decontamination in this chapter). Formaldehyde (5% formalin in water) may be used as a liquid disinfectant.

Formaldehyde is a suspected carcinogen. It is a dangerous, irritant gas that has a pungent smell and its fumes can irritate eyes and mucous membranes. It must therefore be stored and used in a fume-hood or well-ventilated area. National chemical safety regulations must be followed.

Glutaraldehyde

Like formaldehyde, glutaraldehyde ($OHC(CH_2)_3CHO$) is also active against vegetative bacteria, spores, fungi and lipid- and nonlipid-containing viruses. It is non-corrosive and faster acting than formaldehyde. However, it takes several hours to kill bacterial spores.

Glutaraldehyde is generally supplied as a solution with a concentration of about 20 g/l (2%) and some products may need to be "activated" (made alkaline) before use by the addition of a bicarbonate compound supplied with the product. The activated solution can be reused for 1–4 weeks depending on the formulation and type and frequency of its use. Dipsticks supplied with some products give only a rough indication of the levels of active glutaraldehyde available in solutions under use. Glutaraldehyde solutions should be discarded if they become turbid.

Glutaraldehyde is toxic and an irritant to skin and mucous membranes, and contact with it must be avoided. It must be used in a fume-hood or in well-ventilated areas. It is not recommended as a spray or solution for the decontamination of environmental surfaces. National chemical safety regulations must be followed.

Phenolic compounds

Phenolic compounds, a broad group of agents, were among the earliest germicides. However, more recent safety concerns restrict their use. They are active against vegetative bacteria and lipid-containing viruses and, when properly formulated, also show

activity against mycobacteria. They are not active against spores and their activity against nonlipid viruses is variable. Many phenolic products are used for the decontamination of environmental surfaces, and some (e.g. triclosan and chloroxylenol) are among the more commonly used antiseptics.

Triclosan is common in products for hand-washing. It is active mainly against vegetative bacteria and safe for skin and mucous membranes. However, in laboratory-based studies, bacteria made resistant to low concentrations of triclosan also show resistance to certain types of antibiotics. The significance of this finding in the field remains unknown.

Some phenolic compounds are sensitive to and may be inactivated by water hardness and therefore must be diluted with distilled or deionized water.

Phenolic compounds are not recommended for use on food contact surfaces and in areas with young children. They may be absorbed by rubber and can also penetrate the skin. National chemical safety regulations must be followed.

Quaternary ammonium compounds

Many types of quaternary ammonium compounds are used as mixtures and often in combination with other germicides, such as alcohols. They have good activity against some vegetative bacteria and lipid-containing viruses. Certain types (e.g. benzalkonium chloride) are used as antiseptics.

The germicidal activity of certain types of quaternary ammonium compounds is considerably reduced by organic matter, water hardness and anionic detergents. Care is therefore needed in selecting agents for precleaning when quaternary ammonium compounds are to be used for disinfection. Potentially harmful bacteria can grow in quaternary ammonium compound solutions. Owing to low biodegradability, these compounds may also accumulate in the environment.

Alcohols

Ethanol (ethyl alcohol, C_2H_5OH) and 2-propanol (isopropyl alcohol, $(CH_3)_2CHOH$) have similar disinfectant properties. They are active against vegetative bacteria, fungi and lipid-containing viruses but not against spores. Their action on nonlipid viruses is variable. For highest effectiveness they should be used at concentrations of approximately 70% (v/v) in water: higher or lower concentrations may not be as germicidal. A major advantage of aqueous solutions of alcohols is that they do not leave any residue on treated items.

Mixtures with other agents are more effective than alcohol alone, e.g. 70% (v/v) alcohol with 100 g/l formaldehyde, and alcohol containing 2 g/l available chlorine. A 70% (v/v) aqueous solution of ethanol can be used on skin, work surfaces of laboratory benches and biosafety cabinets, and to soak small pieces of surgical instruments. Since ethanol can dry the skin, it is often mixed with emollients. Alcohol-based hand-rubs are recommended for the decontamination of lightly soiled hands in situations where proper hand-washing is inconvenient or not possible. However, it must be remembered

that ethanol is ineffective against spores and may not kill all types of nonlipid viruses.

Alcohols are volatile and flammable and must not be used near open flames. Working solutions should be stored in proper containers to avoid the evaporation of alcohols. Alcohols may harden rubber and dissolve certain types of glue. Proper inventory and storage of ethanol in the laboratory is very important to avoid its use for purposes other than disinfection. Bottles with alcohol-containing solutions must be clearly labelled to avoid autoclaving.

Iodine and iodophors

The action of these disinfectants is similar to that of chlorine, although they may be slightly less inhibited by organic matter. Iodine can stain fabrics and environmental surfaces and is generally unsuitable for use as a disinfectant. On the other hand, iodophors and tinctures of iodine are good antiseptics. Polyvidone-iodine is a reliable and safe surgical scrub and preoperative skin antiseptic. Antiseptics based on iodine are generally unsuitable for use on medical/dental devices. Iodine should not be used on aluminium or copper.

Iodine can be toxic. Organic iodine-based products must be stored at 4–10 °C to avoid the growth of potentially harmful bacteria in them.

Hydrogen peroxide and peracids

Like chlorine, hydrogen peroxide (H_2O_2) and peracids are strong oxidants and can be potent broad-spectrum germicides. They are also safer than chlorine to humans and the environment.

Hydrogen peroxide is supplied either as a ready-to-use 3% solution or as a 30% aqueous solution to be diluted to 5–10 times its volume with sterilized water. However, such 3–6% solutions of hydrogen peroxide alone are relatively slow and limited as germicides. Products now available have other ingredients to stabilize the hydrogen peroxide content, to accelerate its germicidal action and to make it less corrosive.

Hydrogen peroxide can be used for the decontamination of work surfaces of laboratory benches and biosafety cabinets, and stronger solutions may be suitable for disinfecting heat-sensitive medical/dental devices. The use of vaporized hydrogen peroxide or peracetic acid (CH_3COOOH) for the decontamination of heat-sensitive medical/surgical devices requires specialized equipment.

Hydrogen peroxide and peracids can be corrosive to metals such as aluminium, copper, brass and zinc, and can also decolorize fabrics, hair, skin and mucous membranes. Articles treated with them must be thoroughly rinsed before contact with eyes and mucous membranes. They should always be stored away from heat and protected from light.

Local environmental decontamination

Decontamination of the laboratory space, its furniture and its equipment requires a combination of liquid and gaseous disinfectants. Surfaces can be decontaminated using

a solution of sodium hypochlorite (NaOCl); a solution containing 1 g/l available chlorine may be suitable for general environmental sanitation, but stronger solutions (5 g/l) are recommended when dealing with high-risk situations. For environmental decontamination, formulated solutions containing 3% hydrogen peroxide (H_2O_2) make suitable substitutes for bleach solutions.

Rooms and equipment can be decontaminated by fumigation with formaldehyde gas generated by heating paraformaldehyde or boiling formalin. This is a highly dangerous process that requires specially trained personnel. All openings in the room (i.e. windows, doors, etc.) should be sealed with masking tape or similar before the gas is generated. Fumigation should be conducted at an ambient temperature of at least 21 °C and a relative humidity of 70%. (See also section on Decontamination of biological safety cabinets in this chapter.)

After fumigation the area must be ventilated thoroughly before personnel are allowed to enter. Appropriate respirators must be worn by anyone entering the room before it has been ventilated. Gaseous ammonium bicarbonate can be used to neutralize the formaldehyde.

Fumigation of smaller spaces with hydrogen peroxide vapour is also effective but requires specialized equipment to generate the vapour.

Decontamination of biological safety cabinets

To decontaminate Class I and Class II cabinets, equipment that independently generates, circulates and neutralizes formaldehyde gas is available. Alternatively, the appropriate amount of paraformaldehyde (final concentration of 0.8% paraformaldehyde in air) should be placed in a frying pan on an electric hot plate. Another frying pan, containing 10% more ammonium bicarbonate than paraformaldehyde, on a second hot plate is also placed inside the cabinet. The hot plate leads are plugged in outside the cabinet, so that operation of the pans can be controlled from the outside by plugging and unplugging the hot plates as necessary. If the relative humidity is below 70%, an open container of hot water should also be placed inside the cabinet before the front closure is sealed in place with strong tape (e.g. duct tape). Heavy gauge plastic sheeting is taped over the front opening and exhaust port to make sure that the gas cannot seep into the room. Penetration of the electric leads passing through the front closure must also be sealed with duct tape.

The plate for the paraformaldehyde pan is plugged in. It is unplugged when all the paraformaldehyde has vaporized. The cabinet is left undisturbed for at least 6 h. The plate for the second pan is then plugged in and the ammonium bicarbonate is allowed to vaporize. This plate is then unplugged and the cabinet blower is switched on for two intervals of approximately 2 s each to allow the ammonium bicarbonate gas to circulate. The cabinet should be left undisturbed for 30 min before the front closure (or plastic sheeting) and the exhaust port sheeting are removed. The cabinet surfaces should be wiped down to remove residues before use.

Hand-washing/hand decontamination

Whenever possible, suitable gloves should be worn when handling biohazardous materials. However, this does not replace the need for regular and proper hand-washing by laboratory personnel. Hands must be washed after handling biohazardous materials and animals, and before leaving the laboratory.

In most situations, thorough washing of hands with ordinary soap and water is sufficient to decontaminate them, but the use of germicidal soaps is recommended in high-risk situations. Hands should be thoroughly lathered with soap, using friction, for at least 10 s, rinsed in clean water and dried using a clean paper or cloth towel (if available, warm-air hand-dryers may be used).

Foot- or elbow-operated faucets are recommended. Where not fitted, a paper/cloth towel should be used to turn off the faucet handles to avoid recontaminating washed hands.

As mentioned above, alcohol-based hand-rubs may be used to decontaminate lightly soiled hands when proper hand-washing is not available.

Heat disinfection and sterilization

Heat is the most common among the physical agents used for the decontamination of pathogens. "Dry" heat, which is totally non-corrosive, is used to process many items of laboratory ware which can withstand temperatures of 160 °C or higher for 2–4 h. Burning or incineration (see below) is also a form of dry heat. "Moist" heat is most effective when used in the form of autoclaving.

Boiling does not necessarily kill all microorganisms and/or pathogens, but it may be used as the minimum processing for disinfection where other methods (chemical disinfection or decontamination, autoclaving) are not applicable or available.

Sterilized items must be handled and stored such that they remain uncontaminated until used.

Autoclaving

Saturated steam under pressure (autoclaving) is the most effective and reliable means of sterilizing laboratory materials. For most purposes, the following cycles will ensure sterilization of correctly loaded autoclaves:

1. 3 min holding time at 134 °C
2. 10 min holding time at 126 °C
3. 15 min holding time at 121 °C
4. 25 min holding time at 115 °C.

Examples of different autoclaves include the following.

Gravity displacement autoclaves. Figure 10 shows the general construction of a gravity-displacement autoclave. Steam enters the chamber under pressure and displaces the heavier air downwards and through the valve in the chamber drain, fitted with a HEPA filter.

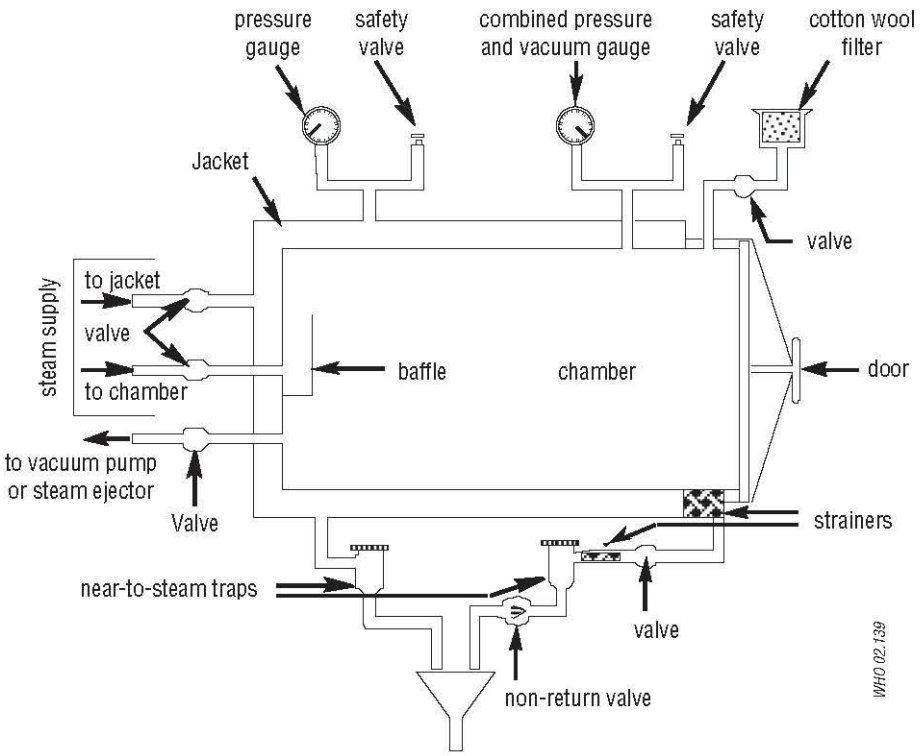


Figure 10. ***Gravity displacement autoclave***

Pre-vacuum autoclaves. These machines allow the removal of air from the chamber before steam is admitted. The exhaust air is evacuated through a valve fitted with a HEPA filter. At the end of the cycle, the steam is automatically exhausted. These autoclaves can operate at 134 °C and the sterilization cycle can therefore be reduced to 3 min. They are ideal for porous loads, but cannot be used to process liquids because of the vacuum.

Fuel-heated pressure cooker autoclaves. These should be used only if a gravity displacement autoclave is not available. They are loaded from the top and heated by gas, electricity or other types of fuels. Steam is generated by heating water in the base of the vessel, and air is displaced upwards through a relief vent. When all the air has been removed, the valve on the relief vent is closed and the heat reduced. The pressure and temperature rise until the safety valve operates at a preset level. This is the start of the holding time. At the end of the cycle the heat is turned off and the temperature allowed to fall to 80 °C or below before the lid is opened.

Loading autoclaves

Materials should be loosely packed in the chamber for easy steam penetration and air removal. Bags should allow the steam to reach their contents.

Precautions in the use of autoclaves

The following rules can minimize the hazards inherent in operating pressurized vessels.

1. Responsibility for operation and routine care should be assigned to trained individuals.
2. A preventive maintenance programme should include regular inspection of the chamber, door seals and all gauges and controls by qualified personnel.
3. The steam should be saturated and free from chemicals (e.g. corrosion inhibitors) that could contaminate the items being sterilized.
4. All materials to be autoclaved should be in containers that allow ready removal of air and permit good heat penetration; the chamber should be loosely packed so that steam will reach the load evenly.
5. For autoclaves without an interlocking safety device that prevents the door being opened when the chamber is pressurized, the main steam valve should be closed and the temperature allowed to fall below 80 °C before the door is opened.
6. Slow exhaust settings should be used when autoclaving liquids, as they may boil over when removed due to superheating.
7. Operators should wear suitable gloves and visors for protection when opening the autoclave, even when the temperature has fallen below 80 °C.
8. In any routine monitoring of autoclave performance, biological indicators or thermocouples should be placed at the centre of each load. Regular monitoring with thermocouples and recording devices in a "worst case" load is highly desirable to determine proper operating cycles.
9. The drain screen filter of the chamber (if available) should be removed and cleaned daily.
10. Care should be taken to ensure that the relief valves of pressure cooker autoclaves do not become blocked by paper, etc. in the load.

Incineration

Incineration is useful for disposing of animal carcasses as well as anatomical and other laboratory waste, with or without prior decontamination (see Chapter 3). Incineration of infectious materials is an alternative to autoclaving only if the incinerator is under laboratory control.

Proper incineration requires an efficient means of temperature control and a secondary burning chamber. Many incinerators, especially those with a single combustion chamber, are unsatisfactory for dealing with infectious materials, animal carcasses and plastics. Such materials may not be completely destroyed and the effluent from the chimney may pollute the atmosphere with microorganisms, toxic chemicals and smoke. However, there are many satisfactory configurations for combustion chambers. Ideally the temperature in the primary chamber should be at least 800 °C and that in the secondary chamber at least 1000 °C.

Materials for incineration, even with prior decontamination, should be transported

to the incinerator in bags, preferably plastic. Incinerator attendants should receive proper instructions about loading and temperature control. It should also be noted that the efficient operation of an incinerator depends heavily on the right mix of materials in the waste being treated.

There are ongoing concerns regarding the possible negative environmental effects of existing or proposed incinerators, and efforts continue to make incinerators more environmentally friendly and energy-efficient.

Disposal

The disposal of laboratory and medical waste is subject to various regional, national and international regulations, and the latest versions of such relevant documents must be consulted before designing and implementing a programme for handling, transportation and disposal of biohazardous waste. In general, ash from incinerators may be handled as normal domestic waste and removed by local authorities. Autoclaved waste may be disposed of by off-site incineration or in licensed landfill sites (see Chapter 3).

For further information see references (*13*) and (*29–39*).

Appendix IV

Biological Waste Management

Appendix IV.
Biological and Regulated Medical Waste Management

There are multiple standards and regulations that govern the management of *biological waste*. Chief among them are the *OSHA Bloodborne Pathogen Standard* (29 CFR 1910.130); the NJ Solid Waste Regulations, Subchapter 3A, *Regulated Medical Wastes* (NJAC 7:26); the Joint CDC/NIH Guidelines entitled *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, 6th Edition and the NIH *Guidelines for Research Involving Recombinant and Synthetic DNA Molecules*, April, 2019.

Biological Waste

In broad terms, biological waste may be defined as:

- liquid or solid waste contaminated with infectious or potentially infectious microorganisms
- tissue culture
- cell cultures
- recombinant DNA
- genetically engineered organisms, plants, or products regulated by the CDC, NIH, USDA/APHIS, or other State and local authorities.

These materials may be classified by the biosafety level (BL) of the contaminant. The CDC/NIH Guidelines describe 4 biosafety levels (BL-1 through BL-4) with BL-1 being the least hazardous and BL-4 being the most hazardous. As NJIT laboratories only manipulate materials regulated at BL-1 and BL-2, no waste beyond BL-2 will be generated. In terms of hazard assessment, the NJIT Institutional Biosafety Committee and NJIT Biosafety Manual regulate human derived materials (e.g., human blood and body fluids, primary human tissue explants and cell lines, as well as commercially obtained human cell lines) at BL-2 containment.

Treatment of Biological Waste

The CDC/NIH Guidelines require that BL-1 and BL-2 waste be decontaminated prior to disposal. Typically, adequate disinfection may be achieved by employing either:

- physical means: typically taken to mean **autoclave** processing which employs a combination of time, temperature, and pressure to achieve disinfection; or
- chemical means: the application of a chemical disinfectant with the appropriate properties that, given the necessary contact time, adequate disinfection will be achieved. Typically, a concentration of **10% liquid chlorine bleach** in direct contact with the waste material for 20 to 30 minutes will be sufficient.

Potentially contaminated biological waste items are accumulated in the laboratory in red or orange autoclave bags. When almost full, these bags are closed, placed in a spill or leak proof tray for transport to the autoclave, if autoclave is located outside the laboratory. Autoclave tape or other sterility indicator shall be used to demonstrate that the bag has been adequately disinfected by the autoclave process. Spill or leak proof trays made of Nalgene, or other autoclavable material, shall be used in the autoclave to contain any leaking material. This is especially important when autoclaving liquid waste or solid waste containing moderate amounts of liquid (e.g., culture flasks and petri dishes).

Following adequate disinfection, biological waste will be placed into Medical Waste boxes, lined with red bags that are supplied by the NJIT EHS Department. The **NJIT Medical Waste label** will be applied to all Medical Waste boxes, once the laboratory begins placing waste into the Medical Waste box. Once properly sealed, full Medical Waste boxes will be stored in a secure location (typically the laboratory) to await pick up by the NJIT EHS Department. EHS transports the full boxes of medical waste to a secure accumulation point to await pickup by the Medical Waste vendor. Alternatively, full boxes of Medical Waste may also be collected directly from the laboratory by the Medical Waste vendor. Medical Waste boxes must have proper labels supplied by the vendor and the NJIT Medical Waste label.

Regulated Medical Waste (RMW)

The State of NJ maintains a 2-step definition for *Regulated Medical Waste* (RMW). To be considered RMW, solid waste must meet both the process and classification definitions that follow.

- Process Definition: RMW is any solid waste generated from one of the following processes: the diagnosis, treatment or immunization of humans or animals; research pertaining to the diagnosis, treatment or immunization of humans or animals; or the production or testing of biologicals.
- Classification Definition: To be considered RMW items that are included in the above process definition must also belong to one of the following 7 classes:
    1. cultures and stocks of infectious agents and associated biologicals
    2. human pathological waste including tissues, organs, other body parts and fluids
    3. human blood and blood products
    4. contaminated sharps
    5. animal waste that may be potentially infectious
    6. isolation waste
    7. unused sharps

"Overclassified" Medical Waste

Some biological waste items generated in NJIT laboratories may resemble RMW in appearance and waste characteristics, but may not meet the specific NJDEP RMW definition. Regardless of the definition, laboratory waste that may have come into contact with potentially infectious material (for example soiled gloves or labware) shall be treated as if it were RMW.

Overclassified medical waste must be packaged, labeled, and stored in the same manner as RMW and is collected by the EHS Department. It is important to note that if the generator classifies biological waste as RMW, the storage, containment and management of the waste are now subject to the NJDEP regulations for RMW regardless of the waste characteristics.

Treatment and Segregation of RMW

One of the principal differences between the regulations concerning biological waste (waste generated by research activities) and Regulated Medical Waste (waste generated clinically-associated activities) is the need for treatment of the waste prior to its placement in the Medical Waste box. In general, there is a regulatory requirement to pre-treat (e.g. disinfect) research waste prior to placing in the Medical Waste box for ultimate disposal. On the clinical side; however, there is no regulatory requirement for pre-treatment.

To avoid any misconceptions, all waste generated by NJIT laboratories that may be contaminated with potentially infectious agents, organisms, or products will be properly decontaminated prior to being placed in the Medical Waste box for ultimate disposal.

Examples of waste items that require decontamination prior to place in a Medical Waste Box include laboratory-generated materials with:

- human blood and other human body fluids;
- human, animal or plant pathogens;
- primary human tissue explants and their clonal derivatives;
- tissue and cell cultures;
- recombinant/genetically altered plants, organisms, or products;
- infected animal products; and
- other potentially infectious waste materials.

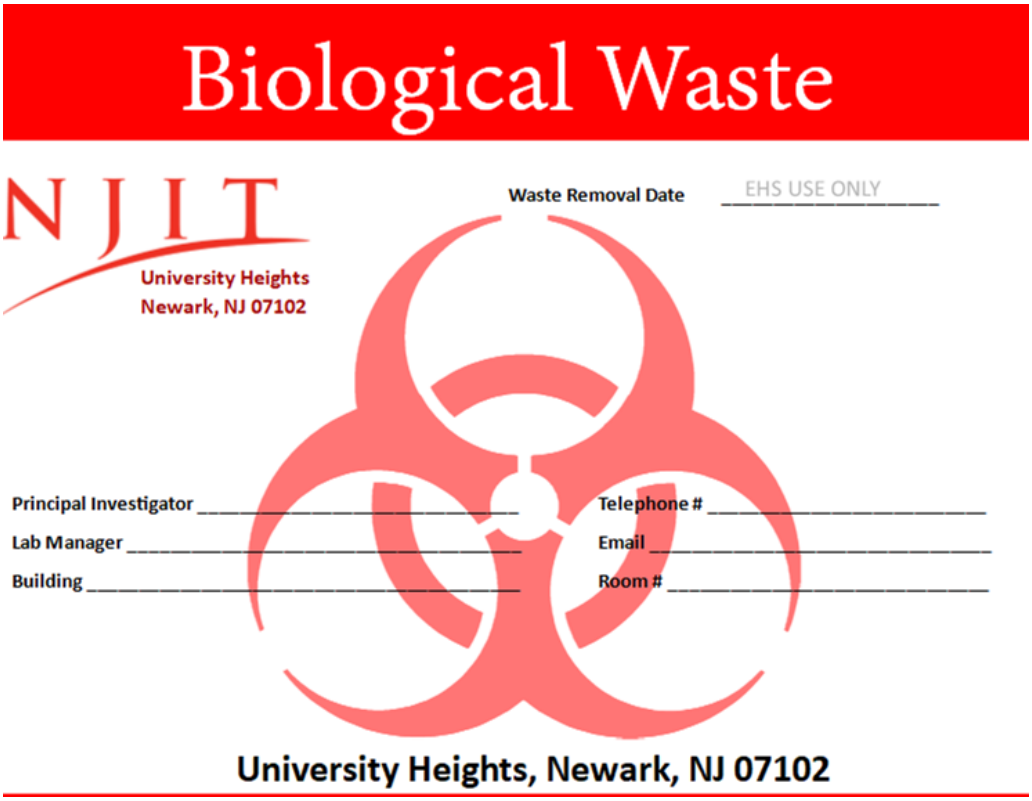
Storage of RMW

Full boxes of RMW will be stored at the point of generation to await regularly scheduled pick up by the EHS Department or Medical Waste vendor. Full boxes should be properly labeled and sealed securely. Small volumes of liquid waste (e.g., blood or cell culture residue) shall be placed in sealed containers with absorbent material prior to being deposited in the Medical Waste box. Volumes of liquid may not exceed 20cc per individual container.

Labeling of RMW

All containers of Biological and RMW must be properly labeled. This applies to the outer container (the Medical Waste box) as well as all inner containers (e.g. sharps containers or cell culture containers with associated liquid residue). Generators of RMW are required to label the outer container and each individual container **immediately upon use**. Typically, the outer RMW container is labeled with the following information:

- generator's or intermediate handler's name and address
- the transporter's name and NJ DEP solid waste registration number
- date of shipment
- identification of contents as medical waste
- example of NJIT's Biological and Medical Waste label is depicted below:



NJIT has developed the Biological Waste label for both the outer shipping container and the inner containers. Example of this label is depicted above and should be applied to both the outer shipping container and the individual inner containers. This label is in addition to any label supplied by the vendor or pre-printed on the Medical Waste box.

Sharps

Sharps such as needles, scalpel blades, broken test tubes, syringes and other sharp instruments contaminated with biological materials present the greatest risk of transmission of bloodborne pathogens in the laboratory setting. Disposable glass or plastic syringes (with or without needles), scalpel blades, and other sharp items should be deposited into an appropriate leak-proof, puncture-resistant, and labeled sharps container immediately after use.

Disposable needles should never be recapped, bent, broken, sheared, or removed from disposable syringes. If an NJIT laboratory worker sustains a needle stick the steps outlined in NJIT Biological Safety Manual and Bloodborne Pathogens Guide shall be followed.

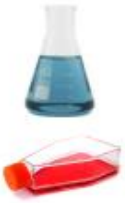
Sharps containers should be located in all work locations where it is reasonably anticipated that sharps may be used. Sharps containers should only be filled to within one inch of the top of the container. Sharps containers should never be overfilled. Never attempt to force additional material into a full container.

As stated above, sharps containers should be properly labeled as an inner container prior to being placed in the Medical Waste box. Once filled, the properly labeled sharps container should be closed, sealed, and placed in a Medical Waste box, lined with a red bag, to await pick up by the medical waste vendor or the NJIT EHS Department.

Please refer to Biological Waste Disposal Chart (below) for additional information. Please contact the NJIT EHS Department with specific biological waste disposal questions.

NJIT New Jersey Institute of Technology

Biological, Recombinant, and Medical Waste Disposal
NJIT Environmental Health and Safety Department

Waste Type	Sharps/tubing	Contaminated glass and plastic labware	Solid waste	Liquid waste
Waste Type and Examples				
Waste Type and Examples	Razor blades, scalpels, syringes, specimen tubes, contaminated broken glass, Pasteur pipettes, broken microscope slides	Contaminated flasks, cylinders, beakers, vials, bottles	Culture dishes, petri dishes, tissues, cells, gloves, masks, and other solid contaminated items	Human blood or body fluids, liquid growth media, animal blood, recombinant DNA waste
Container	 Red Sharps Container			
Decontamination	Prior to placing in the Medical Waste box, full sharps containers contaminated with BL-2 material should be decontaminated by autoclaving or by chemical disinfection with 10% liquid chlorine bleach. Place in Regulated Medical Waste box or Contact EHS for Disposal.	Prior to drain disposal, liquid waste must be decontaminated with 10% liquid chlorine bleach solution, then carefully poured down the drain. Rinse with fresh water. Disposable empty containers may then be handled as solid waste.	Prior to placing in the Regulated Medical Waste box, Biosafety Level 2 waste must me decontaminated. Decontaminate with fresh 10% bleach soln. allow at least 20 minutes contact time OR Autoclave. Contact EHS for disposal.	Prior to drain disposal, liquid waste must be decontaminated with 10% liquid chlorine bleach solution, allowing at least 20 minutes of contact, then carefully poured down the drain. Rinse with fresh water. Empty containers may then be handled as solid waste OR autoclaved.
Disposal		Drain Disposal. Reuse or dispose as solid waste.		Drain Disposal.
Labeling	Apply the **Biological-Medical Waste** label to the waste container when you begin to fill it. Please do not label empty containers. Fill the label out completely. Please complete all necessary information including laboratory contact information. The inner label is dated when EHS is contacted to remove the waste. Please apply the inner label to sharps containers and other containers that are placed in the RMW box. The outer label goes on the outside of the RMW box. **Example:** 			

Contact EHS for Disposal E-Mail completed Waste Pick Up Request to: healthandsafety@njit.edu
If you have any questions, call 973-596-3059

Appendix V

OSHA Bloodborne Pathogens Standard

Part Number:	1910
Part Title:	Occupational Safety and Health Standards
Subpart:	Z
Subpart Title:	Toxic and Hazardous Substances
Standard Number:	1910.1030
Title:	Bloodborne pathogens.
Appendix:	A
GPO Source:	e-CFR

1910.1030(a)

Scope and Application. This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

1910.1030(b)

Definitions. For purposes of this section, the following shall apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

Blood means human blood, human blood components, and products made from human blood.

Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

Exposure Incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

Handwashing Facilities means a facility providing an adequate supply of running potable water, soap, and single-use towels or air-drying machines.

Licensed Healthcare Professional is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

Needleless systems means a device that does not use needles for:

(1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established;

(2) The administration of medication or fluids; or

(3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

Other Potentially Infectious Materials means

(1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

(2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production Facility means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

Sharps with engineered sharps injury protections means a non needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

Work Practice Controls means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

1910.1030(c)
Exposure Control -

1910.1030(c)(1)
Exposure Control Plan.

1910.1030(c)(1)(i)
Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

1910.1030(c)(1)(ii)
The Exposure Control Plan shall contain at least the following elements:

1910.1030(c)(1)(ii)(A)
The exposure determination required by paragraph (c)(2),

1910.1030(c)(1)(ii)(B)
The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and

1910.1030(c)(1)(ii)(C)
The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

1910.1030(c)(1)(iii)
Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.20(e).

1910.1030(c)(1)(iv)
The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

1910.1030(c)(1)(iv)(A)
Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

1910.1030(c)(1)(iv)(B)
Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

1910.1030(c)(1)(v)
An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

1910.1030(c)(1)(vi)
The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

1910.1030(c)(2)
Exposure Determination.

1910.1030(c)(2)(i)
Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

1910.1030(c)(2)(i)(A)
A list of all job classifications in which all employees in those job classifications have occupational exposure;

1910.1030(c)(2)(i)(B)
A list of job classifications in which some employees have occupational exposure, and

1910.1030(c)(2)(i)(C)

A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

1910.1030(c)(2)(ii)
This exposure determination shall be made without regard to the use of personal protective equipment.

1910.1030(d)
Methods of Compliance -

1910.1030(d)(1)
General. Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

1910.1030(d)(2)
Engineering and Work Practice Controls.

1910.1030(d)(2)(i)
Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

1910.1030(d)(2)(ii)
Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

1910.1030(d)(2)(iii)
Employers shall provide handwashing facilities which are readily accessible to employees.

1910.1030(d)(2)(iv)
When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

1910.1030(d)(2)(v)
Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

1910.1030(d)(2)(vi)
Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

1910.1030(d)(2)(vii)
Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.
1910.1030(d)(2)(vii)(A)
Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

1910.1030(d)(2)(vii)(B)
Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

1910.1030(d)(2)(viii)
Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

1910.1030(d)(2)(viii)(A)
Puncture resistant;

1910.1030(d)(2)(viii)(B)
Labeled or color-coded in accordance with this standard;

1910.1030(d)(2)(viii)(C)
Leak-proof on the sides and bottom; and

1910.1030(d)(2)(viii)(D)
In accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

1910.1030(d)(2)(ix)
Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

1910.1030(d)(2)(x)
Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.

1910.1030(d)(2)(xi)
All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

1910.1030(d)(2)(xii)
Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

1910.1030(d)(2)(xiii)
Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

1910.1030(d)(2)(xiii)(A)
The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

1910.1030(d)(2)(xiii)(B)
If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

1910.1030(d)(2)(xiii)(C)
If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

1910.1030(d)(2)(xiv)
Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

1910.1030(d)(2)(xiv)(A)
A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

1910.1030(d)(2)(xiv)(B)
The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

1910.1030(d)(3)
Personal Protective Equipment -

1910.1030(d)(3)(i)
Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered appropriate only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

1910.1030(d)(3)(ii)
Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

1910.1030(d)(3)(iii)
Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

1910.1030(d)(3)(iv)
Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

1910.1030(d)(3)(v)
Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

1910.1030(d)(3)(vi)
If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

1910.1030(d)(3)(vii)
All personal protective equipment shall be removed prior to leaving the work area.

1910.1030(d)(3)(viii)
When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

1910.1030(d)(3)(ix)
Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

1910.1030(d)(3)(ix)(A)
Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

1910.1030(d)(3)(ix)(B)
Disposable (single use) gloves shall not be washed or decontaminated for re-use.

1910.1030(d)(3)(ix)(C)
Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

1910.1030(d)(3)(ix)(D)
If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:

1910.1030(d)(3)(ix)(D)(1)
Periodically reevaluate this policy;

1910.1030(d)(3)(ix)(D)(2)
Make gloves available to all employees who wish to use them for phlebotomy;
1910.1030(d)(3)(ix)(D)(3)
Not discourage the use of gloves for phlebotomy; and

1910.1030(d)(3)(ix)(D)(4)
Require that gloves be used for phlebotomy in the following circumstances:

1910.1030(d)(3)(ix)(D)(4)(i)
When the employee has cuts, scratches, or other breaks in his or her skin;

1910.1030(d)(3)(ix)(D)(4)(ii)
When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

1910.1030(d)(3)(ix)(D)(4)(iii)
When the employee is receiving training in phlebotomy.

1910.1030(d)(3)(x)
Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

1910.1030(d)(3)(xi)
Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

1910.1030(d)(3)(xii)
Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

1910.1030(d)(4)
Housekeeping -

1910.1030(d)(4)(i)
General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

1910.1030(d)(4)(ii)
All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

1910.1030(d)(4)(ii)(A)
Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

1910.1030(d)(4)(ii)(B)
Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift.

1910.1030(d)(4)(ii)(C)
All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

1910.1030(d)(4)(ii)(D)
Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

1910.1030(d)(4)(ii)(E)
Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

1910.1030(d)(4)(iii)
Regulated Waste -

1910.1030(d)(4)(iii)(A)
Contaminated Sharps Discarding and Containment.

1910.1030(d)(4)(iii)(A)(1)
Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

1910.1030(d)(4)(iii)(A)(1)(i)
Closable;

1910.1030(d)(4)(iii)(A)(1)(ii)
Puncture resistant;

1910.1030(d)(4)(iii)(A)(1)(iii)
Leak-proof on sides and bottom; and

1910.1030(d)(4)(iii)(A)(1)(iv)
Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

1910.1030(d)(4)(iii)(A)(2)
During use, containers for contaminated sharps shall be:

1910.1030(d)(4)(iii)(A)(2)(i)
Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);

1910.1030(d)(4)(iii)(A)(2)(ii)
Maintained upright throughout use; and

1910.1030(d)(4)(iii)(A)(2)(iii)
Replaced routinely and not be allowed to overfill.

1910.1030(d)(4)(iii)(A)(3)
When moving containers of contaminated sharps from the area of use, the containers shall be:

1910.1030(d)(4)(iii)(A)(3)(i)
Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;

1910.1030(d)(4)(iii)(A)(3)(ii)
Placed in a secondary container if leakage is possible. The second container shall be:

1910.1030(d)(4)(iii)(A)(3)(ii)(A)
Closable;

1910.1030(d)(4)(iii)(A)(3)(ii)(B)
Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and

1910.1030(d)(4)(iii)(A)(3)(ii)(C)
Labeled or color-coded according to paragraph (g)(1)(i) of this standard.

1910.1030(d)(4)(iii)(A)(4)
Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

1910.1030(d)(4)(iii)(B)
Other Regulated Waste Containment -

1910.1030(d)(4)(iii)(B)(1)
Regulated waste shall be placed in containers which are:

1910.1030(d)(4)(iii)(B)(1)(i)
Closable;

1910.1030(d)(4)(iii)(B)(1)(ii)
Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

1910.1030(d)(4)(iii)(B)(1)(iii)
Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and

1910.1030(d)(4)(iii)(B)(1)(iv)
Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

1910.1030(d)(4)(iii)(B)(2)
If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:

1910.1030(d)(4)(iii)(B)(2)(i)
Closable;

1910.1030(d)(4)(iii)(B)(2)(ii)
Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

1910.1030(d)(4)(iii)(B)(2)(iii)
Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

1910.1030(d)(4)(iii)(B)(2)(iv)
Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

1910.1030(d)(4)(iii)(C)
Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

1910.1030(d)(4)(iv)
Laundry.

1910.1030(d)(4)(iv)(A)
Contaminated laundry shall be handled as little as possible with a minimum of agitation.

1910.1030(d)(4)(iv)(A)(1)
Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

1910.1030(d)(4)(iv)(A)(2)
Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

1910.1030(d)(4)(iv)(A)(3)
Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.

1910.1030(d)(4)(iv)(B)
The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

1910.1030(d)(4)(iv)(C)

When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).

1910.1030(e)
HIV and HBV Research Laboratories and Production Facilities.

1910.1030(e)(1)
This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

1910.1030(e)(2)
Research laboratories and production facilities shall meet the following criteria:

1910.1030(e)(2)(i)
Standard Microbiological Practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)
Special Practices.

1910.1030(e)(2)(ii)(A)
Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

1910.1030(e)(2)(ii)(B)
Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

1910.1030(e)(2)(ii)(C)
Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

1910.1030(e)(2)(ii)(D)
When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard.

1910.1030(e)(2)(ii)(E)
All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

1910.1030(e)(2)(ii)(F)
Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

1910.1030(e)(2)(ii)(G)
Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

1910.1030(e)(2)(ii)(H)
Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)(I)
Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

1910.1030(e)(2)(ii)(J)
Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

1910.1030(e)(2)(ii)(K)
All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

1910.1030(e)(2)(ii)(L)
A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

1910.1030(e)(2)(ii)(M)
A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

1910.1030(e)(2)(iii)
Containment Equipment.

1910.1030(e)(2)(iii)(A)
Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

1910.1030(e)(2)(iii)(B)
Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

1910.1030(e)(3)
HIV and HBV research laboratories shall meet the following criteria:

1910.1030(e)(3)(i)
Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

1910.1030(e)(3)(ii)
An autoclave for decontamination of regulated waste shall be available.

1910.1030(e)(4)
HIV and HBV production facilities shall meet the following criteria:

1910.1030(e)(4)(i)
The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

1910.1030(e)(4)(ii)
The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

1910.1030(e)(4)(iii)
Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

1910.1030(e)(4)(iv)

Access doors to the work area or containment module shall be self-closing.
1910.1030(e)(4)(v)
An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

1910.1030(e)(4)(vi)
A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

1910.1030(e)(5)
Training Requirements. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

1910.1030(f)
Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up -

1910.1030(f)(1)
General.

1910.1030(f)(1)(i)
The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

1910.1030(f)(1)(ii)
The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

1910.1030(f)(1)(ii)(A)
Made available at no cost to the employee;

1910.1030(f)(1)(ii)(B)
Made available to the employee at a reasonable time and place;

1910.1030(f)(1)(ii)(C)
Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

1910.1030(f)(1)(ii)(D)
Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

1910.1030(f)(1)(iii)
The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

1910.1030(f)(2)
Hepatitis B Vaccination.

1910.1030(f)(2)(i)
Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

1910.1030(f)(2)(ii)
The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

1910.1030(f)(2)(iii)
If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

1910.1030(f)(2)(iv)
The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in appendix A.

1910.1030(f)(2)(v)
If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

1910.1030(f)(3)
Post-exposure Evaluation and Follow-up. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

1910.1030(f)(3)(i)
Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

1910.1030(f)(3)(ii)
Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

1910.1030(f)(3)(ii)(A)
The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

1910.1030(f)(3)(ii)(B)
When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

1910.1030(f)(3)(ii)(C)
Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

1910.1030(f)(3)(iii)
Collection and testing of blood for HBV and HIV serological status;

1910.1030(f)(3)(iii)(A)
The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

1910.1030(f)(3)(iii)(B)
If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

1910.1030(f)(3)(iv)
Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

1910.1030(f)(3)(v)
Counseling; and

1910.1030(f)(3)(vi)
Evaluation of reported illnesses.

1910.1030(f)(4)
Information Provided to the Healthcare Professional.

1910.1030(f)(4)(i)
The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

1910.1030(f)(4)(ii)

The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

1910.1030(f)(4)(ii)(A)
A copy of this regulation;

1910.1030(f)(4)(ii)(B)
A description of the exposed employee's duties as they relate to the exposure incident;

1910.1030(f)(4)(ii)(C)
Documentation of the route(s) of exposure and circumstances under which exposure occurred;

1910.1030(f)(4)(ii)(D)
Results of the source individual's blood testing, if available; and

1910.1030(f)(4)(ii)(E)
All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

1910.1030(f)(5)
Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

1910.1030(f)(5)(i)
The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

1910.1030(f)(5)(ii)
The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

1910.1030(f)(5)(ii)(A)
That the employee has been informed of the results of the evaluation; and

1910.1030(f)(5)(ii)(B)
That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

1910.1030(f)(5)(iii)
All other findings or diagnoses shall remain confidential and shall not be included in the written report.

1910.1030(f)(6)
Medical Recordkeeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

1910.1030(g)
Communication of Hazards to Employees -

1910.1030(g)(1)
Labels and Signs -

1910.1030(g)(1)(i)
Labels.

1910.1030(g)(1)(i)(A)
Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

1910.1030(g)(1)(i)(B)

Labels required by this section shall include the following legend:

BIOHAZARD

1910.1030(g)(1)(i)(C)
These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

1910.1030(g)(1)(i)(D)
Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

1910.1030(g)(1)(i)(E)
Red bags or red containers may be substituted for labels.

1910.1030(g)(1)(i)(F)
Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

1910.1030(g)(1)(i)(G)
Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

1910.1030(g)(1)(i)(H)
Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

1910.1030(g)(1)(i)(I)
Regulated waste that has been decontaminated need not be labeled or color-coded.

1910.1030(g)(1)(ii)
Signs.

1910.1030(g)(1)(ii)(A)
The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

BIOHAZARD

(Name of the Infectious Agent)
(Special requirements for entering the area)
(Name, telephone number of the laboratory director or other responsible person.)

1910.1030(g)(1)(ii)(B)
These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

1910.1030(g)(2)
Information and Training.

1910.1030(g)(2)(i)
The employer shall train each employee with occupational exposure in accordance with the requirements of this section. Such training must be provided at no cost to the employee and during working hours. The employer shall institute a training program and ensure employee participation in the program.

1910.1030(g)(2)(ii)
Training shall be provided as follows:

1910.1030(g)(2)(ii)(A)
At the time of initial assignment to tasks where occupational exposure may take place;

1910.1030(g)(2)(ii)(B)
At least annually thereafter.

1910.1030(g)(2)(iii)
[Reserved]

1910.1030(g)(2)(iv)
Annual training for all employees shall be provided within one year of their previous training.

1910.1030(g)(2)(v)
Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

1910.1030(g)(2)(vi)
Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

1910.1030(g)(2)(vii)
The training program shall contain at a minimum the following elements:

1910.1030(g)(2)(vii)(A)
An accessible copy of the regulatory text of this standard and an explanation of its contents;

1910.1030(g)(2)(vii)(B)
A general explanation of the epidemiology and symptoms of bloodborne diseases;

1910.1030(g)(2)(vii)(C)
An explanation of the modes of transmission of bloodborne pathogens;

1910.1030(g)(2)(vii)(D)
An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

1910.1030(g)(2)(vii)(E)
An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

1910.1030(g)(2)(vii)(F)
An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

1910.1030(g)(2)(vii)(G)
Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

1910.1030(g)(2)(vii)(H)
An explanation of the basis for selection of personal protective equipment;

1910.1030(g)(2)(vii)(I)
Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

1910.1030(g)(2)(vii)(J)
Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

1910.1030(g)(2)(vii)(K)
An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

1910.1030(g)(2)(vii)(L)
Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

1910.1030(g)(2)(vii)(M)
An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and

1910.1030(g)(2)(vii)(N)
An opportunity for interactive questions and answers with the person conducting the training session.

1910.1030(g)(2)(viii)
The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

1910.1030(g)(2)(ix)
Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

1910.1030(g)(2)(ix)(A)
The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

1910.1030(g)(2)(ix)(B)
The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

1910.1030(g)(2)(ix)(C)

The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

1910.1030(h)
Recordkeeping -

1910.1030(h)(1)
Medical Records.

1910.1030(h)(1)(i)
The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

1910.1030(h)(1)(ii)
This record shall include:

1910.1030(h)(1)(ii)(A)
The name and social security number of the employee;

1910.1030(h)(1)(ii)(B)
A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

1910.1030(h)(1)(ii)(C)
A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

1910.1030(h)(1)(ii)(D)
The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

1910.1030(h)(1)(ii)(E)
A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

1910.1030(h)(1)(iii)
Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:
1910.1030(h)(1)(iii)(A)
Kept confidential; and

1910.1030(h)(1)(iii)(B)
Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

1910.1030(h)(1)(iv)
The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

1910.1030(h)(2)
Training Records.

1910.1030(h)(2)(i)
Training records shall include the following information:

1910.1030(h)(2)(i)(A)
The dates of the training sessions;

1910.1030(h)(2)(i)(B)
The contents or a summary of the training sessions;

1910.1030(h)(2)(i)(C)
The names and qualifications of persons conducting the training; and

1910.1030(h)(2)(i)(D)
The names and job titles of all persons attending the training sessions.

1910.1030(h)(2)(ii)
Training records shall be maintained for 3 years from the date on which the training occurred.

1910.1030(h)(3)
Availability.

1910.1030(h)(3)(i)
The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

1910.1030(h)(3)(ii)
Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.

1910.1030(h)(3)(iii)
Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

1910.1030(h)(4)
Transfer of Records. The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

1910.1030(h)(5)
Sharps injury log.

1910.1030(h)(5)(i)
The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

1910.1030(h)(5)(i)(A)
The type and brand of device involved in the incident,

1910.1030(h)(5)(i)(B)
The department or work area where the exposure incident occurred, and

1910.1030(h)(5)(i)(C)
An explanation of how the incident occurred.

1910.1030(h)(5)(ii)
The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR part 1904.

1910.1030(h)(5)(iii)
The sharps injury log shall be maintained for the period required by 29 CFR 1904.33.

1910.1030(i)
Dates -

1910.1030(i)(1)
Effective Date. The standard shall become effective on March 6, 1992.

1910.1030(i)(2)
The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.

1910.1030(i)(3)

Paragraphs (g)(2) Information and Training and (h) Recordkeeping of this section shall take effect on or before June 4, 1992.

1910.1030(i)(4)
Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs of this section, shall take effect July 6, 1992.
[56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996; 66 FR 5325 Jan., 18, 2001; 71 FR 16672 and 16673, April 3, 2006; 73 FR 75586, Dec. 12, 2008; 76 FR 33608, June 8, 2011; 76 FR 80740, Dec. 27, 2011; 77 FR 19934, April 3, 2012]