

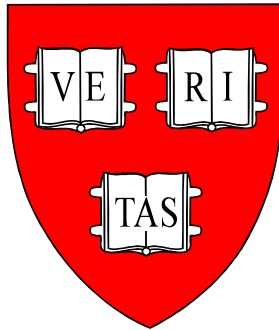
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## **HARVARD UNIVERSITY EXPOSURE CONTROL PLAN**

In 1991 the Occupational Safety and Health Administration (OSHA) issued a standard on Occupational Exposure to Bloodborne Pathogens. Its purpose is to ensure that workers are protected from exposure to the *Human Immunodeficiency Virus* (HIV), *Hepatitis B Virus* (HBV), and other disease causing organisms in human blood, body fluids, and tissues.

The Harvard University Biosafety Office has prepared this manual to be used as a guide in developing a site-specific plan for reducing exposures to bloodborne pathogens in your workplace. It also summarizes pertinent Harvard University Policies and Procedures.

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Boston, MA 02115  
Tel. No. 432-1720  
Fax No. 432-4730

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## I. BLOODBORNE PATHOGENS 101

### ***What are bloodborne pathogens?***

Bloodborne pathogens are pathogenic microorganisms present in human blood and are capable of causing disease in humans. These pathogens may be present in other potentially infectious materials: body fluids, tissues, and organs from infected persons and experimental animals.

### ***What are the most common types of bloodborne pathogens?***

Hepatitis B Viral Infection is caused by the *Hepatitis B Virus* (HBV) which was formerly known as "*serum hepatitis*". Of all bloodborne diseases, *HBV* poses the greatest risk for infection among health care providers and laboratory researchers because it can be easily transmitted through needle sticks and other types of percutaneous exposures. The virus causes inflammation of the liver and can lead to serious and occasionally fatal disease. An effective vaccine is available and should be offered to workers who may be exposed.

Hepatitis C Viral Infection is caused by the *Hepatitis C Virus* (HCV) and was formerly known as "*non /non B viral hepatitis*". *HCV* also poses a risk for infection among health care providers and laboratory researchers because it is transmitted through needle sticks and other types of percutaneous exposures. Similar to *HBV*, the virus causes inflammation of the liver and can lead to serious and occasionally fatal disease. Specific diagnostic tests for *HCV* have only become available recently. Although there is no vaccine available to prevent *HCV*, interferon has been used in some cases as with chronic *HBV* conditions.

Acquired Immunodeficiency Syndrome (AIDS) is a disease caused by *Human Immunodeficiency Virus* (HIV). *HIV* is a retrovirus which suppresses the immune system leaving the infected individual vulnerable to opportunistic infections and cancers. These infections become increasingly severe and eventually lead to death. No cure for *HIV* has been found. Drug prophylaxis such as AZT is available, although its efficacy is debated within the medical community. Protease inhibiting drugs have slowly become a part of the treatment process and seems to hold some promise according to some medical experts.

In addition to *HIV*, *HBV*, and *HCV*, other viruses, bacteria and parasites may also be present in blood, human body fluids, or tissues. Some of them are:

<b><u>DISEASE</u></b>	<b><u>CAUSATIVE AGENT</u></b>
<b>SIV Infection</b>	Simian Immunodeficiency Virus
<b>Malaria</b>	<i>Plasmodium species</i>
<b>Syphilis</b>	<i>Treponema pallidum</i>
<b>Babesiosis</b>	<i>Babesia microti</i>
<b>Brucellosis</b>	<i>Brucella species</i>
<b>Leptospirosis</b>	<i>Leptospira interrogans</i>
<b>Viral Encephalitis</b>	Arboviruses
<b>Creutzfeldt-Jakob Disease (CJD)</b>	Prion
<b>Viral Hemorrhagic Fevers</b>	Ebola, Marburg, Lassa fever viruses

The bacterial and parasitic diseases listed above are treatable with antibiotics or other therapy. There are no specific, effective treatments for the viral diseases.

### ***Where are bloodborne pathogens found?***

Bloodborne pathogens may be present in blood, body fluids, tissues, and other potentially infectious materials. Other potentially infectious materials include:

- *Semen*
- *Vaginal secretions*
- *Cerebrospinal fluid*
- *Synovial fluid*
- *Peritoneal fluids*
- *Pericardial fluids*
- *Pleural fluid*
- *Amniotic fluid*
- *Saliva in dental procedures*
- *Body fluids visibly contaminated with blood or in situations where it is impossible to differentiate fluids*

Some materials handled by laboratory researchers are also classified as infectious materials. These materials should be handled in the same manner as human blood or body fluids. They include the following:

- *Cell lines or tissue cultures containing HIV, HBV or HCV*
- *Culture media or other solutions which contain HIV, HBV or HCV*
- *Primary human cell and tissue cultures*
- *Human T-lymphocyte cultures*
- *Blood and tissues from experimental animals infected with HIV, HBV or HCV*
- *Animals that have been experimentally infected with HIV, HBV or HCV*

### ***How are bloodborne pathogens transmitted in the laboratories?***

Bloodborne pathogens can be transmitted if infectious material comes in contact with your blood and body fluids. Laboratory exposures often occur through needle sticks, direct contact of materials on a non-intact skin, or splashes to the eyes, mouth, and nose.

## II. SCOPE AND APPLICATION OF THE STANDARD

### ***Who is covered by the OSHA standard?***

Anyone who has a reasonable chance of encountering human blood, body fluids and other potentially infectious materials while performing their normal job duties is covered by the standard.

### ***Who is at risk?***

The first step in protecting workers from bloodborne pathogens is to determine who needs protection. The standard requires that employees risk of exposure to bloodborne diseases be made based on their normal job responsibilities or performance of tasks where exposure may likely be encountered. Workers at risk are identified based on their *Job Classifications* (e.g., phlebotomist, nurse, or physician) or the *Tasks and Procedures* associated with the work they perform (e.g., laboratory researcher handling blood, technician in charge of washing contaminated glass wares, etc..)

### ***How is Risk Determination accomplished?***

Appendix 1 lists examples of *Job Classifications* and *Tasks and Procedures* in which workers are at risk of occupational exposure to bloodborne pathogens. Appendix 1 also provides forms for listing workers with occupational risk at your work site. These forms can also be used with new employees to discuss their risk of contact with bloodborne pathogens.

In addition, Appendix 6A, *Occupational Exposure to Bloodborne Pathogens* Form, is also provided to assist in determining who is covered by the standard and record employee vaccinations. Each employee with potential exposure must complete this form. Additional forms are available through the Department Administrators, Office of Human Resources, UHS at 275 Longwood Avenue, and the Biosafety Office.

## III. METHODS OF COMPLIANCE

This section is intended as a guide to the general compliance requirements of the OSHA Bloodborne Pathogens Standard. Additional specific methods need to be drawn up by the Principal Investigator or by the Employee Supervisor for each work site or activity. Further guidance is available through the Biosafety Office 432-1720. The OSHA Bloodborne Pathogens Standard, included as [Appendix 8](#), is also a useful guide to developing safe laboratory procedures.

### ***How can I be protected from exposure?***

The Centers for Disease Control developed the concept of *Universal Precautions* to help prevent the spread of infectious diseases in the workplace. *Universal Precautions* assumes that **all** blood, body fluids, and tissues are infectious for *HIV*, *HBV*, and other bloodborne diseases. Because no test method can offer complete assurance for the absence of all bloodborne pathogens, *Universal Precautions* must always be observed when handling blood and other materials collected from any source.

Certain work practices are necessary to conform to *Universal Precautions*. These are:

## **A. WORK PRACTICES**

Work practices are methods and procedures followed by employees to protect themselves from exposure. The following *Work Practices* are derived from the OSHA standard. [Appendix 2](#) can be used to detail site-specific work practices for your work area.

### Hand washing

The number one defense against infection is clean hands. Hands should be washed with soap and running water after removing the gloves and before leaving the work area. If a sink is not available, hands should be cleaned with disinfectant wipes and washed with soap and water as soon as a sink becomes available. Overly vigorous hand washing is not recommended, as it may cause skin breaks and chapped hands.

### Sharps & Containers

The use of syringes and needles, glass Pasteur pipettes, and other sharps such as scalpels, razors, and suture needles should be minimized. Used sharps and contaminated broken glassware must be disposed into sharps containers as soon as possible. The sharps containers shall be labeled with the universal biohazard symbol, and shall be puncture-resistant, leak-proof, and closable for transport. Containers must be located where sharps can be disposed of immediately after use.

Used needles should not be recapped or removed by hand. If recapping needles is necessary for a specific procedure, use forceps, hemostats, or a one-handed technique. Reusable sharps must be handled in a manner that reduces the risk of cuts during decontamination and cleaning. Wear heavy utility gloves and reach into the decontamination pans with tongs to prevent hand injuries.

### Work Area Restrictions

Eating, drinking, smoking, applying cosmetics, and handling contact lenses are prohibited in areas where blood and other potentially infectious materials are handled or stored. Food and drinks must not be kept in freezers, refrigerators, and other places used to handle or store other potentially infectious materials. Areas where blood and other potentially infectious materials are stored or

worked with must be posted to make persons entering the area aware of the potential hazards present. Mouth pipetting practices shall not be allowed.

Specimen Handling & Transport

Specimens and other materials to be transported between work sites should be placed in a secondary container that is leak-proof and labeled with the universal Biohazard symbol. Labels are available through the Biosafety Office. Portable "six-pack" coolers are typical for this use.

Containers for shipping specimens must meet the Department of Transportation and United States Postal Service requirements. International shipping may require permits or authorization from the United States Department of Agriculture or Centers for Disease Control. Contact the Biosafety Office at 432-1720 for more information.

Contaminated Equipment

Equipment used to store or handle blood and other potentially infectious materials shall be labeled with the biohazard symbol. It must be cleaned and decontaminated before being serviced, repaired, or transported from the work area. Any parts of the equipment that can not be decontaminated should be labeled with the biohazard symbol and the information communicated to all affected people.

Personal Protective Equipment

Personal Protective Equipment (PPE) refers to devices or apparel that helps protect workers from injuries. Selection of appropriate PPE should be made based on the specific hazard or anticipated exposures that may be incurred. It must be provided to all employees whose work puts them at risk and should be readily available when needed. The employer provides for the cost of obtaining, maintaining, replacing and disposing of personal protective equipment..

***What are some examples of Personal Protective Equipment?***

Some common examples of PPE that are used in the workplace are:

- i. Gloves      Disposable gloves should be worn when there is possible contact with blood and other potentially infectious materials. They should be replaced when they are cut, damaged, or when they are visibly contaminated. Double gloving is recommended when working with high concentrations of pathogenic microorganisms. Heavy rubber gloves may be needed when decontaminating equipment or cleaning spills. Utility gloves may be decontaminated and reused but must be discarded when cracked or torn.
- ii. Safety Glasses      Safety glasses with temple and side protection prevent direct splashes to the eyes. Goggles or face shields provide better protection when working with materials or performing procedures which may cause splashes and spraying.
- iii. Lab Coats      Lab coats protect skin surfaces and street clothing from contamination. Disposable water-resistant gowns should be used when working with materials which may splash or splatter. Contaminated gowns should be removed and replaced as soon as possible.

Housekeeping

Benchtops, counters, and all other equipment used to work with blood and other potentially infectious materials must be disinfected at the end of the work day, when work surfaces are overtly contaminated, or after a spill.

Commonly used disinfectants include 10% household bleach or 70-75% ethanol. Other suitable disinfectants are listed in [Appendix 4](#). The Biosafety Office can provide additional information.

Work surfaces and equipment may be covered to prevent contamination with infectious materials. Protective coverings should be removed and replaced at the end of the work, after a spill, or when they are overtly contaminated. Coverings must be discarded as biological waste.

Spills

Spills must be cleaned up immediately. Use personal protective apparel available in your work area. Absorb liquid material with paper towels or other absorbent materials to prevent from spreading. Use tongs or a similar device to pick up broken glassware or sharps, and dispose them in a sharps container. Sharps must never be handled with bare hands.

Disinfect the spill area with 10% bleach or other appropriate disinfectants and let it stand for a few minutes (15-20 minutes if 10% is used). This allows the disinfectant time to kill the organisms present. If you need advice or assistance, you can call the Biosafety Office at 432-1720.

Regulated Waste

Harvard University and the Commonwealth of Massachusetts Department of Public Health require that medical waste be segregated from general waste and disposed of in a manner which protects the waste handlers, the general public, and the environment. Materials that come in contact with blood or other potentially infectious materials should be collected into biohazard bags, autoclaved and disposed into medical waste burn boxes for incineration. Although the State allows liquid blood to be poured down the drain, laboratories should first decontaminate the materials by bleaching or autoclaving before sink disposal.

Sharps are discarded of in special puncture-resistant, leak-proof sharps containers. These containers should be replaced once they are 2/3 full. [Appendix 2B](#) is useful in identifying the areas where these containers are stored and used.

Labeling

Waste containers, equipment, storage freezers, and other materials that come in contact with blood and potentially infectious materials 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 lettering and symbol.



**UNIVERSAL BIOHAZARD SYMBOL**

Laundry

Workers should replace laboratory gowns or coats regularly and when they become contaminated. Contaminated laundry that can be reused should be placed in leak-proof bags labeled with the biohazard symbol or color-coded red before transporting for decontamination or cleaning.

HIV/HBV Research  
Laboratory and  
Production Facility

Guidelines and procedures for laboratories conducting research on *HIV* or *HBV* are detailed in paragraph e of the Bloodborne Pathogen Standard. The Centers for Disease Control and the National Institutes of Health also publish guidelines.

Appendix 7 contains excerpts from these guidelines. Principal Investigators should contact the Biosafety Office for assistance in setting up an *HIV* or *HBV* research facility.

## **B. ENGINEERING CONTROLS**

*Engineering Controls* refer to equipment and laboratory design that either eliminates the hazard from the work area or isolates the worker from it. They should be maintained on a regular basis to ensure their effectiveness. *Engineering Controls* used in your work area and their maintenance records should be recorded in Appendix 3.

Examples of *Engineering Controls* used in the work area to prevent worker exposure are:

Biological Safety Cabinets Commonly referred to as "*tissue culture hoods*," these provide protection from aerosols. Class II biosafety cabinets not only protect the person using them, but also protect the work from contamination. They should be inspected and recertified annually and whenever moved.

Mechanical Pipettors Mechanical pipetting devices and other pipetting aids should be used instead of mouth pipetting.

Self-sheathing Needles Self-sheathing needles are recommended for procedures that require recapping.

Sharps Containers Rigid, hard-sided, leak-proof, and puncture-resistant containers are used to dispose of sharps. These containers are labeled with the biohazard symbol and should be in the immediate area where sharps are handled.

Splash Guards Procedures that may generate splatters (e.g. opening specimen tubes) can be safely done behind a transparent shield or in the biosafety cabinet.

## IV. MEDICAL SURVEILLANCE PROGRAM

The OSHA standard requires employers to establish procedures that assure medical attention is available in the event of an occupational exposure to bloodborne pathogens. This is not a "surveillance" program per se. Serum levels are not monitored for any viruses or other pathogens. Rather, it is a medical support program consisting of two aspects, Hepatitis B vaccination and post-exposure medical assistance.

### A. Hepatitis B Vaccine

#### *Who needs to get vaccinated?*

All workers at risk of job related exposure to bloodborne pathogens must be offered vaccination against HBV. Vaccine is available and administered by the Harvard University Health Services at no cost to the employee. Reimmunizations and boosters, if recommended by the United States Public Health Services in the future, will also be offered to employees at no cost.

#### *Is the HBV vaccine safe?*

The first HBV vaccines were derived from pooled human plasma and had associated health hazards. A new vaccine, in use since 1986, is made from a yeast based recombinant DNA system. This vaccine has been documented to be 90% effective and immunity lasts approximately 7-10 years.

#### *Are there any side effects of the vaccine?*

Side effects and other reactions to the vaccine varies between different individuals. The most common reactions are: mild temperature, and soreness or slight swelling around the vaccinated area. Individuals with allergies to yeast or thimerosal preservative should consult the administering health care professional.

#### *When should the vaccine be administered?*

Newly hired employees with risk of occupational exposure to bloodborne pathogens must be offered the HBV vaccine within ten days of being appointed the position or immediately after the training.

#### *What happens if I don't want the vaccination?*

As with any medical treatment, the decision to take the vaccination is yours. If you decline the vaccine, you must sign a waiver statement. If at a later date you change your mind and decide to obtain the vaccine, it will be available to you at no cost. [Appendix 6B](#) is the *HBV Declination Statement Form*. This form **must** be completed by each employee who declines the vaccination.

#### *How do I get the vaccine?*

After completing the *Occupational Exposure to Bloodborne Pathogens Form* in [Appendix 6A](#) with your supervisor or department administrator, call the UHS immunization desk (432-1370) to make an appointment. The HBV vaccination is a series of three injections. It is the employee's responsibility to set up and keep the appointments. You must bring the completed and signed request for vaccination with you to the first appointment.

### B. Exposure Incident

#### *How do laboratory exposures occur?*

Exposures to bloodborne pathogens most often occur through:

1. Needle sticks and lacerations or punctures with contaminated sharps;
2. contamination or exposure to a non-intact skin; and
3. direct splashes to the mouth, eyes, and nose.

***What do I do if I have an exposure?***

1. Wash the affected area with soap and running water.
2. If possible, force-bleed the injured area.
3. Cover the injury with sterile gauze or clean material.
4. Report the incident immediately to the Principal Investigator or Employee Supervisor.
5. Proceed to the Harvard University Health Services for immediate treatment. \*

***Whom do I call? Where do I go for treatment of injuries?***

<b>HARVARD LONGWOOD CAMPUS</b>
Medical Area Health Service, 275 Longwood Avenue, Tel. No. 432-1370
<b>AFTER WORK HOURS, WEEKENDS</b>
University Health Services, Holyoke Center, Tel. No. 495-5711
* In case of a severe injury, report immediately to <b><u>Brigham &amp; Women's Hospital Emergency Room</u></b> . Call 432-1212 for emergency transportation to the hospital.

**C. Post-Exposure Evaluation and Follow-Up**

***What happens after an exposure?***

The first priority is the health and well-being of the affected worker. Call Harvard University Health Services (UHS). They will immediately conduct an evaluation of the incident and recommend appropriate follow-up care. If possible, the source patient or material will be tested for *HIV* and/or *HBV* and the results will be made available to you and your health care provider. All treatment is provided by licensed health care providers. Test results and other medical records are confidential.

***What if I my health insurance is not through UHS or HUGH/P?***

You should still report to UHS for initial exposure evaluation. UHS will provide any immediate care needed and then refer you to your personal health care provider. For work-related exposure incidents, UHS will continue your care. UHS will transfer records and consult with your primary health care provider if you move your follow-up care. Be sure to complete and submit a Harvard University Accident Report to activate Worker's Compensation for any costs incurred at your health care provider.

***What is the University Work-Related HIV Benefit Plan?***

The Plan Sponsor has developed a benefit plan to provide financial assistance to eligible persons who become infected with the HIV as a result of a work-related incident. The Benefits Department should be contacted at 495-2757 for more information about the plan.

***What are my responsibilities as a Principal Investigator or Employee Supervisor?***

The circumstances surrounding the injury or exposure should be investigated immediately by the supervisor. Information on the incident, source material, and employees' vaccination status should be provided to UHS and/or the employee's health care provider. Site-specific procedures should be reevaluated and revised as necessary to prevent recurrences of similar incidents. The Biosafety Office is available to assist you with this.

**V. INFORMATION, TRAINING AND RECORD KEEPING**

## A. Labels and Signs

Special labels which incorporate the *Universal Biohazard Symbol* warn people that blood and other potentially infectious materials are present in an area. Appropriate labels have a predominant fluorescent orange or orange-red background with lettering and symbols in contrasting color.

### ***What needs to be labeled?***

Any equipment and instruments which may become contaminated with blood and other potentially infectious materials should be labeled. Examples of these materials include:

1. Containers of contaminated waste.
2. Refrigerators and freezers where blood or other potentially infectious materials are stored.
3. Incubators used for primary cell cultures.
4. Centrifuges and biosafety cabinets when containing blood or other potentially infectious materials.
5. Containers used to store, transport or ship blood and other potentially infectious materials. Labels are not required on individual containers of blood or other potentially infectious materials if they are placed in labeled secondary, leak-proof, containers.

*HIV* and *HBV* research laboratories and production facilities are required to have biohazard warning signs at all entrances. Door signs and stickers are available through the Biosafety Office.

## B. Training

Everyone working with blood and other potentially infectious materials needs training. Training should be given before the employee starts working with blood and other potentially infectious materials. Covered employees should be retrained annually. The training must be conducted by persons who are knowledgeable in the OSHA *Bloodborne Pathogens Standard*. Materials to be discussed are specified by the standard ([Appendix 8, paragraph g section 2](#)).

Schools and Departments are responsible for the training. The Biosafety Office can provide training or assist you in setting up your own training.

## C. Record Keeping

As with most OSHA regulations, the *Bloodborne Pathogens Standard* requires record keeping. Schools, Departments, Principal Investigators, or supervisors should maintain all relevant records.

### Training Records

All training records must be kept for three years from the date of the training and should include the following:

- a. Training Date.
- b. Summary of the training contents.
- c. Names and qualifications of the trainer(s).
- d. Names and job titles of the individuals who attended the training.

The Biosafety Office maintains records of training sessions it conducts. Copies will be sent to the department.

Medical Records

All medical records must be kept confidential and maintained for the duration of the employment plus 30 years. Medical records should contain the following information:

- a. Employee name and social security number.
- b. Hepatitis B vaccination status including vaccination dates and medical records relevant to the employee's vaccination status.
- c. Results and relevant opinions and results of post-exposure evaluations, examinations, medical testing, and follow up procedures.

The Harvard University Health Services maintains medical records of employees that received their services.

Availability and Transfer of Records

All medical and training records will be made available to the Director of the National Institute for Occupational Safety and Health, the Assistant Secretary of Labor for Occupational Safety and Health, and their designated representatives upon their request. Training records will be available to employees or employee representatives upon their request. Medical records can be obtained by the employee or by a representative with the employee's written consent.

## **VI. RESPONSIBILITIES**

### **A. Schools, Department, Principal Investigator or Employee Supervisor**

Development, implementation, and review of policies and procedures that will reduce or minimize the risk of occupational exposure for employees and will comply with the requirements of the standard.

Development, implementation and annual review of policies and procedures that will identify employees at risk and will assure that the following are provided to each employee at risk:

1. Information and training about the hazards associated with their work, Universal Precautions, and other methods of compliance as specified in the standard.
2. Personal protective equipment that is appropriate for the hazards involved in the work and is readily accessible.
3. Hepatitis B vaccination and boosters (if recommended) at no cost to the employee.
4. Information and procedures for exposure incidents, treatment, post exposure evaluation, and follow up.

### **B. Employee**

Participation in training and education programs that provide information about the epidemiology and transmission of bloodborne pathogens and prevention of occupational exposures.

Adoption of the *Universal Precautions* and compliance with other employee requirements as outlined in the standard and the site-specific plans.

### **C. Environmental Health & Safety Department**

EH&S will assist Schools, Departments, Principal Investigators, and Supervisors with site-specific compliance efforts, including:

1. Development and presentation of training and education programs.
2. Assistance in development of written site-specific Exposure Control Plans.
3. Assistance in monitoring University status of compliance with the components of the standard.
4. Assistance in accident investigations upon request.
5. Liaison with University Health Services upon request.
6. Resource for current information and assistance to each site.

APPENDIX 1

**RISK DETERMINATION**

Some of the tasks or procedures performed by the employees that present potential exposures to bloodborne pathogens are listed below:

1. Handling human blood or blood components (e.g. plasma, serum).
2. Handling unfixed human organs or tissues
3. Culturing primary human cells.
4. Working with cell cultures or other preparations known to contain HBV or HIV.
5. Handling Other Potentially Infectious Materials.\*
6. Working with human-derived materials that may be visibly contaminated with blood (e.g. urine, saliva)
7. Using human blood products such as proteins or research kits containing human serum.
8. Performing research with or handling research animals infected with HBV or HIV or caring for these animals.
9. Removing wastes or processing contaminated glassware known to contain the materials listed above.

Please fill out the forms on the next two pages:

- A. In *Table A*, list the Job Classifications of employees that are at risk. Under each classification, fill in the name, date of employment, and the date of termination for each employee if applicable.

EXAMPLE:

Research Associate or Assistant in HIV or HBV Research Laboratories  
Dentist  
Nurse  
Doctor  
Emergency First Aid Provider

- B. In *Table B*, list Job Classifications and corresponding Tasks at your work site where employees are at risk to exposure because of some duties they perform. Under each classification, fill in the name, job title, date of employment, and date of termination for each employee if applicable.

EXAMPLE:

<u>Job Classification</u>	<u>Tasks Performed</u>
Laboratory Technician	<i>Who handle or wash contaminated glassware</i>
Animal Care Technician	<i>Who handle experimental animals that shed bloodborne pathogens</i>
Plumbers	<i>Who are assigned to fix contaminated plumbing lines</i>

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\* Other Potentially Infectious Materials include: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, unfixed human tissue or organs, animals and tissues of animals known to be infected with HIV or HBV, and all other body fluids in situations where it is difficult or impossible to differentiate between body fluids.

# RISK DETERMINATION

## TABLE A

Job classifications of employees who are exposed to blood and other potentially infectious materials:

<b>JOB TITLE:</b>		
EMPLOYEE NAME	DATE OF HIRE	DATE OF TERMINATION
<b>JOB TITLE:</b>		
EMPLOYEE NAME	DATE OF HIRE	DATE OF TERMINATION
<b>JOB TITLE:</b>		
EMPLOYEE NAME	DATE OF HIRE	DATE OF TERMINATION

# RISK DETERMINATION

## TABLE B

Job classifications of employees exposed to blood and other potentially infectious materials due to **Tasks** they perform:

<b>JOB TITLE:</b> _____ Tasks that present risk to the employees in this classification: 1. 2. 3. 4.		
EMPLOYEE NAME	DATE OF HIRE	DATE OF TERMINATION
<b>JOB TITLE:</b> _____ Tasks that present risk to the employees in this classification: 1. 2. 3. 4.		
EMPLOYEE NAME	DATE OF HIRE	DATE OF TERMINATION
<b>JOB TITLE:</b> _____ Tasks that present risk to the employees in this classification: 1. 2. 3. 4.		
EMPLOYEE NAME	DATE OF HIRE	DATE OF TERMINATION

## APPENDIX 2

### **SITE SPECIFIC WORK PRACTICES**

The following sections have been set up to describe and document the work practice controls used in the work area.

The Principal Investigator, Employee Supervisor, or other responsible individual should complete all applicable sections.

APPENDIX 2:

APPENDIX 2A: Sink, Eye Wash and Safety Shower Locations

APPENDIX 2B: Sharps: Protocols for reusable sharps

APPENDIX 2C: Work Area Restrictions

APPENDIX 2D: Personal Protective Equipment

APPENDIX 2E: Spill Kit Contents and Locations

APPENDIX 2F: Spill Procedures

APPENDIX 2A

**WORK PRACTICES CONTROLS – *Sink, Eyewashes & Safety Showers***

**Sinks for handwashing are located in:**

(Indicate building and room number)

**Eyewashes are located in:**

(Indicate building and room number)

**The safety shower is located in:**

(Indicate building and room number)

APPENDIX 2B

**WORK PRACTICES CONTROLS – *Reusable Sharps***

**The following non-disposable sharps are used at this work site:**

(Indicate building and room number)

**The following procedures require the use of non-disposable sharps:**

**Sharps that need to be decontaminated for cleaning and reuse are treated in the following manner:**

APPENDIX 2C

**WORK PRACTICES CONTROLS – *Work Site Restrictions***

<b>List all the hazardous biological materials handled in the work area:</b>		
Hazardous Biological Material(s)	Date of Initial Use	Date Discontinued
<b>List entry restrictions to the facility:</b>		
(i.e. vaccinations, training, etc.)		
<b>List areas where food and drinks are allowed:</b>		
(Indicate building and room number. Please identify area use if possible, i.e. office, lounge, etc.)		

APPENDIX 2D

**WORK PRACTICES CONTROLS – *Personal Protective Equipment***

<b>Protective Clothing</b>
Laboratory coats or gowns should be worn when working with blood or other potentially infectious materials. The following tasks or procedures require the use of protective clothing:
List the disposal, decontamination, or laundry procedures for all used or contaminated protective clothing:
<b>Eye Protection</b>
The following procedures may generate splashing, splattering, or sprays and necessitate eye and face protection:
<b>Gloves</b>
Gloves are required when handling blood or other potentially infectious materials. Gloves in this work area are:
(Indicate manufacturer and type)
The following tasks and procedures require the use of utility gloves or other specialty gloves:

APPENDIX 2E

**WORK PRACTICE CONTROLS – *Spill Kits***

Spill Kits should be available where blood or other potentially infectious materials are handled or stored.

**SPILL KIT CONTENTS:**

- a. Household bleach or other appropriate chemical disinfectants
- b. Paper towels or other absorbent
- c. Disposable latex gloves (e.g. Platex gloves)
- d. Forceps or tongs
- e. Autoclave bags or biohazard red bags
- f. Spray bottle (to prepare working dilution of disinfectant)
- g. Rigid, leak-proof container for sharps

**List additional materials that are included in the spill kit and the suppliers:**

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**List of spill kit location(s):**

Building & Room	Date Replenished	Date Inspected

APPENDIX 2F

**WORK PRACTICES CONTROLS – *Spill Procedures***

Spills of biological materials should be cleaned up as soon as possible. The following procedures are recommended for biological spills in the laboratory. Additional clean up procedures may be found in the Harvard University *Biosafety Training Guide*, available from the Biosafety Office.

**Guidelines for spills in the laboratory:**

- a. Notify the supervisor and other employees about the spill.
- b. Evacuate the area if necessary. Wait for approximately 30 minutes for aerosols to settle before going back into the spill area.
- c. Call Environmental Health & Safety, Biosafety Office if you need assistance at 432-1720 (495-5560 during nights and weekends).
- d. Wear protective clothing: lab coats, disposable gloves, goggles or face shield.
- e. Ring the spill using disposable paper towels.
- f. Apply working disinfectant solution (10% bleach is generally used) on the liquid spill. Work from the outer reaches of the spill towards the center. Allow appropriate contact time (approximately 20 – 30 minutes if 10% bleach is used) to disinfect the spilled material.
- g. Absorb the spill with paper towels. Again, work from the outer reaches of the spill towards the center. Clean area using fresh towels soaked in disinfectant.
- h. Discard all non-sharps solid wastes into an autoclave bag or biohazard red bag. Discard all sharps including broken glass into sharps containers.
- i. Wash your hands with soap and water immediately after removing your gloves.

<b>List additional or special procedures to clean up spills in the work area:</b>

### APPENDIX 3

## **SITE SPECIFIC ENGINEERING CONTROLS**

The following sections have been set up for use at each work site to describe engineering protection controls in use.

The Principal Investigator, Employee Supervisor, or other persons responsible should complete all applicable sections. Additional sections should be added for each work site as needed.

APPENDIX 3:

APPENDIX 3A: Biological Safety Cabinets

APPENDIX 3B: Sharps Containers

APPENDIX 3C: Re-sheathing Needles

APPENDIX 3A

**ENGINEERING CONTROLS – *Biosafety Cabinets***

**LOCATION OF BIOSAFETY CABINET**

BUILDING: \_\_\_\_\_

ROOM NUMBER: \_\_\_\_\_

CONTACT PERSON: \_\_\_\_\_

TELEPHONE NUMBER: \_\_\_\_\_

**BIOSAFETY CABINET DESCRIPTION**

<b>MANUFACTURER</b>	
<b>MODEL</b>	
<b>CLASS</b>	
<b>SERIAL NUMBER</b>	
<b>RECERTIFICATION DATE</b>	

The Principal Investigator or Employee Supervisor must complete an Engineering Control Form for **EACH** Biosafety Cabinet used in the work area.

APENDIX 3B

**ENGINEERING CONTROLS – *Sharps Containers***

**LOCATION OF SHARPS CONTAINERS**

BUILDING: \_\_\_\_\_

ROOM(S): \_\_\_\_\_

CONTACT PERSON: \_\_\_\_\_ TELEPHONE NUMBER: \_\_\_\_\_

<b>Sharp containers are available through:</b>
(Name of supplier, i.e. EH&S, Baxter, Fisher, etc.)  
<b>Sharps containers are disposed by:</b>
(i.e. custodial, etc.)  
<b>Waste treatment or disposal procedure:</b>
AUTOCLAVED (Y/N): _____ TEMPERATURE: _____ PRESSURE: _____ CHEMICALLY DISINFECTED (Y/N): ___ CHEMICAL USED: _____ CONCENTRATION: _____ DISPOSED INTO BURN BOXES (Y/N): _____ OTHERS (EXPLAIN): _____ _____

APPENDIX 3C

**ENGINEERING CONTROLS – *Recapping of Needles***

**Needles should be recapped or removed from syringes during the following procedures:**

**When recapping of needles becomes necessary, specially manufactured self-sheathing needles are used:**

(Indicate company & model)

**The following additional safety methods and / or devices are used to avoid injury:**

APPENDIX 4

**CHEMICAL DISINFECTANTS**

<b>DISINFECTANT</b>	<b>WORKING SOLUTION</b>	<b>GENERAL USE</b>
<b>Bleach</b>	10%	Disinfects work areas, floors, walls, glassware. Good general all around disinfectant. Disinfects liquid cultures for disposal.
<b>Quaternary Ammonia</b> (Commercial Grade)	10 – 100 ppm	Disinfects floors, work surfaces, glassware
<b>Phenolics</b> (Commercial Grade)	2.8 – 3.0 % Active Ingredient	Disinfects instruments, and work surfaces.
<b>Glutaraldehyde</b>	2 – 3 %	Disinfects instruments, including endoscopic tubes.
<b>Isopropyl Alcohol</b>	70 – 85 %	Disinfects work surfaces, equipment; antiseptic and non-corrosive.
<b>Ethyl Alcohol</b>	70 – 85 %	Disinfects work surfaces, equipment; antiseptic, low toxicity, and non-corrosive.
<b>Iodophor</b>	75 – 150 ppm	Disinfects instruments and surfaces, non-corrosive.

Other effective chemical disinfectants may be available for use against biological materials. Contact the biosafety Office for information on other chemical disinfectants.



APPENDIX 6

**OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS FORM  
&  
HBV VACCINE DECLINATION STATEMENT FORM**

Employees who are at risk of exposure to bloodborne pathogens must complete the *Occupational Exposure to Bloodborne Pathogens* Form Appendix 6A. Workers who wish to decline Hepatitis B vaccination must complete a *HBV Vaccine Declination Statement* Form Appendix 6B. These forms are written records that the employer has offered Hepatitis B vaccination to all affected employees. Employees who decline to be vaccinated may acquire the vaccine at a later date should they change their mind.

The Employee Supervisor or Department Administrator should ensure that the forms are completed and copies be kept in the departmental files.

APPENDIX 6:

\*\*APPENDIX 6A: *Occupational Exposure to Bloodborne Pathogens* Form

\*\*\*APPENDIX 6B: *HBV Vaccine Declination Statement* Form

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\*\* Original *Occupational Exposure to Bloodborne Pathogens* Form, in NCR format (triplicate carbon copies), must be completed. Please call your Department Administrator, Office of Human Resources, or the Biosafety Office for additional forms.

\*\*\* Original *HBV Vaccine Declination Statement* Form, in NCR format (triplicate carbon copies), must be completed. Please call your Department Administrator, Office of Human Resources, or the Biosafety Office for additional forms.

## APPENDIX 7

### **OSHA Recommended Practices and Procedures for HIV/HBV Research and Production Facilities**

Laboratories conducting research on Human Immunodeficiency Virus (HIV) or Hepatitis B Virus (HBV) and facilities engaged in the production, culture, and concentration HIV and HBV should perform such functions in compliance with the recommendations put forth in the CDC and NIH guidelines; policies and recommendations of the Institutional Biosafety Committee, and the designated Safety Officers; and other applicable federal, state or local standards and regulations.

Principal Investigators or employee supervisors should ensure that compliance with the additional requirements for work in HIV/HBV research laboratories are followed:

*a.) Training:*

Employees working in HIV or HBV research or production facilities shall receive the following training in addition to the training outlined in the standard:

- i. Employees who have no previous experience in handling human pathogens shall initially train with non-infectious materials and progress to activities involving HIV or HBV as proficiency is gained.
- ii. Employees shall be trained to ensure that they are proficient in procedures and knowledgeable with the hazards specific to the facility.
- iii. Training shall be documented and shall be done annually.

*b.) Special Work Practices:*

Employees in HBV or HIV research or production facilities shall observe following recommended practices in addition to site-specific procedures implemented by the facility:

- i. Laboratory doors shall be kept closed when work with HIV and HBV are in progress.
- ii. Contaminated materials are to be placed in a durable, leak-proof labeled or color-coded container that is covered before transfer from work area before decontamination.
- iii. Access to the area shall be limited to authorized persons. Written policies and procedures shall be established. Only persons who have been advised of potential biohazard, who meet specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas.
- iv. A hazard warning sign incorporating the *Universal Biohazard Symbol* shall be posted on all access doors when potentially infectious materials or infected animals are present in the work area.
- v. 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.
- vi. 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.
- vii. Special care should be taken to avoid skin contact with potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.
- viii. All waste from work areas and animal rooms shall be incinerated or decontaminated by a method such as autoclaving to effectively destroy bloodborne pathogens.
- ix. Vacuum lines shall be protected with liquid disinfectant traps and HEPA (High Efficiency Particulate Air) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.
- x. Hypodermic needles and syringes shall be used only for parenteral and aspiration of fluids from laboratories from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units shall be used for injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. Needles shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and the syringe shall be promptly placed in a puncture resistant container and autoclaved or decontaminated autoclaved or decontaminated before reuse or disposal.
- xi. 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.
- xii. A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

xiii. A biosafety manual shall be prepared or adopted and reviewed and updated at least annually and or as often as necessary. Personnel shall be advised of the potential hazards, required to read instructions on practices and procedures, and required to follow them

*c.) Containment Equipment:*

- i. Certified biological safety cabinets (Class I, II, or III) and appropriate combination of personal protection or physical containment devices (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.
- ii. Biological safety cabinets shall be certified when installed, whenever they are moved, and at least annually.

*d.) Specific Requirements for HIV and HBV Research Laboratories:*

- i. Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.
- ii. An autoclave shall be available and used for decontamination of regulated waste.

*e.) Specific Recommendations for HIV and HBV Production Facilities:*

- 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 is a basic requirement for entry into the work area from access corridors or other contiguous areas.
- ii. The surfaces of doors, walls, floors, and ceilings in the work area shall be water resistant for ease in cleaning and decontamination. Penetrations in these surfaces shall be sealed or capable of being sealed for decontamination.
- iii. Each work area shall contain a sink for washing hands and an eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.
- iv. Access doors to the work area or containment module shall be self-closing.
- v. An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.
- vi. A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of airflow shall be verified.

Additional recommendations for work area practices and restrictions may be found in Biosafety in Microbiological and Biomedical Laboratories, 3<sup>rd</sup> edition, CDC/NIH, May 1993. Copies are available at the Environmental Health and Safety, Biosafety Office.

## General Industry

Part 1910 of title 29 of the Code of Federal Regulations is amended as follows:

### **PART 1910 - (AMENDED)**

#### **Subpart Z - (Amended)**

1. The general authority citation for subpart Z of 29 CFR part 1910 continues to read as follows and a new citation for 1910.1030 is added:

Authority: Sections 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657. Secretary of Labor's Orders Numbers 12-71 (36 FR 8754), 8-76 (41 FR 25059) or 9-83 (48 FR 35726) as applicable; and 29 CFR part 1911.

Section 1910.1030 also issued under 29 U.S.C. 653.

2. Section 1910.1030 is added to read as follows:

# 1910.1030

# BLOODBORNE PATHOGENS

**(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 the purposes of this section, the following shall apply:

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

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

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

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

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

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

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

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

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

**Engineering Controls** means controls (e.g., Sharps disposal containers, self-sheathing needles) that isolate or remove the bloodborne pathogens hazard from the workplace.

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

**Hand washing Facilities** means a facility providing an adequate supply of running potable water, soap and singly use towels or hot air drying machines.

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

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.

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, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
- (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
- (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV- containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events as 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 or 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 fluid 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**

#### **(1) Exposure Control Plan**

(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.

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

(A) The exposure determination required by paragraph (c)(2).

(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) The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(I).

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

(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.

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

**(2) Exposure Determination**

(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:

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

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

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

**(d) Methods of Compliance**

**(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.

**(2) Engineering and Work Practice Controls**

(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 protection equipment shall also be used.

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

(iii) Employers shall provide Hand washing facilities which are readily accessible to employees.

(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 hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

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

(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.

(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.

(A) Contaminated needles and other contaminated sharps shall not be recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure.

(B) Such recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

(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:

(A) Puncture resistant;

(B) Labeled or color-coded in accordance with this standard;

(C) Leakproof on the sides and bottom; and

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

(ix) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas

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

(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.

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

**(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.

**(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 utilize 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 or containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(I) is required when such specimens or containers leave the facility.

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

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

**(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.

**(A)** A readily observable label in accordance with paragraph (g)(1)(I)(H) shall be attached to the equipment stating which portions remain contaminated.

**(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.

### (3) Personal Protective Equipment

**(I)** Provision: When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protection 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 protection 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.

**(ii)** Use: The employer shall ensure that the employee uses appropriate personal protection equipment unless the employer shows that the employee temporarily and briefly declined to use personal protection equipment when, under rare and extraordinary circumstances, it was the employee's professional judgement 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.

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

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

**(v)** Repair and Replacement: The employer shall repair or replace personal protection equipment as needed to maintain its effectiveness, at no cost to the employee.

**(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.

**(vii)** All personal protection equipment shall be removed prior to leaving the work area.

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

**(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 as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

**(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.

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

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

- (1)** Periodically reevaluate this policy;
- (2)** Make gloves available to all employees who wish to use them for phlebotomy;
- (3)** Not discourage the use of gloves for phlebotomy, and
- (4)** Require that gloves be used for phlebotomy in the following circumstances:
  - (a)** when the employee has cuts, scratches, or other breaks in his or her skin;
  - (b)** when the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and
  - (c)** when the employee is receiving training in phlebotomy.

**(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.

**(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.

**(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).

#### (4) Housekeeping

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

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

**(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.

**(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.

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

**(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.

#### **(iii) Regulated Waste**

**(A) Contaminated Sharps Discarding and Containment**

**(1)** Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

- (a)** closable;
- (b)** puncture resistant;
- (c)** Leakproof on sides and bottom; and
- (d)** labeled or color-coded in accordance with paragraph (g)(1)(I) of this standard.

**(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.

**(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)** closable;
- (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.

**(B) Other Regulated Waste Containment**

**(1)** Regulated waste shall be placed in containers which are:

**(a)** Closable

**(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.

**(2)** If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:

**(a)** Closable

**(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.

**(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.

**(iv) Laundry**

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

**(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.

**(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.

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

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

**(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) of this standard.

**(e) HIV and HBV Research Laboratories and Production Facilities**

*(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.*

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

**(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.

**(ii) Special Practices**

**(A)** Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

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

**(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.

**(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)(I) of this standard.

**(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.

**(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.

**(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.

**(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.

**(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.

**(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.

**(K)** All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with other potentially infectious materials

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

**(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.

**(iii) Containment Equipment**

**(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.

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

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

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

**(ii)** An autoclave for decontamination of regulated waste shall be available

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

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

**(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.

**(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.

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

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

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

**(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).

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

**(1) General**

**(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.

**(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:

**(A)** Made available at no cost to the employee;

**(B)** Made available to the employee at a reasonable time and place;

(C) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed health care professional; and

(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).

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

(2) Hepatitis B Vaccination

(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.

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

(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.

(iv) The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in appendix A.

(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).

(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:

(I) Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred.

(ii) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

(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.

(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.

(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.

(iii) Collection and testing of blood for HBV and HIV serological status:

(A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

(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.

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

(4) Information Provided to the Healthcare Professional

(I) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

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

(A) A copy of this regulation;

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

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

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

(E) All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

(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.

(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.

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

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

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

(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(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**

#### **(1) Labels and Signs**

##### **(I) Labels**

(A) Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious materials; 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).

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



**BIOHAZARD**

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

(D) Labels required by affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

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

(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) 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.

(H) Labels required for contaminated equipment shall be in accordance with this paragraph and shall also states which portions of the equipment remain contaminated.

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

##### **(ii) Signs**

(A) The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratories and Production Facilities, which shall bear the following legend:



BIOHAZARD

(Name of the Infectious Agent)

(Special requirements for entering the area)

(Name, telephone number or the laboratory director or other responsible person.)

(B) These signs shall be fluorescent orange-red or predominately so, with lettering or symbols in a contrasting color.

(2) Information and Training

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

(ii) Training shall be provided as follows;

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

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

(C) At least annually thereafter.

(iii) For employees who have received training of 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.

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

(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.

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

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

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

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

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

(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;

(E) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

(F) An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protection equipment;

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

(H) An explanation of the basis for selection of personal protection equipment;

(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;

(J) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

(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;

(L) Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

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

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

(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.

(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

(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.

(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.

(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**

#### **(1) Medical Records**

(I) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.20.

(ii) This record shall include:

(A) The name and social security number of the employee;

(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);

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

(D) The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

(E) A copy of the information provided to the health care professional as required by paragraphs (f)(4)(ii)(B),(C), and (D).

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

(A) Kept confidential; and

(B) Are 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.

(iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.20.

#### **(2) Training Records**

(I) Training records shall include the following information:

(A) The dates of the training sessions;

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

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

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

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

#### **(3) Availability**

(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.

(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 in accordance with 29 CFR 1910.20.

(iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.20.

#### **(4) Transfer of Records**

(I) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.20(h).

(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.

**(l) Dates**

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

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

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

(4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protection Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect July 6, 1992.

**APPENDIX A TO SECTION 1910.1030 - HEPATITIS B VACCINE DECLINATION  
(MANDATORY)**

*I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccine at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.*

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