## TABLE OF CONTENTS

A. Introduction ............................................................................................................. 3  
B. Personnel Training Requirements ........................................................................... 5  
C. Personal Protective Equipment ............................................................................. 7  
D. Biosafety Cabinets .................................................................................................. 8  
E. Sharps and Prevention of Skin Lacerations, Abrasions and Punctures ................. 11  
F. Spill Response and Cleanup ................................................................................ 12  
G. Occupational Medical Program ............................................................................ 14  
H. Shipping and Receiving Biological Materials ....................................................... 18  
I. Exposure Control Plan for Bloodborne Pathogen .................................................... 19  
J. Disinfection and Sterilization ............................................................................... 24  
K. Treatment and Disposal of Biological Waste ...................................................... 26  
L. Reference Documents
A. INTRODUCTION

Tufts University (TU) is responsible for ensuring that scientific research associated with human source material is conducted safely and in compliance with federal, state and local regulations. This Exposure Control Plan (ECP) covers scientific biological research that uses human blood, unfixed human tissue and human cell lines conducted on TU campuses located in Boston, Medford, Somerville, and Grafton, Massachusetts. In order to fulfill this responsibility, TU:

NOTE: Refer to the TU/TMC Biosafety Manual to assess whether the proposed experiment is regulated by this Plan only or also regulated by the Tufts Institutional Biosafety Committee (IBC).

- Require that principal investigators (PIs) responsible for research covered by federal, state, and local regulations comply with the various provisions of the Exposure Control Plan and provide assistance to these PIs accordingly.

- Ensure appropriate training for the PIs, laboratory supervisors, and laboratory staff regarding OSHA 1910.1030 Bloodborne Pathogens and additional regulations referred to. Initial training and annual training is required by this regulation for all persons handling human source material (HSM) as defined herein.

- Determine the necessity for medical surveillance of personnel following an Exposure Incident in which one or more individuals has contact with HSM via any of several routes of exposure including skin, mucous membrane, inhalation or ingestion.

FEDERAL RULES

OSHA enacted the Bloodborne Pathogens (BBP) Standard in order to reduce or eliminate exposures to and infections from BBP such as human immunodeficiency virus (HIV-1, HIV-2), SIV, and the hepatitis viruses. This regulation applies to all researchers working with human or non-human primate blood, blood products, tissues, cells, bodily fluids, or other items that can be assumed to contain or be contaminated with BBP. A copy of the OSHA BBP Standard, Title 29 Code of Federal Regulations (CFR) Section 1910.1030, is available from Tufts Environmental Health and Safety (EH&S) and at the webpage provided in the Reference section.

Universal Precautions is a key element of the OSHA BBP Standard and must be followed by all laboratories that are rated as Biosafety Level (BL) 2 or higher. Universal Precautions is an approach to infection control under which all human blood and certain human bodily fluids are treated as if known to be infectious for HIV, HBV, and/or other BBPs. For example, blood from any source should be handled as having BBPs, even if it is from an HIV-seronegative control donor.
OSHA BBP Standard:

NEW INVESTIGATOR INFORMATION

This section outlines the requirements for new investigators proposing to conduct scientific research at TU. The information is broken down based on the type of work.

Experiments Involving the Use of Human Blood, Body Fluids, Tissues or Human Cell Lines

Prior to initiating experiments involving these agents, the TU Investigator must read this Exposure Control Plan. Upon employment and annually thereafter, all staff members who will be involved in such experiments must attend OSHA-required BBP training and receive information on a Hepatitis B vaccination (This section does not apply to TMC Employees).

PRINCIPAL INVESTIGATOR RESPONSIBILITIES

The PI is responsible for complying fully with all Federal, State, Local and TU/TMC Guidelines for research involving human blood, human tissue, and human cell lines.
B. PERSONNEL TRAINING REQUIREMENTS

TRAINING REQUIREMENTS FOR TECHNICAL STAFF

All laboratory staff members, including students, postdoctoral trainees, research scientist, interns, volunteers, and summer students, must be adequately trained to handle human or non-human primate blood, tissues or cells. Individual training for technical staff members includes:

- The biology of the organisms, chemicals or other agents used in experiments with emphasis on potential biohazards,

- Good aseptic techniques

- OSHA-mandated BBP training

- Proper techniques for decontamination, disinfection and waste handling,

- Radioactive Materials and High Hazard chemical handling if appropriate.

- All aspects of the Tufts Research and Laboratory Safety Guide, also called the Red Book (All laboratories should have a copy of this manual. If one is NOT available, call the campus EH&S Office or Biosafety Officer to obtain one.)

- Laboratory-specific safety training provided by Principal Investigators and TEH&S. Please refer to the training checklists found at http://publicsafety.tufts.edu/chs/training/

Before staff members can begin work, they must:

- Read the Tufts Exposure Control Plan

- Read the Tufts Research and Laboratory Safety Guide. Lab safety training is also required.

- Complete any required medical surveillance steps

- Demonstrate working knowledge to the PI of all relevant safety practices, with an understanding of the research they will undertake and its potential hazards. Laboratories must keep a record of all staff training.
TRAINING REQUIREMENTS FOR NON-TECHNICAL STAFF

The Biosafety Officer will train all non-technical staff members as to the potential hazards with biological research in general.

- All such workers are shown the universal biohazard and radiation signs and instructed to avoid, if at all possible, areas posted with such signs.

- In general, all non-technical staff members (except glassware washers and custodial staff) must not enter the laboratory research area, unless properly supervised by a technical staff member.

In addition to the above training, custodians must become familiar with the laboratory area where they must go in order to perform their duties.

- They must be instructed not to handle any containers designated for radioactive or biohazardous waste and to avoid refrigerators, freezers, and other containers designated for storage of biological or radioactive materials.

- All non-technical staff are prohibited from any areas designated for BSL2, BSL3, ABSL2 or ABSL3 activity while such work is in progress.

Glassware washers must be fully informed of all waste disposal procedures, particularly autoclaving methods, as well as emergency procedures for handling spills of biohazardous materials.
C. PERSONAL PROTECTIVE EQUIPMENT

As discussed in Chapter D, PPE is an essential element of laboratory safety, and must be provided to all staff members free of charge. PPE provided to staff members includes, but is not limited to:

- Gloves
- Laboratory coats (impervious)
- Side shields (for glasses)
- Face shields/masks
- Safety glasses
- Prescription safety glasses
- Goggles
- Hoods
- Shoe covers
- Respiratory protection
- Other site-specific personal protective equipment

At a minimum, laboratory personnel must wear gloves and a laboratory coat whenever handling biological agents, cells and tissues. Safety glasses with side shields, goggles, or face shield must be worn when these materials could potentially be splashed in the face. Laboratory personnel should wear other personal protective equipment (apron, face shield, mask, etc.) as needed or required to prevent potentially infectious materials from reaching their clothes, skin, eyes, mouth, or other mucous membranes. PPE must be removed prior to leaving the work area and placed in designated areas. PPE must be treated as medical waste when discarded. If PPE is not disposable, it must be cleaned with disinfectant before and after use. Lab coats are not laundered at home. You may wish to consult the Tufts PPE Plan http://publicsafety.tufts.edu/ehs/files/PPE_Plan_2012.pdf
D. BIOSAFETY CABINETS

Biological safety cabinets (BSCs) provide a primary level of containment for working safely with potentially hazardous biological materials. When combined with good microbiological practices, BSCs can protect both laboratory personnel and the environment. Although many may think that the principal function of BSCs is to protect cells and cultures from contamination by bacteria and fungi, their primary purpose is to protect the laboratory workers from exposures to potentially infectious agents.

BSCs are designated as Class I, II, or III based on specific airflow patterns within the BSC and on the locations of high efficiency particulate air (HEPA) filters within the unit (Table E.1). HEPA filters are usually composed of a pleated sheet of borosilicate fiber material that has been treated with a wet-strength water-repellent binder. These filters are specifically designed to remove particles equal and greater than 0.3 microns with an efficiency of 99.97%. This filtration level will capture a majority of bacteria, spores, and viruses from the filtered air. Figure E.1 illustrates typical airflow patterns in a BSC.

<table>
<thead>
<tr>
<th>New NSF Class and Type</th>
<th>Previous NSF Class and Type</th>
<th>Face Velocity (linear ft./min.)</th>
<th>Airflow Pattern</th>
<th>Use of Volatile Toxic Chemicals and Radionuclides</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>II, A</td>
<td>75</td>
<td>70% of intake air recirculated; 30% exhausted from a common plenum to the room. Plenum contaminated with biological materials under positive pressure</td>
<td>No</td>
</tr>
<tr>
<td>A2</td>
<td>II, A/B3</td>
<td>100</td>
<td>70% of intake air recirculated; 30% exhausted from a common plenum to the room. Plenum contaminated with biological materials under negative pressure or surrounded by negative pressure</td>
<td>Yes (small amounts²)</td>
</tr>
<tr>
<td>A2</td>
<td>II, B3</td>
<td>100</td>
<td>70% of intake air recirculated; 30% exhausted from a common plenum to the room. Plenum contaminated with biological materials under negative pressure or surrounded by negative pressure.</td>
<td>Yes (small amounts)</td>
</tr>
<tr>
<td>B1</td>
<td>II, B1</td>
<td>100</td>
<td>40% of intake air recirculated; 60% exhausted from cabinet; exhaust air pulled through dedicated exhaust duct into facility exhaust system. All plenums contaminated with biological materials are negative to the room or surrounded by negative pressure plenums.</td>
<td>Yes (small amounts²)</td>
</tr>
<tr>
<td>B2</td>
<td>II, B2</td>
<td>100</td>
<td>No intake air recirculated; 100% exhausted from cabinet. Exhaust air pulled through dedicated exhaust duct into facility exhaust system. All ducts and plenums are under negative pressure; all ducts contaminated with biological materials are under negative pressure or surrounded by directly exhausted negative pressure ducts or plenums.</td>
<td>Yes (small amounts)(^2)</td>
</tr>
</tbody>
</table>

| NSF | National Sanitation Foundation |
| ft/min. | feet per minute |

\(^1\) Information from Baker Labs.
\(^2\) Under no circumstances should the chemical concentration approach the lower explosion limits of the compound.

**Figure E.1** Class II, Type B1 Biological Safety Cabinet (classic design). B. sash, C. exhaust HEPA filter, D. supply HEPA filter. E. negative pressure exhaust plenum, F. blower, G. additional HEPA filter for supply air. Note: The cabinet's exhaust needs to be connected to the building exhaust system. (Figure taken from BMBL5).

Following the procedures below will ensure optimal operation of a BSC:

- Front and rear grills are kept free of objects to allow proper air intake;
- Sash should not be raised above the specified level;
- Bunsen burner use is avoided to prevent airflow disruptions and damage to the HEPA filter; and
• Annual certification must be performed.

BSCs are required to be tested and certified annually by qualified technicians. BSCs must also be certified when they are first installed and whenever they are moved, even to a nearby laboratory, because the HEPA filters may be dislodged from their proper fitting during these moves. Laboratory personnel should contact the EH&S Office for additional assistance with BSC certifications.
E. SHARPS

Some of the most serious accidents in biological laboratories are those caused by puncture wounds through skin (percutaneous exposures). All objects that can puncture skin are designated as sharps. Examples of sharps include hypodermic needles, glass Pasteur pipettes, razor blades, broken glass, and suture needles. Massachusetts regulations classify any item that may cause punctures or cuts as a sharp, and require special disposal treatment. Sharps must be disposed of separately from all other waste streams. This is accomplished by segregating sharps waste from other wasted (i.e. regulated medical waste) and placing sharps waste into hard-walled plastic containers for commercial pick up and disposal.

Federal regulations concerning sharps primarily focus on work with human bodily fluids. Researchers are encouraged to use engineered sharps if the research work conducted is with animals only; however, retractable needles, are recommended for use whenever practical. Because the majority of laboratory biohazard injuries are due to hypodermic needles, special attention has focused on their use and disposal. Some guidelines include:

- Laboratory staff should minimize the use of needles and syringes.
- Staff should not bend, shear or break needles.
- Staff should not recap needles.
- Staff should not remove needles from syringes.
- Staff should throw away the entire syringe-needle combination.
- Staff must not fill sharps containers more than ¾ full.
- Laboratory staff should be careful during cleanup; some sharp items may be hidden in the waste materials.
- If a staff member does stick him/herself, the injured area washed, then medical attention immediately sought.

In response to the Needlestick Safety and Prevention Act, OSHA revised the BBP Standard 29 CFR 1910.1030 in 2001. The revised standard clarifies the need for employers to select needle devices that are safer than a basic needle and syringe, and to involve employees in identifying and choosing these devices. The updated standard also requires employers to maintain a log of injuries from contaminated sharps.
F. SPILL RESPONSE AND CLEANUP

If a large volume of a biological material spills or if equipment (e.g., a centrifuge, homogenizer, or biosafety cabinet) malfunctions while processing biological materials, laboratory personnel should leave the area to allow aerosols to settle, following normal exit procedures, and call the Tufts Biosafety and/or EH&S office for immediate consultation to implement appropriate measures to contain the spill. To manage small spills of blood, bodily fluids, or other potentially infectious materials, the following procedures are recommended:

- **Wear gloves and proper protective clothing.** Heavyweight, puncture-resistant, utility gloves should be worn over disposable latex or nitrile gloves. If the spill contains broken glass or other objects, these should be removed and discarded without contact with the hands. In addition, full face protection, such as a face shield or goggles with a surgical mask, should be worn while cleaning up the spill. Respiratory protection, such as an N-95 respirator or a PAPR, should be worn if the material spilled possess an aerosol transmission risk. Rigid sheets of cardboard used as a "pusher" and "receiver" may be used to handle such objects and should be discarded with the objects into an appropriate biohazard container. If the spill is large and/or there is a potential of contaminating the worker’s shoes, water-impermeable shoe covers should be worn.

- **Absorb the spill.** Because most disinfectants are less active, or even ineffective in the presence of the high concentrations of protein found in blood and serum, the bulk of the spilled liquid should be absorbed prior to disinfection, using disposable absorbent material (e.g., paper towels, gauze pads, or tissue paper wipes). If the spill is large, granular absorbent material may be used to absorb the liquid. Absorbent granular material, which contains a chemical that releases chlorine upon wetting, is commercially available (e.g., Isolyzer). However, its efficacy for disinfection is unknown and, therefore, it should not be relied upon to disinfect a spill. After absorption of the liquid, all contaminated materials should be discarded as solid biological waste.

- **Clean the spill site** of all visible spilled material using an aqueous detergent solution. Any household detergent may be used. The intent is to dilute the spilled material, lyse red blood cells, and further remove proteins from the contaminated area. Absorb the bulk of liquid prior to disinfection to prevent dilution of the disinfectant. The use of a disinfectant detergent is not necessary.

- **Disinfect the spill site** using an appropriate intermediate to high-level hospital disinfectant, such as a dilution of household bleach (see Table 1.1). Flood the spill site or wipe down the spill site with disposable towels soaked in disinfectant to make the site "glistening wet."
  **Note:** If bleach does not disinfect the material, then using an EPA-approved disinfectant, then ensuring the proper contact time prior to disposal, are required.

- **Rinse the spill site** with water to remove any noxious chemicals or odors. Dry the spill site to prevent slipping.
- **Doff PPE and dispose** all disposable materials used to decontaminate the spill into a solid biological waste container. Handle the material in the same manner as other infectious waste.

- **Remove Gloves and Wash hands** at the completion of the spill decontamination and clean up and before leaving the laboratory. Gloves should be the final PPE doffed upon completion of cleaning up a small spill.
G. OCCUPATIONAL MEDICAL PROGRAM

During the course of their work, some TU/TMC employees are at the risk of exposure to biological agents that can cause injury and disease and to materials, which are known to or may harbor such biological agents. The PI and laboratory supervisor in partnership with the IBC and the EH&S Biosafety Program make every effort to minimize exposures through engineering controls, administrative controls, correct work practices and the use of personal protective equipment.

The Occupational Medical Program (OMP) provides several services to individuals exposed to select agents and toxins, infectious agents and laboratory animals. These services include:

MEDICAL SURVEILLANCE

The purpose of the medical surveillance component is to identify persons who, because of certain medical conditions, are at a higher risk of injury or disease. In addition, the program identifies changes over time in the medical condition of each employee that may affect their resistance to disease. Actions include:

a. review of baseline medical questionnaire
b. review of respirator questionnaire
c. review of annual medical questionnaire

LIMITED PHYSICAL EXAMINATIONS

The purpose of the examinations is to investigate specific conditions identified in the medical questionnaire.

VACCINATIONS

There are vaccinations available for certain infectious agents, including, but not limited to Hepatitis B.

DIAGNOSTIC TESTING

Diagnostic testing offered to employees includes Tuberculosis testing-PPD, pulmonary function testing and antibody titer evaluation using a commercial clinical laboratory.

Cummings School of Veterinary Medicine at Tufts University: A physician is on call 24 hours a day, 7 days a week to respond to suspected occupational infections or diseases.

School of Medicine in Boston: The Occupational Medical provider (from 7:30 am to 5:00 pm Monday through Friday) or alternate medical coverage (the on-call Tufts Medical Center ID Fellow and ID Attending or the emergency department) is on call or available 24/7 to respond to incidents in which workers sustain an exposure to infectious agents through laceration, splash,
spray, spill, ingestion or inhalation of aerosolized infectious agents. The 24/7 contact information will be posted in the laboratory.

**LIMITED MEDICAL TREATMENT**

Limited medical treatment is offered, along with referral to other medical service providers, including referring employees to their primary medical care provider.

**MEDICAL PROGRAM CONSULTATION**

Medical program consultation to Tufts Administration and designated committees, including the IACUC and the IBC, is also offered.

**MEDICAL RECORDS MANAGEMENT**

All medical information is maintained in a secure and confidential manner.

**OMP PARTICIPATION**

Employees whose work activities require contact with or handling of the following materials must participate in the OMP:

- Staff exposed to or handling human blood, blood products or other potentially infectious materials including human cell lines (OSHA 1910.1030).

- Staff that must wear respiratory protective devices as part of routine procedures or emergency procedures.

- Staff whose medical condition might warrant special precautions, such as HIV infection, immunosuppressive conditions, or drug therapy that suppresses the immune system.

**ROLES AND RESPONSIBILITIES**

The OMP is a cooperative effort among the EH&S Office, the schools and departments that sponsor covered activities, and the relevant supervisors and employees.

**Environmental Health and Safety Office**

The TU EH&S Office’s specific responsibilities for TU employees are to:
- Identify, review and select qualified occupational medical services providers on each campus;
- Administer the OMP on the Medford and Grafton campuses;
- Coordinate payment for all of the costs associated with the program; and
• Evaluate the OMP annually and correct deficiencies.

Schools and Departments

The schools and departments’ specific responsibilities are to:
• Support supervisors’ training in the requirements of the OMP and their duties within the
  program; and
• In the case of Boston DLAM, administer the OMP on the Boston campus.

Supervisors

Supervisors’ specific responsibilities are to:
• Assess the job functions for each employee to determine whether participation in the OMP is
  required; and
• Follow-up with employees to ensure that necessary forms have been completed and submitted
  to the physician or other provider.

Employee

The employee’s specific responsibilities are to:
• Complete the OMP form(s) and discuss his or her essential job activities to determine whether
  participation is voluntary or mandatory;
• Complete the basic medical questionnaire;
• Complete the medical information release form;
• If respiratory protective devices are required for the safe conduct of essential work activities,
  complete the OSHA Respiratory Protection questionnaire; and
• Submit completed questionnaires to the Occupational Medical Services Provider by hand,
  mail, email or other method that protects the confidentiality of the information provided.
PROCEDURE

The OMP provider will review the basic medical questionnaire and if required, the OSHA respiratory protective device questionnaire; and determine whether there are any medical conditions that require additional follow-up. The follow-up actions range from requesting responses to additional questions to scheduling an appointment for a physical examination and, as necessary, ordering diagnostic tests.

Potential areas for additional medical review include:

- Employee’s immunization records are incomplete, requiring additional information about immunization status.
- Employee reports significant allergy or asthma conditions, or specific allergies to laboratory animals.
- Employee reports conditions that could significantly affect his or her ability to wear a respirator.
- Employee reports condition(s) that could affect normal immunity and resistance to infection.

PREGNANCY

Women of child bearing age should be aware of the risks associated with studies using certain infectious agents that are known to affect embryonic development. Researchers living with women of childbearing age should also know of the risks, as they should be especially careful to NOT bring infectious agents home on clothing or other laboratory materials.

Pregnant researchers or those who wish to become pregnant, along with their household members, are encouraged to meet with the OMP provider and EH&S Office to discuss risks and precautions associated with their work. In addition, it is recommended that these researchers inform their obstetrician and gynecologist of any infectious agents and any chemicals encountered at work.
H. SHIPPING AND RECEIVING BIOLOGICAL MATERIALS

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

The PHS defines etiological agents as viable microorganisms and microbial toxins that cause disease in humans; infectious substances are those substances that contain etiologic agents. As most specimens are shipped by air or by a carrier that may ship by air, we will concentrate on IATA terminology and definitions. Infectious substances are known or reasonably expected to contain pathogens. The pathogens are divided into two main categories. Category A is defined as an infectious substance capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals upon exposure. An example would be a culture of Hepatitis B Virus (HBV). However a serum specimen containing HBV can usually be assigned to Category B for several reasons. One is that the viral concentration is lower in serum than in culture. Culture intentionally propagates pathogens. IATA defines exposure as physical contact when the infectious substance is released outside of the packaging. Thankfully intact skin generally provides a barrier. Note that IATA and the OSHA Bloodborne Pathogen Standard do not agree on term definitions. Both packaging and paperwork are more extensive for Category A materials.

Fortunately there are additional definitions for other less hazardous materials. Note there is no requirement for an airline or a courier to accept what are termed “dangerous goods”. Requirements that exceed the regulations may be imposed by an airline or courier. They are binding on the shipper. People cannot put infectious substances in either checked or carry-on baggage.

All researchers shipping or receiving potentially hazardous materials, including select agents, infectious agents, genetically modified organisms and dry ice, must have DOT/IATA shipping training. This training is provided by TEH&S (http://publicsafety.tufts.edu/ehs/training/schedule/)

There are many regulations on how and where select agents may be used and transported. The list of select agents is available at the CDC website: http://www.selectagents.gov. Some agents on the list have exemption amounts; refer to the website for details.
I. EXPOSURE CONTROL PLAN FOR BLOODBORNE PATHOGENS (1910.1030)

OVERVIEW

The purpose of this Exposure Control Plan (ECP) is to minimize or prevent TU employees' exposure to bloodborne pathogens (BBPs), and by controlling exposure, prevent infection and disease. BBPs are pathogenic microorganisms that are transmitted primarily through blood, human tissue and human cell lines.

This plan is intended to comply with the requirements of 29 CFR 1910.1030(c).

BBPs include human immunodeficiency virus (HIV), Hepatitis B and C viruses and 30 other microbial agents that may contaminate human blood. BBPs may contaminate human blood, blood products, organs, tissues, other bodily fluids and human cell lines.

Universal precautions states that all human blood or other potentially infectious materials must be assumed to be contaminated with one or more pathogens and must be stored, processed and disposed of in accordance with this ECP.

COMPONENTS OF ECP

A. Exposure determination

This plan covers any employee that handles human blood or other potentially infectious material in the research laboratory. Tufts University is required to identify all jobs within the University that should be classified as jobs where there is a potential for exposure to Bloodborne Pathogen material or otherwise Potentially Infectious Material (OPIM) as defined in the standard.

**Outside Research laboratories:** the identification of jobs with potential exposure is done by the supervisor. Supervisors are encouraged to work with TEHS to provide appropriate training to their staff. Risky activities may involve work with knives, blades, clean-up of human blood, maintenance or repairs on equipment contaminated with blood or OPIM. Supervisors are asked to remind employees to report exposure to blood or human body fluids that are not sweat, saliva or tears. Employees should contact the Tufts Police if they are not trained to clean-up these fluids. Job classifications that fall under this category are custodial, facilities and police personnel.

**In Research laboratories:** identification is done through a requirement where Principal Investigators must register all work with human source material, OPIM, and human cell lines, with the Institutional Biosafety Committee. All individuals are identified as an individual that has the potential for exposure to bloodborne pathogens. A database of these individuals is kept in the Tufts EHS Office. Employees identified as potentially exposed individuals must attend Bloodborne Pathogen training within 90 days of start date and annually thereafter.
The following is a list of tasks and procedures, in which occupational exposure may occur for individuals under this category:

- Working in HIV and HBV research laboratories, where the culture, production, concentration, experimentation, or manipulation, of HIV or HBV occurs.
- Use of needles or other sharp devices. A puncture of the skin via a needle or other sharp device that is contaminated with human blood, tissue or body fluid is considered a high risk route of exposure to a bloodborne pathogen.
- Handling human material, blood, OPIM or human cell lines: The manipulation of this material can result in exposure to non-intact skin, aerosol exposure to mucous membranes, or, the most unlikely route of ingestion.
- Working with animals that have been infected with or exposed to bloodborne pathogens, OPIM, or human cells. Percutaneous injuries (needle sticks while performing injections, bites and scratches) are the most likely route of exposure when work with animals.

B. Vaccination program

TU will make available the HBV vaccination, at no cost, to all employees who have occupational exposures to BBP. Those who decline to take part in the vaccination program must sign the "Vaccination Declination Form." However, they will have the opportunity to be vaccinated at a later date.

C. Exposure incident

An exposure incident is defined as a specific event in which blood or other potentially infectious materials come into contact with the eye, mouth, other mucous membrane, non-intact skin, or penetrate through the intact skin via needle, broken glass or laceration. Any affected employee must report all exposures must be reported to his or her supervisor and the EH&S Office.

D. Post exposure evaluation and follow-up

The EH&S Office will offer all employees who incur exposure post-exposure evaluation and follow-up according to the OSHA standard. The OMP provider will provide all post-exposure follow-ups. In some instances, if the employee saw a physician at a hospital emergency room, that physician may provide the post-exposure follow-up.

The OMP provider responsible for the employee's HBV vaccination is provided with the following:
- A description of the exposed employee's duties as they relate to the exposure incident.
- A description of the route of exposure and circumstances under which exposure occurred.
- Results of the source individuals blood testing, if available.
- All medical records relevant to the appropriate treatment of the employee including vaccination status.
The OMP provider's written opinion for HBV vaccination must be limited to whether HBV vaccination is indicated for an employee, and if the employee has received such vaccination. The OMP provider's written opinion for post-exposure follow-up is limited to the following information:

- A statement that the employee has been informed of the results of the evaluation.
- A statement that the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials (OPIM), which require further evaluation or treatment.

NOTE: All other findings or diagnosis shall remain confidential and will not be included in the written report.

E. Communication of hazards to employees

1. Labels and signs
   Containers of regulated waste, refrigerators, and freezers containing blood or OPIM; and other containers used to store, transport, or ship blood or OPIM must be labeled with the biohazard warning label. The label must incorporate the universal biohazard sign and a predominant florescent orange or orange-red background with contrasting letter and symbol.

Informational signage will be posted at the entrance to laboratories where researchers are working with BBP or other infectious materials.

2. Training of TU employees on the BBP Standard and this ECP will be conducted annually by TU EH&S Office.

F. Control of hazards

**Personal Protective Equipment**

Personal Protective Equipment (PPE) is a secondary line of defense against BBP exposures. TU/TMC staff must be trained in the use of the appropriate PPE for their job classifications and for the activities they perform with BBP. Additional training will be provided by PIs or their designees, e.g., when an employee takes a new position or new job functions are added. BBP training is a component of the safety training provided by the EH&S Office. BBP training is an annual requirement for laboratory employees working with BBP.

The following procedures are implemented during the handling of BBP:

- A laboratory coat is worn whenever potential exposure is anticipated.
- If any garments are penetrated by blood or other infectious materials, they are removed immediately, or as soon as is feasible.
• All PPE is removed prior to leaving a work area.
• Gloves are worn in the following circumstances:
  – Whenever employees anticipate hand contact with OPIMs.
  – When handling or touching contaminated items or surfaces.
• Disposable gloves are replaced as soon as practical after contamination or if they are torn, punctured, or otherwise lose their ability to function as an exposure barrier.
• Utility gloves are decontaminated for reuse unless they are cracked, peeling, torn, or exhibit other signs of deterioration.
• Full-face protection, such as facemasks, face shields, and eye protection, is used whenever splashes or sprays may generate droplets of infectious materials.
• Head covers/hoods and/or shoe covers/boots are used in any instances where gross contamination is anticipated, such as perfusion activities.

**Engineering and Work Practice Controls**

In addition to PPE use, the following engineering and work practice controls are used at TU/TMC:

• Hands and any other skin are washed with soap and water, and eyes or mucous membranes are flushed with water immediately or as soon as feasible following contact of such body areas with blood or OPIM.
• Contaminated needles and other contaminated sharps are not bent, recapped, or removed from their syringes.
• After use, sharps (e.g., needles, scalpels, razor blades, Pasteur pipettes, etc.) are placed in red, fluorescent orange or orange-red leak proof, rigid, puncture-resistant, shatterproof containers that are marked prominently with the universal biohazard warning symbol and the word “Biohazard” in a contrasting color.
• Eating, drinking, chewing gum, smoking, applying cosmetics, and handling contact lenses are prohibited in work areas where exposure to infectious materials may occur.
• Food and drink are not kept in refrigerators, freezers, on countertops, or in other storage areas where blood or OPIM are present.
• Procedures involving blood or OPIM are performed carefully to minimize splashing, spraying, splattering, and producing droplets or aerosols of blood or OPIM.
• Mouth pipetting/suctioning of blood or OPIM are prohibited.
• All equipment and work surfaces are cleaned and disinfected on a routine basis and as soon as possible following spills or other exposure to blood or OPIM.
• Leak-proof, labeled containers are used for disposal of contaminated waste.
• Biosafety cabinets (BSCs) are used as primary containment of BBP and OPIM.
• The use of safer medical devices, such as self-shielding needles, is advised to help reduce needle sticks and other sharps injuries.

G. HIV and Hepatitis B laboratories

This ECP applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. Such research laboratories and production facilities are also required to meet the criteria of BSL-2.
This ECP does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs.

H. Medical and biological waste processing (see Chapter J, “Treatment and Disposal of Biological Waste” that follows)

I. Recordkeeping

Medical records shall be maintained in the occupational medical clinics (Boston/Grafton) in accordance with OSHA Standard 29 CFR 1910.20. These records shall be kept confidential, and must be maintained for at least the duration of employment plus 30 years.
**J. DISINFECTION AND STERILIZATION**

Disinfection is the planned reduction of the concentration of microbial agents and is therefore a relative term. Generally disinfection is used to describe the elimination of microbial agents but not necessarily their spores; ethanol is a commonly used disinfectant. By contrast, sterilization is an absolute term, which means the planned elimination of all microbial agents. Sterilization eliminates all biological agents, including their spores, and can be chemical or physical; autoclaving is the most commonly used sterilant within the laboratory.

Microbial agents exhibit a range of resistance to chemical and physical agents. A summary of disinfectants and their uses follows:


<table>
<thead>
<tr>
<th>Disinfectant</th>
<th>Common dilution</th>
<th>Examples</th>
<th>Active against</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Hypochlorite (Bleach)</td>
<td>1:10 (~500ppm)</td>
<td>Austin A-1</td>
<td>+ + + + + + ± +</td>
</tr>
<tr>
<td>Chlorine Dioxide</td>
<td>1:3:1 or 1:18:1</td>
<td>MB-10 Clidx®-S</td>
<td>+ + + + + ± + +</td>
</tr>
<tr>
<td>Alcohols</td>
<td>70-85%</td>
<td>Ethanol, Isopropanol</td>
<td>+ + + ± + - +</td>
</tr>
<tr>
<td>Phenolic compounds</td>
<td>1:128 (or 0.4-5%)</td>
<td>Vesphene®</td>
<td>+ + + ± + - -</td>
</tr>
<tr>
<td>Iodophors</td>
<td>25-1600 ppm</td>
<td>Wescodyne</td>
<td>+ + + + + ± - +</td>
</tr>
<tr>
<td>Hydrogen peroxide</td>
<td>3-25%</td>
<td></td>
<td>+ + + + + ± ± ±</td>
</tr>
<tr>
<td>Quaternary ammonium</td>
<td>0.4-1.6%</td>
<td>Quatricide®</td>
<td>± + ± - - - +</td>
</tr>
<tr>
<td>Peroacetic acid</td>
<td>12-2250 ppm</td>
<td></td>
<td>+ ± + ± + + + +</td>
</tr>
</tbody>
</table>

1. (+) yes; (-) no; (±) variable.
2. Follow manufacturer’s instructions regarding concentration and contact time.
3. The use of brand names does not imply a recommendation.

Researchers must be aware of and use the appropriate means of disinfection/sterilization for the organisms involved in their research. While 70% ethanol and/or 10% bleach are the most commonly used disinfectants in the laboratory, they are not effective against all organisms used in TU/TMC research labs.
Below is the order of resistance to inactivation: from most resistant to most susceptible, some examples are also provided:

1. Bacterial spores (*Bacillus subtilis, Clostridium sporogenes*)
2. Mycobacteria (*Mycobacterium tuberculosis*, Non-tuberculous mycobacteria)
3. Non-lipid or small viruses (Poliovirus, Coxsackievirus, Rhinovirus)
4. Fungi (*Trichophyton, Cryptococcus, Candida spp*)
5. Vegetative bacteria (*Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella enterica, Enterococci*)
6. Lipid or medium-size viruses (Herpes Simplex virus, Cytomegalovirus, Hepatitis B virus, Hepatitis C virus, HIV, Respiratory syncytial virus, Influenza viruses)
K. TREATMENT AND DISPOSAL OF MEDICAL AND BIOLOGICAL WASTE

Biological waste may be disposed of in three ways: in designated biological waste boxes, by chemical disinfection, or by steam sterilization/autoclave. The PI, with IBC review and approval, will choose and use the appropriate disinfection procedures in order to ensure adequate decontamination of biological wastes. Category A Infectious Substances must never be picked up and disposed of by a commercial vendor; it must be disposed of onsite.

Prior to treatment, all solid infectious and potentially infectious waste, as well as waste containing nucleic acids, must be disposed of in designated biological waste boxes. Each box is labeled with the universal biohazard symbol (Figure J.1) and is lined with a red plastic bag to reduce the likelihood of leakage. If the waste will be sent off site for treatment, the bag is individually sealed with tape when the biological waste box is between two-thirds (2/3) and three-quarters (3/4) full. The box itself should be sealed with two-inch tape. The boxes must not be overfilled. Boxes that leak any liquid or that exceed 55 pounds will not be moved or removed for disposal.

![Universal Biohazard Symbol](image)

Figure J.1 Universal Biohazard Symbol

Solid biological waste that will be autoclaved onsite must be stored and transported in appropriate, closable, leak-proof secondary containment labeled with the Universal Biohazard Symbol.

Autoclaves used for treatment of biological waste must be calibrated at least annually by a qualified technician to ensure that correct sterilization parameters are being met. In addition, all autoclave waste runs must be logged and biological challenge testing will be performed quarterly on autoclaves used to sterilize biological waste. Quarterly testing shall be performed using a bacterial indicator organism, such as *Geobacillus stearothermophilus*, and the results logged in accordance with 105 CMR 480.

If treated solid biological waste is not sent off-site for disposal, it must be labeled or otherwise marked so as to clearly identify it as noninfectious and to identify the laboratory staff person responsible for the treatment. Failure to do so may result in fines and civil penalties. Sharps must be sent off-site for incineration and disposal.

In Massachusetts, sharps include, but are not limited to, needles, blades, contaminated broken glass and slides, all glass Pasteur pipettes, and dental wire. Sharps must be disposed of in designated sharps containers. Sharps containers must be red, fluorescent orange or orange-red,
leak proof, rigid, puncture-resistant, shatterproof containers that that are marked prominently with the universal biohazard warning symbol and the word “Biohazard” in a contrasting color. To encourage their use, sharps containers must be placed in convenient locations near work areas. Sharps containers should not be overfilled; they should be sealed for pick-up or disposal when approximately three-quarters (3/4) full.

Liquid biological and nucleic acid waste must be rendered non-infectious by steam sterilization or chemical disinfection prior to sink disposal. If chemical disinfection is selected, full-strength household chlorine bleach may be added to the waste container, such as an aspiration flask, so that the final solution concentration of bleach is 10%. Contact time should be at least 30 minutes prior to sink disposal for bleach.

If bleach is not an adequate disinfectant for the biological agent in use, the researcher must use a U.S. Environmental Protection Agency (EPA) approved disinfectant and ensure the proper contact time prior to disposal.

Before disposing of the treated solution down the sink, check the pH to ensure it is within the permissible pH range under the Massachusetts Water Resources Authority (MWRA) discharge permit (5.5 – 12.0 standard units), if applicable to the campus. If it is within the permissible range, then the researcher should use running tap water when disposing of the treated solution, to minimize possible plumbing damage from the corrosive effects of the disinfectants. In addition, use of mercury-free bleach is recommended to prevent mercury contamination in the plumbing. Autoclaving bleach-containing solutions is not permitted due to the potential for producing toxic chlorine gas.

Disinfected waste must be logged as being treated onsite or offsite. As noted earlier, the IBC must approve the method of treatment. The log for onsite treatment of waste is available at: http://www.mass.gov/ehohs/docs/dph/environmental/sanitation/105cmr480-medical-waste-on-site-log.pdf. This log would apply all waste that is disinfected on site.

For waste shipped off site as infectious waste, an off-site treatment log is used. A sample log for off-site treatment is available at:

GENERAL LABORATORY AND BIOSAFETY INSPECTIONS

TU EHS staff conduct BBP inspections prior to the initiation of regulated research and yearly or every other year thereafter in order to ensure compliance with federal regulations.

After each such annual inspection, the inspection results are transmitted to the Principal Investigator. The Principal Investigator generally has 90 days in which to correct all deficiencies. A response with a plan of correction is expected by the date noted in the letter. If necessary, the EHS staff member will recommend one or more alternatives to any non-compliant actions in order to achieve essential compliance and resolution of deficiencies.
Reference Documents

Tufts University Documents
(available on Tufts EH&S website: http://publicsafety.tufts.edu/ehs/ )

- Laboratory Safety: Respiratory Protection Program
- Laboratory Safety: Hazard Communication Plan
- Laboratory Safety: Personal Protective Equipment Plan
- Chemical Safety: Chemical Hygiene Plan
- Biological Safety: Medical and Biological Wastes
- Biological Safety: Maintaining Biosafety Cabinets
OSHA Regulations (Standards - 29 CFR)
Bloodborne Pathogens - 1910.1030

OSHA Regulations (Standards - 29 CFR) - Table of Contents

Standard Number: 1910.1030
Standard Title: Bloodborne pathogens.
Subpart Number: Z
Subpart Title: Toxic and Hazardous Substances

(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.

(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 is 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 that 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) 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 result from the performance of an employee's duties.

"Hand washing Facilities" means a facility providing an adequate supply of running potable water, soap and single use towels or hot 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.

"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 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 needle sticks, 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.

"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).
(c)
Exposure Control.

(c)(1)
Exposure Control Plan.

(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.

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

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

..1910.1030(c)(1)(ii)(B)

(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) Record keeping, of this standard, and

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

(c)(1)(iii)
Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e).

(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.

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

(c)(2)
Exposure Determination.

(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:

(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)

(c)(2)(i)(B)
A list of job classifications in which some employees have occupational exposure, and
(c)(2)(i)(C)  
A list of all tasks and procedures or groups of closely related tasks 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.

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

(d)  
Methods of Compliance.

(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.

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

(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)

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

(d)(2)(iii)  
Employers shall provide hand-washing facilities, which are readily accessible to employees.

(d)(2)(iv)  
When provision of hand-washing 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.

(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.

(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.

(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)

(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.
(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.

(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:

(d)(2)(viii)(A)
puncture resistant;

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

(d)(2)(viii)(C)
leak proof on the sides and bottom; and

(d)(2)(viii)(D)
in accordance with the requirements set forth in paragraph

(d)(4)(ii)(E) for reusable sharps.

(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.

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

(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.

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

(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.

(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.

(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 processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.
(d)(2)(xii)(C)
If the specimen could puncture the primary container, the primary container shall be placed within a secondary container that is puncture-resistant in addition to the above characteristics.

(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.

(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.

(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)

(d)(3)
Personal Protective Equipment.

(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.

(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.

(d)(3)(iii)
Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the work site 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.

(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.
(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.

(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.

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

(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.

(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.

(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.

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

(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.

(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:

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

(d)(3)(ix)(D)(2)
Make gloves available to all employees who wish to use them for phlebotomy;

(d)(3)(ix)(D)(3)
Not discourage the use of gloves for phlebotomy; and

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

[i] When the employee has cuts, scratches, or other breaks in his or her skin;
[ii] When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

[iii] When the employee is receiving training in phlebotomy.

.1910.1030(d)(3)(x)

(d)(3)(x)
Masks, Eye Protection, and Face Shields. 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.

(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.

(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).

(d)(4)
Housekeeping.

(d)(4)(i)
General. Employers shall ensure that the work site 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.

(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)

(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.

(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 work shift if they may have become contaminated during the shift.

(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.
(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 dustpan, tongs, or forceps.

(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.

(d)(4)(iii)
Regulated Waste.

..1910.1030(d)(4)(iii)(A)

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

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

[a] Closeable;

[b] Puncture resistant;

[c] Leak proof on sides and bottom; and

[d] Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

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

[a] 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);

[b] Maintained upright throughout use; and

[c] Replaced routinely and not be allowed to overfill.

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

[a] Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;

[b] Placed in a secondary container if leakage is possible. The second container shall be:

[i] Closeable;

[ii] Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and

[iii] Labeled or color-coded according to paragraph (g)(1)(i) of this standard.

(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.
(d)(4)(iii)(B) Other Regulated Waste Containment.

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

[a] Closeable;

[b] Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

[c] Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

[d] Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(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:

[a] Closeable;

[b] Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

[c] Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

[d] Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(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)

(d)(4)(iv) Laundry.

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

(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.

(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.

(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 that prevent soak-through and/or leakage of fluids to the exterior.

(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)

(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).

(e)

HIV and HBV Research Laboratories and Production Facilities.

(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.

(e)(2)

Research laboratories and production facilities shall meet the following criteria:

(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.

(e)(2)(ii)

Special Practices

(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)

(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, leak proof, labeled or color-coded container that is closed before being removed from the work area.

(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.

(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.
(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.

(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.

(e)(2)(ii)(G)

(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.

(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.

(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.

(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.

(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.

(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.

(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.

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

(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.

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

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

..1910.1030(e)(3)(i)

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

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

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

(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-door 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.

(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)

(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.

(e)(4)(iv)
Access doors to the work area or containment module shall be self-closing.

(e)(4)(v)
An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

(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 re-circulated 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).

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

(f)(1) General.

(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.

(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:

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

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

(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

(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).

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

(f)(2) Hepatitis B Vaccination.

(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.

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

(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.
(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.

(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).

(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:

(f)(3)(i)
Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

..1910.1030(f)(3)(ii)

(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;

(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.

(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.

(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.

(f)(3)(iii)
Collection and testing of blood for HBV and HIV serological status;

(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)

(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.

(f)(3)(iv)
Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

(f)(3)(v)
Counseling; and
(f)(3) (vi)
  Evaluation of reported illnesses.

(f)(4)
  Information Provided to the Healthcare Professional.

(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.

(f)(4)(ii)
  The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

(f)(4)(ii)(A)
  A copy of this regulation;

(f)(4)(ii)(B)
  A description of the exposed employee's duties as they relate to the exposure incident;

(f)(4)(ii)(C)
  Documentation of the route(s) of exposure and circumstances under which exposure occurred;

(f)(4)(ii)(D)
  Results of the source individual's blood testing, if available; and

(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.

(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.

(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.

(f)(5)(ii)
  The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

(f)(5)(ii)(A)
  That the employee has been informed of the results of the evaluation; and

(f)(5)(ii)(B)
  That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials that require further evaluation or treatment.

(f)(5)(iii)
  All other findings or diagnoses shall remain confidential and shall not be included in the written report.
(f)(6) Medical Record-keeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

(g) Communication of Hazards to Employees.

(g)(1) Labels and Signs.

(g)(1)(i) Labels.

(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).

(g)(1)(i)(B) Labels required by this section shall include the following legend:

(g)(1)(i)(C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

(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.

(g)(1)(i)(E) Red bags or red containers may be substituted for labels.

(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).

(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.

(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.

(g)(1)(i)(I) Regulated waste that has been decontaminated need not be labeled or color-coded.

(g)(1)(ii) Signs.

(g)(1)(ii)(A) The employer shall post signs at the entrance to work areas specified in paragraph (c), 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)

(g)(1)(ii)(B)
These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

(g)(2)
Information and Training.

(g)(2)(i)
Employers shall ensure that all employees with occupational exposure participate in a training program that must be provided at no cost to the employee and during working hours.

(g)(2)(ii)
Training shall be provided as follows:

(g)(2)(ii)(A)
At the time of initial assignment to tasks where occupational exposure may take place;

(g)(2)(ii)(B)
Within 90 days after the effective date of the standard; and

(g)(2)(ii)(C)
At least annually thereafter.

(g)(2)(iii)
For employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of the standard which were not included need be provided.

(g)(2)(iv)
Annual training for all employees shall be provided within one year of their previous training.

..1910.1030(g)(2)(v)

(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.

(g)(2)(vi)
Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

(g)(2)(vii)
The training program shall contain at a minimum the following elements:

(g)(2)(vii)(A)
An accessible copy of the regulatory text of this standard and an explanation of its contents;

(g)(2)(vii)(B)
A general explanation of the epidemiology and symptoms of bloodborne diseases;

(g)(2)(vii)(C)
An explanation of the modes of transmission of bloodborne pathogens;

(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;

(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)

(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;

(g)(2)(vii)(G)
Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

(g)(2)(vii)(H)
An explanation of the basis for selection of personal protective equipment;

(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;

(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;

(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;

(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)

(g)(2)(vii)(M)
An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and

(g)(2)(vii)(N)
An opportunity for interactive questions and answers with the person conducting the training session.

(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.

(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.

(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.

(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.

(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.

(h)

Record-keeping.

(h)(1)

Medical Records.

(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.

(h)(1)(ii)

This record shall include:

(h)(1)(ii)(A)

The name and social security number of the employee;

(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);

(h)(1)(ii)(C)

A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

(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)
(b)(1)(ii)(E)
A copy of the information provided to the healthcare professional as required by paragraphs (b)(4)(ii)(B)(C) and (D).

(b)(1)(iii)
Confidentiality. The employer shall ensure that employee medical records required by paragraph (b)(1) are:

(b)(1)(iii)(A)
Kept confidential; and

(b)(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.

(b)(1)(iv)
The employer shall maintain the records required by paragraph (b) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

(h)(2)
Training Records.

(h)(2)(i)
Training records shall include the following information:

(h)(2)(i)(A)
The dates of the training sessions;

(h)(2)(i)(B)
The contents or a summary of the training sessions;

(h)(2)(i)(C)
The names and qualifications of persons conducting the training; and

(h)(2)(i)(D)
The names and job titles of all persons attending the training sessions.

(h)(2)(ii)
Training records shall be maintained for 3 years from the date on which the training occurred.

(h)(3)
Availability.

(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.

(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.
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)

(b)(4)
Transfer of Records.

(b)(4)(i)
The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

(b)(4)(ii)
If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.

(i)
Dates.

(i)(1)
Effective Date. The standard shall become effective on March 6, 1992.

(i)(2)
The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.

(i)(3)
Paragraph (g)(2) Information and Training and (h) Record keeping shall take effect on or before June 4, 1992.

(i)(4)